



## **Mainstreaming of Biosafety and Institutional Capacity Building to strengthen effective implementation of Cartagena Protocol on Biosafety**

### **Part I: Project Information**

#### **GEF ID**

10773

#### **Project Type**

MSP

#### **Type of Trust Fund**

GET

#### **CBIT/NGI**

**CBIT No**

**NGI No**

#### **Project Title**

Mainstreaming of Biosafety and Institutional Capacity Building to strengthen effective implementation of Cartagena Protocol on Biosafety

#### **Countries**

India

#### **Agency(ies)**

UNEP

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

Ministry of Environment, Forest and Climate Change (MoEFCC)

#### **Executing Partner Type**

Government

#### **GEF Focal Area**

Biodiversity

#### **Taxonomy**

Climate Change, Climate Change Adaptation, Focal Areas, Certification -National Standards, Mainstreaming, Certification - International Standards, Biodiversity, Biosafety, Supplementary Protocol to the CBD, Access to Genetic Resources Benefit Sharing, Trade Unions and Workers Unions, Civil Society, Academia, Non-Governmental Organization, Community Based Organization, Stakeholders, Individuals/Entrepreneurs, Private

Sector, Communications, Awareness Raising, Education, Public Campaigns, Type of Engagement, Information Dissemination, Consultation, Partnership, Participation, Capacity Development, Gender results areas, Gender Equality, Knowledge Generation, Capacity, Knowledge and Research, Targeted Research, Innovation, Knowledge Exchange, Learning, Theory of change, Adaptive management, Mainstreaming adaptation, Species, Influencing models, Demonstrate innovative approaches, Strengthen institutional capacity and decision-making, Transform policy and regulatory environments, Beneficiaries, Local Communities, Gender Mainstreaming, Sex-disaggregated indicators, Women groups, Access to benefits and services, Knowledge Generation and Exchange, Participation and leadership

**Sector**

**Rio Markers**

**Climate Change Mitigation**

Climate Change Mitigation 0

**Climate Change Adaptation**

Climate Change Adaptation 0

**Duration**

48 In Months

**Agency Fee(\$)**

190,000.00

**Submission Date**

3/22/2021

**A. Indicative Focal/Non-Focal Area Elements**

<b>Programming Directions</b>	<b>Trust Fund</b>	<b>GEF Amount(\$)</b>	<b>Co-Fin Amount(\$)</b>
BD-3-8	GET	2,000,000.00	10,775,000.00
<b>Total Project Cost (\$)</b>		<b>2,000,000.00</b>	<b>10,775,000.00</b>

## B. Indicative Project description summary

### Project Objective

Institutional Strengthening and Mainstreaming Biosafety for effective implementation of the Cartagena Protocol on Biosafety

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
1: Stocking Assessment and Mainstreaming biosafety into policy and planning processes	Technical Assistance	1.1 Biosafety policies and training agenda mainstreamed into selected Programmes and Planning processes	1.1.1 Updated National Policies with specific training strategy developed at the State Level.  1.1.2 Revised policies and programmes relevant for biosafety integration and mainstreaming to be developed.  1.1.3 Review and update Curricula on Biosafety and incorporated in national curriculum for Tertiary and non-formal Education	GET	250,000.00	600,000.00

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
2: Regulations for new LMOs and emerging technologies	Technical Assistance	2.1 An updated Risk Assessment and Risk Management Regulatory Framework with supportive guidelines, standard procedures and expertise set up and streamlined to support biosafety decision making on new LMOs and related technologies	<p>2.1.1 Risk Assessment and Risk Management procedures and guidelines are prepared/updated incorporating new categories of LMOs (Trees, Algae, Mosquitoes) and emerging technologies (gene editing, gene drives and synthetic biology) published and used for training.</p> <p>2.1.2 Resource documents, policy briefs and guidance documents are developed for risk assessment and risk management through consultative approach for shortlisted LMOs and technologies.</p> <p>2.1.3 Databases are developed to store relevant information including sequences for LMOs under regulatory evaluation through an interoperable site of the GEAC and the LMO Detection Network Portal.</p> <p>2.1.4 Proceedings of 8 Training meetings at national and</p>	GET	350,000.00	900,000.00

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
3: Strengthening institutional capacity at Central and State levels	Technical Assistance	3.1 Infrastructure and human resources are strengthened for quarantine and other enforcement mechanisms for regulating unintentional and illegal entry and local misuse of LMOs.	<p>3.1.1 Biosafety supporting Unit (GEAC Secretariat) established for supporting Central/State Governments</p> <p>3.1.2 Best practices for monitoring of pre-release and post-release activities documented.</p> <p>3.1.3 e-learning tools and mechanism in place for capacity building at State level on sustainable basis.</p> <p>3.1.4 Capacities of enforcement agencies viz. customs, quarantine, SBCCs, DLCs, seed inspectors etc. are enhanced through workshops and providing effective training tools.</p> <p>3.1.5 Testing labs at state level (seed, food etc.) are strengthened through human resource development.</p>	GET	700,000.00	5,000,000.00
		3.2 By 2025, well defined operational systems are in place at State level.	3.2.1 Guidelines and procedures published in place for			

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
4: Liability and redress	Technical Assistance	4.1 National strategies and administrative framework with supportive institutional capacity established for the implementation of the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress (NKSLP).	<p>4.1.1 Policy briefs are prepared for implementation of NKLSP.</p> <p>4.1.2 Institutional and Administrative guidelines on implementation of NKLSP prepared.</p> <p>4.1.3 Outreach materials and dissemination interventions among regulatory agencies, developers, legal persons, economists etc. about NKLSP developed.</p>	GET	120,000.00	325,000.00

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
5: Outreach and cooperation	Technical Assistance	<p>5.1 Biosafety Related education integrated and promoted in relevant national and State Level programmes.</p> <p>5.2 Biosafety education at graduate and post graduate levels is strengthened and updated.</p> <p>5.3 South-South Cooperative measures to support sharing of best practices and regional approaches operationalized in the Indian Biosafety Framework</p>	<p>5.1.1 Communication and awareness strategies are developed to ensure sustainable communication with concerned stakeholders.</p> <p>5.2.1 Stakeholder specific Educational and awareness materials on biosafety in different languages and modules developed for Tertiary and Non-Formal Education.</p> <p>5.3.1 Biosafety newsletters are prepared and regularly, distributed.</p> <p>5.3.2 The national Biosafety website and BCH is updated in line with the new unified web strategy of the CBD</p> <p>5.3.3 National, regional and international workshops are organized for targeted audience.</p>	GET	330,000.00	2,250,000.00



Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
Project Monitoring	Technical Assistance	Project effectively monitored, lessons codified and mainstreamed in national biosafety system	Lessons Learnt, Mid Term and Terminal Evaluation Reports Audit Reports	GET	70,000.00	700,000.00
<b>Sub Total (\$)</b>					<b>1,820,000.00</b>	<b>9,775,000.00</b>

**Project Management Cost (PMC)**

GET	180,000.00	1,000,000.00
<b>Sub Total(\$)</b>	<b>180,000.00</b>	<b>1,000,000.00</b>
<b>Total Project Cost(\$)</b>	<b>2,000,000.00</b>	<b>10,775,000.00</b>

Please provide justification

**C. Indicative 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	Ministry of Environment, Forest and Climate Change	In-kind	Recurrent expenditures	1,000,000.00
Recipient Country Government	Ministry of Environment, Forest and Climate Change	Grant	Recurrent expenditures	1,775,000.00
Beneficiaries	State Government and others	In-kind	Recurrent expenditures	5,250,000.00
Beneficiaries	Network of Laboratories	In-kind	Recurrent expenditures	2,750,000.00
<b>Total Project Cost(\$)</b>				<b>10,775,000.00</b>

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

N/A

**D. Indicative 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	India	Biodiversity	BD STAR Allocation	2,000,000	190,000	2,190,000.00
<b>Total GEF Resources(\$)</b>					<b>2,000,000.00</b>	<b>190,000.00</b>	<b>2,190,000.00</b>

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

PPG Required **true**

**PPG Amount (\$)**

50,000

**PPG Agency Fee (\$)**

4,750

<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	India	Biodiversity	BD STAR Allocation	50,000	4,750	<b>54,750.00</b>
<b>Total Project Costs(\$)</b>					<b>50,000.00</b>	<b>4,750.00</b>	<b>54,750.00</b>

## Core Indicators

### Indicator 11 Number of direct beneficiaries disaggregated by gender as co-benefit of GEF investment

	<b>Number (Expected at PIF)</b>	<b>Number (Expected at CEO Endorsement)</b>	<b>Number (Achieved at MTR)</b>	<b>Number (Achieved at TE)</b>
<b>Female</b>	2,000			
<b>Male</b>	4,000			
<b>Total</b>	6000	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 proposed project interventions will contribute to the Implementation of the Cartagena Protocol on Biosafety as outlined under Focal Area Programming Direction BD 3-8. This will ensure tools, interventions and capacity is installed to support science-based decision making in the sustainable utilization of biodiversity through modern biotechnology. The results and deliverables shall contribute to Aichi Targets 13 and 14 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 at the Central and State Levels.

## **Part II. Project Justification**

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

1a. *Project Description.* Briefly describe:

approaches on sustainable utilization of Biodiversity in different languages for dissemination. 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) innovation, sustainability and potential for scaling up.

*1) Global environmental and/or adaptation problems, root causes and barriers that need to be addressed (systems description);*

India is a megadiverse country rich in biodiversity and traditional knowledge. Protection of biodiversity, which is a part of its cultural heritage, is therefore a national priority for which required regulations and institutional frameworks are in place. India is a Party to the Convention on Biological Diversity (CBD) and its two protocols, namely Cartagena Protocol on Biosafety (CPB) and Nagoya Protocol on Access and Benefit Sharing. India has also ratified Nagoya Kuala-Lumpur Supplementary Protocol on Liability and Redress in the context of CPB, which came into force in March 2018. Ministry of Environment, Forest and Climate Change (MoEFCC) is the nodal ministry for the implementation of CBD, its protocols and supplementary protocol in India.

India has been an early mover in the development of biotechnology regulations. Rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells, were notified in 1989 under the Environmental Protection Act (1986). MoEFCC is the lead ministry for implementation of the national biosafety regulations for living modified organisms (LMOs) derived from modern biotechnology.

These rules are implemented jointly by MoEFCC, DBT and state governments through six statutory committees. The rules are supported by a series of guidelines prepared by MoEFCC and Department of Biotechnology (DBT) on various aspects of the development process such as contained research, confined field trials, environmental safety assessment, food safety assessment, etc. In line with the advances in development of biotechnology and its applications, the guidelines are updated regularly.

The need for updating the biosafety framework to meet current trends and developments has been recognized in the country and efforts initiated towards setting up of a dedicated Biotechnology Regulatory Authority of India (BRAI) by enacting a new law.

Key challenges being faced globally and specifically in India include mitigating and adapting to climate change, achieving inclusive food, water, energy and health security, addressing urban vulnerabilities, and extensive loss to biodiversity and natural resources. While novel technological developments can help deal with some of these challenges, the application and use of such technologies have to be done in a safe and sustainable manner. Limited capacities for risk benefit analyses, ensuring sustainable use in a rapidly advancing technology landscape and social acceptance lead to uncertainties in adaptation of novel technologies including modern biotechnology. The Government of India has endorsed modern biotechnology as a key tool to address challenges in accessing food, water and health needs whilst ensuring the sustainable use of biodiversity and natural resources. In addition to the challenges of food security and inadequate measures related to technology update, the issues of coordinated management of biosafety measures and decision making processes especially in relation to environmental releases need to be translated and mainstreamed from the Union to State Level which usually are the receiving environments. Another challenge relates to inadequate and dedicated capacity in the review of applications, monitoring and enforcement after approvals which by the Rules of 1989 is under the the management of State Level regulatory system. This also requires a clearly defined and operational workflow, with entry points for monitoring and enforcement at the sub national and district levels through the State Biotechnology Coordination Committees and the District Level Coordination Committees as per the Rules of 1989.

## ***2) Baseline scenario and any associated baseline projects,***

India has been at the forefront in adopting state-of-the-art science and technology across various sectors in meeting its socioeconomic and environmental challenges. Modern Biotechnology is one of the key thrust areas identified by the Government of India, for promoting research, development and its innovative applications. There is a dedicated Department of Biotechnology (DBT) in the Ministry of Science and Technology, working towards accelerated development of biotechnology in the country. Significant efforts have been made to create infrastructure for research and development of new technologies/products both in public and private sector. More than 500 organisations are actively engaged in activities involving modern biotechnology. While several products have been approved for commercial use in healthcare, Bt cotton is the only Living Modified (LM) crop approved so far for environmental release in the country. Bt cotton has been widely accepted and covers more than 90% area under cotton cultivation. Two other crops, i.e., Bt brinjal and GM mustard have been recommended by regulatory authorities but not released so far for commercial cultivation, because of divergent opinion of stakeholders. Several other crops are under research and confined field trials; more than 80 crops were reported to be under research as per a survey conducted by the Ministry of Environment, Forest and Climate Change (MoEFCC) in 2014. The National Biotechnology Development Strategy (2015-2020) has identified the biotechnology sector as a frontline area of

science with immense potential to address sustainable socio-economic transformation. Major investments have been proposed in research in gene discovery, genomics, Nano-biotechnology in diverse application areas, viz., healthcare, food, agriculture, biofuels, insects, animals, marine, process industry, environment among others.

India's regulatory experience with commercialization of GM crops is limited to Bt cotton, Bt Brinjal and DMH- 11 GM Mustard. However, Indian Public-Sector plant biotechnology R&D is very rich, and innovations are being used to develop plant products that are relevant to Indian agriculture today. There is significant research on traits that are relevant to mitigating the impacts of climate change on agriculture, which will be important to ensuring that agricultural productivity is maintained and ultimately improved. Productivity constraints in crops (including yield, pest resistance and herbicide tolerance) that are particularly relevant to smallholder farmers (e.g., pulses, millets) are also receiving significant attention, with important implications for improved food and nutrition security. Currently there are more than 85 plant products with multiple traits in the R& D pipeline but majority (80%) are in the early phase of development either at the experimental stage or proof-of-concept phase with only 20% having progressed into event selection trials. This information emphasizes that the biosafety regulatory system must be responsive to all types of agricultural biotechnology research, be it for knowledge generation or product development. Anticipated private sector R&D for commercial product release also highlights the prospective gaps in biosafety risk assessment and regulation needs which needs to be updated, India is also beginning to look at new and emerging issues on Synthetic Biology, Gene Drives, Genome Editing and new Plant breeding Techniques which calls for a review of the current regulatory system and the development of new and specific interventions to ensure products from such interventions can be assessed and managed to ensure safe use and transfer of the developed modern biotechnologies.

During the development of any new product, , the role of State Governments is very critical for ensuring strict compliance and effective monitoring of biosafety considerations. But India being a diverse country pose several challenges in effective coordination and dissemination of information regarding appropriate guidelines to officials of State Governments and accordingly enhancing capacities of State officials is a pre-requisite for addressing challenges for safe conduct and transfer of Living Modified Organisms (LMOs).

Capacity building in biosafety in India has been commensurate with developments in biotechnology and biosafety through both national and international resources. Series of awareness and training workshops for concerned stakeholders have been organized by MoEFCC, DBT and Ministry of Agriculture and Farmers Welfare. India has implemented two projects supported by GEF, i.e., World Bank/GEF Project from 2004-2007, and UNEP/GEF Project from 2012-2016. While the first project focused on strengthening implementation of biosafety regulatory framework in general, the Phase II project focused on four key thrust areas, viz., Risk Assessment and Risk Management, Handling



Transport, Packaging and Identification, Socioeconomic Considerations and Public Awareness limited to Agriculture Biotechnology. These areas were aligned with the Strategic Plan for CPB for the period 2011-2020.

With all the above efforts, India now has the basic capacity to comply with obligations under CPB. However, there is a felt need for building on these efforts and reaching out to multiple stakeholders in line with the advances in modern biotechnology for development of LMOs at national and global levels, This position was strongly emphasized by the Terminal Evaluation of the UNEP-GEF Project - **?Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India / Phase II?**. The Evaluation recommended that the Competent National Authority (MoEFCC) devotes efforts to build robust follow-up systems in order to measure effects and steer action in relation to: a) Human Resources capacity development; b) Information and Public awareness and this is achievable when the biosafety system is translated from the Union to the State levels through the mandated and targeted institutions.

***3) the proposed alternative scenario with a brief description of expected outcomes and components of the project;***

India being a vast country with large population and active biotechnology research centres, needs to utilise a variety of means towards strengthening the implementation of biosafety regulations, and promoting outreach. Research has been initiated in several organizations in new and emerging technologies and accordingly, rules and guidelines need to be reviewed and updated guided by current science and new standard operating procedures and provide clarity about approval process if required, for both in-country use and transboundary movement of LMOs. Strengthening implementation of rules and regulations at the level of States and local bodies is a priority area as monitoring and enforcement of environmental releases is under State Control. India has been an active participant in the meetings of Conference of Parties (COP) to the CBD and COP serving as Meeting of Parties (COP-MOP) to the two protocols. At the global level, efforts are being made to integrate deliberations related to CBD and its Protocols. Accordingly, several cross-cutting issues such as use of synthetic biology, digital sequences, etc. need to be looked at vis-?-vis the existing national biosafety regulatory frameworks, through active involvement of concerned stakeholders.

The institutional Policy and regulatory context is extremely critical to a science based approach to the management of modern biotechnology. The key requirements which is the basis of the alternative scenario is to ensure science based and coordinated decision making system supported by the designated strengthened institutions with mandates as spelt below.

The core institutional stakeholders are defined into Environment (Protection) Act, 1986 and the Rules, 1989, attributing clear mandate to six Ministries / Departments (see annex, diagram) and six Competent Authorities; namely:

A- Ministries:

1. Ministry of Environment, Forest and Climate Change
    - a. Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of GMOs/LMOs
    - b. Nodal agency for implementing Rules, 1989 and the Cartagena Protocol on Biosafety
  2. Department of Biotechnology (Ministry of Science & Technology)
    - a. Nodal department for promoting biotechnology programs
    - b. Provides scientific support in implementation of biosafety regulations
    - c. Provide services in areas of research, infrastructure, generation of human resource
  3. Ministry of Agriculture
    - a. Policies aimed at agriculture growth.
    - b. Indian Council of Agricultural Research (ICAR) responsible for monitoring agronomic benefits of GM technology.
    - c. Monitoring post-release performance of GM crops.
  4. Ministry of Health and Family Welfare
    - a. Policies aimed at protecting and monitoring human health.
    - b. Food Safety and Standards Authority of India responsible for regulating genetically engineered foods.
  5. Ministry of Commerce and Industries
    - a. Enhance trade with other countries through export/import policies.
    - b. Nodal agency for implementing DGFT[1]<sup>1</sup> notification on GMOs
-

6. Central Board of Excise and Customs, Department of Revenue, Ministry of Finance
- a. Enforcement of regulation pertaining to transboundary movement of GMOs/LMOs at point of entry

B- Competent Authorities, under the Rules, 1989, implemented under **a)** the Ministry of Environment Forest & Climate Change; **b)** Ministry of Science & Technology; **c)** Government of India and **d)** State Governments:

1. Advisory: The Recombinant DNA Advisory Committee (RDAC)
2. Approval: Institutional Biosafety Committee (IBSC)
3. Approval: Review Committee on Genetic Manipulation (RCGM)
4. Approval: Genetic Engineering Appraisal Committee (GEAC)
5. Monitoring: State Biotechnology Coordination Committee (SBCC)
6. Monitoring: District Level Committee (DLC)

The proposed project components and envisaged outcome as outlined below will support the regulatory mandates and strengthen the institutions outlined above in meeting their mandates in the management of LMOs through the interplay of Union and State Level supportive systems in decision making.

### **Project Components and Outcomes**

#### **1: Stocktaking Assessment and Mainstreaming biosafety into policy and planning processes**

Stock taking assessment of biosafety capacities will be undertaken for planning activities and work out stakeholder engagement in concerned sectors as well as at State level to ensure mainstreaming in a sustainable manner. The project will focus on assessing the State Level capacity especially under the State Coordination Committees to monitor transboundary movements and handling of Living Modified Organisms. The Stock taking process will also assess the relevant sector interventions and planning processes and identify entry points for mainstreaming and mobilizing resources for the safe use of modern biotechnology. The proposed interventions are expected to lead to outcomes including State and Sector Specific Biosafety policies with clearly defined training agenda. It is also expected that

biosafety issues will be integrated into the planning processes not only at the Federal but also the State Level. There are 29 states and 6 union territories in India with varying level of biotechnology and biosafety activities and priorities. The Stock taking assessment will be used to review and finalized selected States based on a set of criteria where the developed tools will be tested and customized to meet their needs. A key criteria is existing field trials or potential to be a receiving environment for approved and potential illegal boundaries of LMOs. The key envisaged outcome will be the mainstreaming of biosafety policies and training agenda into selected national Programmes and Planning processes.

## **2: Regulations for new LMOs and emerging technologies**

Whilst there is a Biosafety Regulatory Framework in India, post project reviews, the Terminal Evaluation of the last Biosafety Project and ongoing developments indicate the need for a review of the regulatory framework with entry points, tools and standard operating procedures to enable India to manage the new LMOs and emerging technologies as envisaged under the current national biotechnology strategy. So far the major areas for biosafety regulations relates to biopharmaceuticals, particularly biosimillars<sup>[2]</sup> and GM crops. Extensive research efforts are underway in India and also at global level for new LMOs such as trees, algae, mosquitoes etc. Dedicated support in terms of both funding and technical assistance is being provided for research interventions for varied LMOs at national level. New LMOs are being approved at global level and also likely to be traded internationally, The proposed interventions are expected to lead to an updated Risk Assessment and Risk Management Regulatory Framework in India with supportive regulations, guidelines, standard procedures and expertise set up and streamlined to support biosafety decision making on new LMOs and related technologies. Training at national and international levels will help in famillaring pool of experts from multiple disciplines with requirements under the CPB particularly related to RA/RM. There is also a need to strengthen the documentation system for better handling and identification through interaction with detection laboratories.

## **3: Strengthening institutional capacity at Central and State Level**

Whilst there has been some installed regulatory capacity at the Union level, field trials and releases in the environment happens are under State Control. It is therefore extremely important that institutional capacity in monitoring and enforcement and handling of LMOs is strengthened through legally designated State level Coordination Committees and district level committtees along with supporting stakeholders such as agriculture departments/universities, food safety inspectors, state biodiversity

---

boards, testing labs and Customs and Border control officials.. It is envisaged that by 2025, well defined operational systems will be in place at the State level for implementing obligations under Indian biosafety regulatory framework and CPB. This will ensure that each intentional introduction into the environment is guided by science-based decision supporting units with supportive follow up monitoring and enforcement systems at the Union and State Levels. In addition, infrastructure and human resources are expected to be strengthened with adequate quarantine and other enforcement mechanisms for regulating unintentional and illegal entry and illegal usage of LMOs across States and neighbouring countries. A coordinated Biosafety Regulatory system with active State Level presence is envisaged as a key outcome to help ?tie? in the loose ends of the Indian Biosafety Regulatory Framework

#### **4: Liability and Redress**

This component will focus on interventions to support the Implementation of the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress. The interventions are expected to lead to strengthening supportive institutional capacity for the implementation of the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress (NKSLP). Tools developed under the project such as policy briefs, resource documents, outreach material etc will be used to support in training of the identified operators by the Competent Authority on Liability and Redress. Institutional, administrative guidelines and checklists will be developed to support the implementation of a liability and redress regime in India.

#### **5: Outreach and cooperation**

The component focuses on outreach and cooperation on Biosafety issues at the Union and the State Level. Key outcomes expected include the integration of Biosafety related issues in the education system at the Tertiary and non-formal level in relevant national and State educational programmes. Biosafety education at graduate and post graduate levels are envisaged to be strengthened and updated with new and emerging issues. In addition, State specific and customized outreach materials will be developed to support and implement the Communication plans to be developed. India will also create a platform and partnerships to support Outreach and Cooperation on Biosafety. In addition, Bollywood, the Indian Movie industry, will be partnered to develop movies on modern biotechnology with biosafety measures and story lines or digital story telling

#### **6: Project Monitoring**

The component will focus on developing project monitoring tools that will help capture key lessons and best practices to support the Indian Biosafety process. Lessons learnt shall be codified and shared internally and with countries in the Region.

In view of the above, the MoEFCC proposes to access funds from GEF during GEF 7 cycle for a project on biosafety, with a view to strengthening implementation of biosafety management system in India, continuing with UNEP as the GEF Implementation agency with a view to translating biosafety monitoring and enforcement measures from the Central to the mandated State Coordination Biosafety systems. The proposed areas to be covered under the project inter alia include the following:

1. To mainstream biosafety considerations in sectoral policies and procedures, in line with Sustainable Development Goals, National Biodiversity Targets and National Biodiversity Strategy and Action Plan.
2. To further strengthen implementation of biosafety regulations and enhance institutional capacity for effective implementation of the national biosafety system in line with the obligations under the CPB.
3. To further develop and support implementation of scientific tools and approaches for risk assessment and risk management, particularly for new LMOs and emerging technologies
4. To strengthen capacities for enforcement of the regulatory requirements related to handling, transport, packaging and identification of LMOs
5. To enhance institutional capacity building at State level for a cohesive approach with a view to promoting effective monitoring mechanisms.

To review measures for a liability and redress regime for LMOs, in the Indian biosafety regulations keeping in view its international obligations under the supplementary protocol.

6. To further raise public awareness, promote education and participation through structured communication strategies and information exchange mechanisms concerning safe use of LMOs.

Project effectively monitored, lessons codified and mainstreamed in national biosafety system

States Government of Maharashtra, Telangana (GM Cotton), Assam (GM Rubber) and New Delhi (Trade Point and GM Mustard) are the 4 pilot project sites proposed. The potential criteria for selection of the proposed pilot sites were selected based on documented field trials and institutional structures for Handling, monitoring and enforcement of decisions on GM releases. This will be further reviewed during the PPG phase

#### ***4. Alignment with GEF focal area and/or Impact Program strategies;***

In more recent time, the global community through the Cancun Declaration 'Mainstreaming the Conservation and Sustainable Use of Biodiversity for Well-Being' adopted by COP 13 in Decision XIII/3 has endorsed its commitment to mainstream biodiversity across all sectors. In Decision XIII /3-14 Urges Parties, when implementing the 2030 Agenda for Sustainable Development, to mainstream biodiversity in the implementation of all relevant Sustainable Development Goals, thus promoting linkages between efforts to implement national biodiversity strategies and action plans and Sustainable Development Goal strategies and plans. Further, Decision XIII/21 invites the Global Environment Facility and other donor and financial institutions to provide financial assistance for country-driven projects that address cross-sectoral mainstreaming when requested by developing country Parties, in particular the least developed among them and small island developing States, and countries with economies in transition.

Decision BS VIII/3, Urges Parties and other Governments to integrate biosafety in their national biodiversity strategies and actions plans and broader national development strategies to implement the 2030 Agenda for Sustainable Development and its Sustainable Development Goals. Decision BSVII/5, Urges Parties and invites other Governments to integrate and prioritize biosafety within their national biodiversity strategies and action plans and national development plans and programmes, as appropriate. The role and relevance of the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit Sharing, as well as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), in contributing to sustainable food systems and agriculture has also been recognized by COP.

The proposed project is aligned to the GEF Biodiversity Focal Area and relates directly to the program BD-3-8 'Further development of biodiversity policy and institutional frameworks through the Implementation of the Cartagena Protocol on Biosafety?'. The proposed interventions will develop updated and revised regulatory tools and thematic or issue specific actions to support implementation of the Cartagena Protocol on Biosafety at the Union and State Levels in India especially interventions on risk assessment, detection on new LMOs and monitoring and enforcement in addition to tools for implementation of the new supplementary protocol on Liability and Redress. The envisaged project activities are expected to contribute to global benefits and impact transboundary movements in South Asia specifically and Asia as well.

The interventions will contribute regulations, tools, guidelines and operating procedures to add on to existing biosafety interventions in managing biosafety at the State Level. A stronger monitoring and enforcement regime will be in place to ensure that each intentional introduction of LMOs in the

environment is made based on scientific risk assessment with supportive monitoring and enforcement measures. The mandate for monitoring and enforcement per the Biosafety Rules is assigned to the States through State Biotechnology Coordination Committees.

***5) Incremental/additional cost reasoning and expected contributions from the baseline, the GEFTF, LDCF, SCCF, and co-financing***

Indian biosafety regulations have provision for involvement of concerned ministries of Central governments, State governments, and other key stakeholders. Though mechanisms are in place for their involvement, there is an urgent need to enhance capacities for effective implementation. Preliminary efforts initiated in previous projects need to be institutionalized to ensure sustainability. The external assistance is a catalyst in strengthening capacity in biosafety management, which may be overlooked. A Global Environment Facility (GEF) intervention would complement baseline activities in India by ensuring that key required capacities for implementation of the CPB continue to be developed. This project is perfectly in line with the GEF strategy on biosafety.

The incremental reasoning is buttressed on the principle of translation of knowledge, experience and further developments from the Federal or Union Level through the State and District levels. In addition, the previous interventions focused more on contained and confined field trials mainly in the area of agricultural biotechnology. The proposed project will further broaden the scope and build capacity in the area of environmental/commercial release not only in agriculture biotechnology but capacity to cover the management of all Living Modified organisms developed or received into India. It will also allow for supportive and institutional linkages between the GEAC in relation to Environmental releases and the State Coordination Committee which have a legal responsibility to do post approval monitoring and enforcement of permit conditions on the ground or State level. It will also allow for internalization and mainstreaming of the biosafety regulatory instruments and additional deliverables to enable India have a more dedicated and streamlined biosafety decision making and follow up processes from federal to the end users at the State Level

***6) global environmental benefits (GEFTF) and/or adaptation benefits (LDCF/SCCF);***

With GEF support through this project, incremental financial resources necessary for effective review/ updating and/or translation of the Indian Biosafety system to the State Level will strengthen the State Biosafety Coordination systems mandated with monitoring, enforcement and translation of confined field trials to deliberate, commercial and release of LMOs into the Environment. The project will also



provide the technical and financial resources for institutional capacity building for relevant and designated stakeholders with clearly defined roles and responsibilities under the national biosafety systems at the State Level to support the work of the Genetic Engineering and Appraisal Committee. The development of liability and redress measures which was not handled in the previous biosafety interventions will strengthen the decision-making processes to ensure that each intentional introduction of LMOs into the environment have back up procedures to handle issues of liability and redress. The proposed project will implement measures that will ensure a cost-effective approach and a coherent intervention strategy to maximize the possibilities of achieving the identified outcomes. By building on the baseline with GEF support for the countries, the project will translate the current baseline into updated functional and operational biosafety frameworks to support handling and decision making on LMOs in line with obligations of the Cartagena Protocol. The results of the proposed project will set up measures guided by a strong policy regime focused on conservation of globally significant biodiversity in agriculture, medicine, food and the new/emerging biotechnologies beyond Agriculture biotechnology as has been the case of the previous phases. The project will ensure sustainable use of the components of globally significant biodiversity guided by a strengthened risk analysis framework-based approach to decision making.

#### ***7) innovation, sustainability and potential for scaling up.***

India being a vast country, the proposed activities will be taken up at pilot level. The outputs developed will be adopted by regulatory agencies for implementation across the system to strengthen the Indian Biosafety System at the Federal and State Levels. The previous projects were more focused at the Central or Union Level to set up the structures. The tools and interventions will be mainstreamed into the institutional mandate and obligations to support modern biotechnology level at the marketplace and for deliberate release with a strong focus on State Level coordination through the State Coordination Committees and the State Agriculture Board. Due to the diverse ecological zones in India, tools and guidance, the best practices and lessons developed can be shared across different regions and potentially replicated in other countries across the region, especially the South Asia region. The project will develop tools and regulatory responses to support the management of new LMOs and emerging biotechnologies across not only Agriculture but other areas of LMO development which is lacking in most biosafety regulatory frameworks. India, being a potential importer and exporter of LMOs, will develop Liability and Redress measures which can be tested with real life applications. The lessons and best practices will be helpful to similar situations across the region and has a potential for uptake and scale up across several countries.

The proposed project will develop innovative tools including mobile android and web-based applications to support e-training, e-monitoring and enforcement in the management of intentional introduction of new LMOs and related new biotechnologies at the State Level. The partnership with Bollywood and the IT industry in Bangalore will provide innovative tools to support dissemination of

Biosafety which will lead to potentials for scale up across the region. The mix of Union and State Level interventions will provide replicas with tools for scale up across the region among countries with similar ecosystems and environments. In addition, a focused *buy in* at the State level with appropriate resource mobilization plans will be key in sustaining the Indian Biosafety System

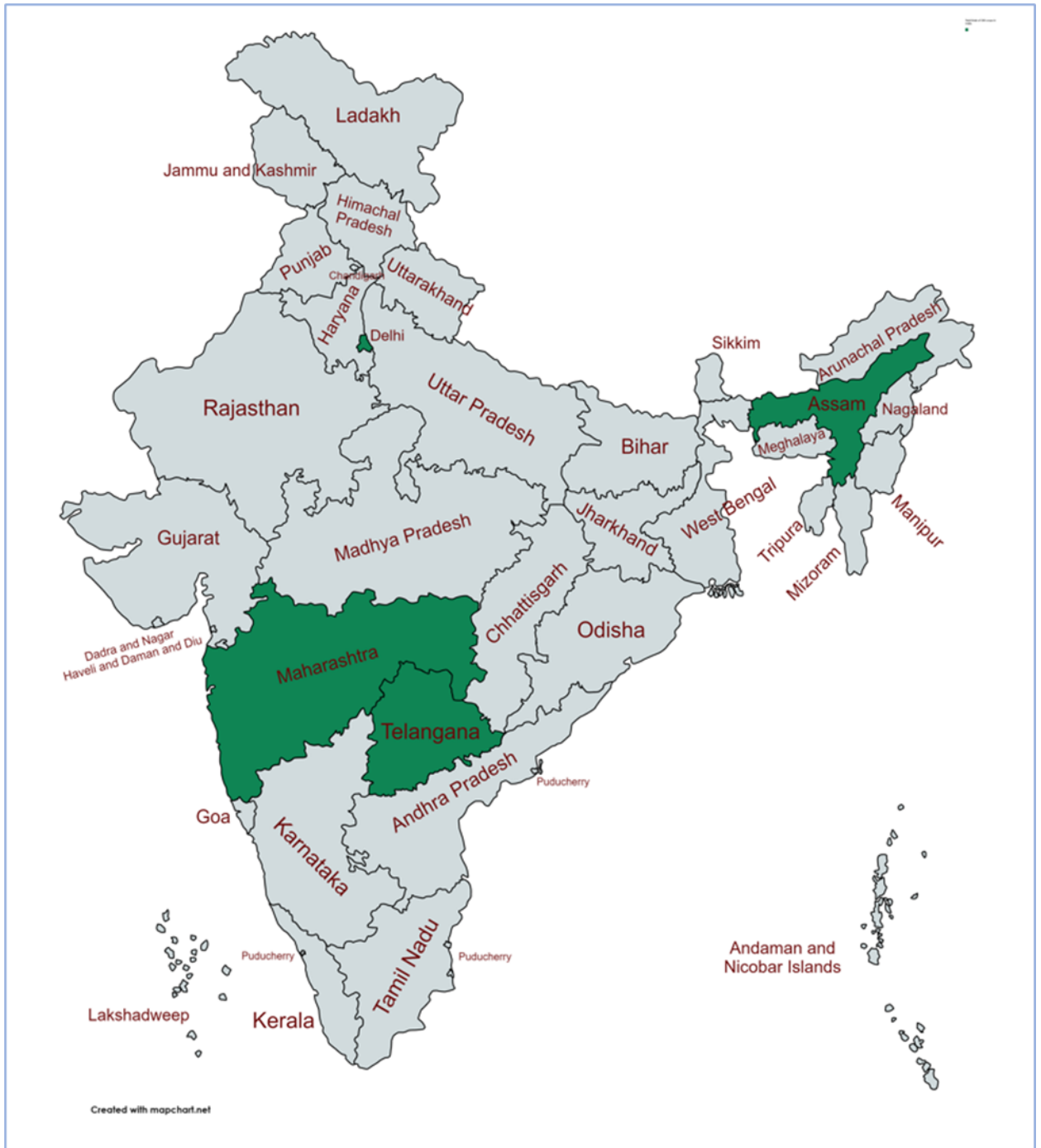
---

[1] Directorate General of Foreign Trade

[2] <https://creakyjoints.org/treatment/what-are-biosimilars/>

#### **1b. Project Map and Coordinates**

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



The Project Map with highlighted states, where the pilot studies are proposed to be conducted is provided (See Annex A). States Government of Maharashtra, Telangana (GM Cotton), Assam (GM Rubber) and New Delhi (Trade Point and GM Mustard) are the 4 pilot project sites proposed. The potential criteria for selection of the proposed pilot sites were selected based on documented field trials and institutional structures for Handling, monitoring and enforcement of decisions on GM releases. This will be further reviewed during the PPG phase

The tools and interventions envisaged in the proposed project will be tailor made to address State specific needs, ecosystems and environments. The final selection of targeted States will be based on the results of the Stocking taking assessments under Component 1.

**2. Stakeholders**

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

**Indigenous Peoples and Local Communities** Yes

**Civil Society Organizations** Yes

**Private Sector Entities** Yes

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

**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**

Stakeholders	Type of involvement
Decision makers/policy makers:	? Members of National Steering Committee and the Genetic Engineering Appraisal Committee (GEAC) ? Consultations and meetings on key issues at national, sub-regional and regional level. ? Resource persons in programmes on awareness raising.
Scientists/ technical experts, researchers and technicians from public and private sectors including academic institutions	? Consultations and workshops for training of trainers and awareness. ? Developing training modules and working knowledge documents. ? Developing outreach materials for different target groups.
Legal experts and economists	? Consultations on documents related to socio-economic assessment.

Enforcement officials including Customs, Plant Quarantine, state agricultural departments, members of SBCCs, DLCs and IBSCs etc.	? Participate in training workshops for post-release monitoring and enforcement at border controls.
Interest groups [Private Sector, Civil Society, Indigenous Peoples and Local Communities], teachers, students, mass media and extension workers	? Participate in awareness raising meetings ?Receiving outreach material designed for the different target groups.  . Community and targeted outreach engagements

The key stakeholders consulted besides the designated government ministries and agencies in Agriculture, Environment, Science and Technology, Health and Finance including Customs during the preparation of the PIF are grouped above are indicated above. The main stakeholders consulted are the following:

- 1) Federation of Seed Industry; - The Federation is one of the umbrella body in India and provided information on seed movement generally and specifically LMOs. In addition, they highlighted issues related to monitoring and reporting which needs to be streamlined.
- 2) Confederation of Indian Industry ? The confederation and the Chambers of Commerce highlighted the need for flexibility and efficiency in port management and monitoring of approvals. They highlighted traceability as critical
- 3) Federation of Indian Chambers of Commerce and Industries;
- 4) National Seeds Corporation;
- 5) All India Biotech Association (AIBA)
- 6) National Biodiversity Authority; Is the key national agency tasked with Biodiversity management and provided support on the critical issues of biodiversity conservation and monitoring to ensure sustainable use
- 7) Biotechnology Consortium of India Limited (BCIL) ? They provide technical support in the development of the PIF as they were the facilitating agency for all the previous GEF Biosafety project.
- 8) Institute of Forest Genetics and Tree Breeding (IFGTB) ? The institute highlighted the importance of research and high quality data in decision making and emphasized that as a critical role for risk assessment and decision from the earlier work on biology documents

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

**Briefly include below any gender dimensions relevant to the project, and any plans to address gender in project design (e.g. gender analysis).**

Gender equality and women empowerment is a powerful tool for achieving gender mainstreaming to ensure that the benefits of technology reach the society. Due emphasis would be essential when organizing various capacity building trainings and activities both at national and state level while keeping a gender perspective in policy / programme formulation for effective dissemination. Government focuses on ensuring that gender commitments are translated into budgetary commitments through various schemes and projects as women, constitute 48% of India's population, but they lag behind men on many social indicators like health, education, economic opportunities, etc. Women and youth also play a critical role in the management, handling and trade issues related to biodiversity at the community level. They warrant special attention due to their vulnerability and lack of access to resources. The way Government budgets allocate resources, has the potential to transform these gender inequalities. 33% members of the Biodiversity Management Committees (BMC) in India are women and every BMC is part of local government, therefore the same would be involved in Biosafety activities, thereby promoting gender equality and the empowerment of women. Other issues for consideration which will be taken up during the PPG are the involvement of women and youth in biosafety governance, tailor made capacity building support. In addition, though already mandated, dedicated efforts will made to ensure clearly defined entry points for women and youth in the use, monitoring and enforcement as part of the gender equality considerations in relation to the proposed biosafety project.

Gender Equality and Women's Empowerment issues will be guided by the attached Gender Action Plan. This will be further reviewed and updated during the PPG phase. The Gender Action plan (annexed to the PIF) will be continuously reviewed through an interactive and data gathering process throughout the project execution phase. The PPG phase will be used to update the logframe with gender specific indicators and budgeting to support the execution of the identified actions. The Project Management Unit will appoint gender expert to guide the execution of project activities and also ensure the gender dimensions are fully monitored and documented during the project execution phase.

The planned interventions to assist in analysing and assessing actions are captured in the Gender Action which is outlined in the table below

|

Outcome	Outputs	Gender Action	Indicator
<b>Component 1 - Stock taking Assessment and Mainstreaming biosafety into policy and planning processes</b>			

Outcome	Outputs	Gender Action	Indicator
<p>1.1 Biosafety policies and training agenda mainstreamed into selected national Programmes and Planning processes</p>	<p>1.1.1 Updated National Policies with specific training strategy developed at the State Level.</p> <p>1.1.2 Revised policies and programmes relevant for biosafety integration and mainstreaming developed.</p> <p>1.1.3 Review and update Curricula on Biosafety and incorporated in national curriculum for Tertiary and non-formal Education.</p>	<p>- Encourage women representation in the National Core Teams of Experts to be capacitated and mentored in national policy review and development/implementation of biosafety training agenda.</p> <p>- ensure gender issues are included in the adopted laws, policies and plans</p> <p>- Encourage women participation in analysis and identification of opportunities for mainstreaming of biosafety and promotion of biosafety mainstreaming into NBSAPs and Post 2020 GBF.</p> <p>- Strengthen women's participation by organizing women led discussions with the relevant stakeholders in the review of laws and policies.</p> <p>Promote gender representation in training on biosafety legislation and enforcement.</p> <p>- Promote and encourage participation of women in peer-to-peer mentoring, advisory services and training on biosafety</p>	<p>- percentage of women representation in the National Core Teams of experts</p> <p>- proportion of women who participated in identifying opportunities and promoting mainstreaming of Biosafety into NBSAPs and Post 2020 GBF</p> <p>-Number of women-led discussions with the relevant stakeholders in the review of laws and policies</p> <p>- Percentage of female government officials, legal experts and magistrates, regulatory officials, and national experts trained on biosafety legislation and enforcement</p> <p>- Proportion of women participating in peer-to-peer mentoring, advisory services and training on biosafety</p>



Outcome	Outputs	Gender Action	Indicator
<b>Component 2: Regulations for new Living Modified Organisms and (LMOs) and emerging technologies</b>			

Outcome	Outputs	Gender Action	Indicator
<p>2.1 An updated Risk Assessment and Risk Management Regulatory Framework with supportive guidelines, standard procedures and expertise set up and streamlined to support biosafety decision making on new LMOs and related technologies</p>	<p>2.1.1 Risk Assessment and Risk Management procedures and guidelines are prepared/updated incorporating new categories of LMOs (Trees, Algae, Mosquitoes) and emerging technologies (gene editing, gene drives and synthetic biology) published and used for training.</p> <p>2.1.2 Resource documents, policy briefs and guidance documents are developed for risk assessment and risk management through consultative approach for shortlisted LMOs and technologies.</p> <p>2.1.3 Databases are developed to store relevant information including sequences for LMOs under regulatory evaluation through an interoperable site of the Genetic Engineering Approval Committee (GEAC) and the LMO Detection Network Portal.</p> <p>2.1.4 Proceedings of 8 Training meetings at national and international level for regulators and scientists for</p>	<ul style="list-style-type: none"> <li>- Ensure inclusion of women in the training and mentorship on adaptation of guidelines on Biosafety risk assessment (RA) and Risk Management (RM).</li> <li>- Include the trained women in training on RA&amp;RM at national levels</li> <li>- Encourage women's participation in the carrying of biosafety RA and RM</li> <li>- Encourage equal participation of men and women in training meetings at national and international levels for regulators and scientists for conducting RARM for new LMOs and emerging technologies</li> </ul>	<ul style="list-style-type: none"> <li>- number of women participating the RA &amp; RM trainings</li> <li>- number of women participating and carrying out Biosafety risk assessment and risk management frameworks</li> </ul>

Outcome	Outputs	Gender Action	Indicator
<b>Component 3: Strengthening institutional capacity at Central and State levels</b>			
<p>3.1: Infrastructure and human resources are strengthened for quarantine and other enforcement mechanisms for regulating unintentional and illegal entry and local misuse of LMOs</p>	<p>3.1.1 Biosafety supporting Unit (GEAC Secretariat) established for supporting Central/State Governments</p> <p>3.1.2 Best practices for monitoring of pre-release and post-release activities documented.</p> <p>3.1.3 e-learning tools and mechanism in place for capacity building at State level on sustainable basis.</p> <p>3.1.4 Capacities of enforcement agencies viz. customs, quarantine, SBCCs, DLCs, seed inspectors etc. are enhanced through workshops and providing effective training tools.</p> <p>3.1.5 Testing labs at state level (seed, food etc.) are strengthened through human resource development.</p>	<p>- Encourage inclusion of women in biosafety administrative structures at the Central and State Levels</p> <p>- Include and encourage women's participation in the training on biosafety administrative systems</p> <p>- Promote women representation in regulatory and institutional committees on biosafety</p>	<p>- Percentage of women in biosafety administrative structures at the Central and State Levels</p> <p>- Number of women participating in training workshops on biosafety administrative systems</p>

Outcome	Outputs	Gender Action	Indicator
<p>3.2 By 2025, well defined operational systems are in place at State level for implementing obligations under Indian biosafety regulatory framework and CPB.</p>	<p>3.2.1 Guidelines and procedures published in place for effective coordination of activities involving LMOs at State level.</p>	<ul style="list-style-type: none"> <li>- Include and encourage women's participation in training and mentorship of biosafety related issues for implementation compliance and enforcement of updated National Biosafety frameworks</li> <li> </li> <li> </li> <li> </li> <li> </li> <li> </li> <li>- Number of women training at Central and State levels on monitoring and enforcement systems for follow-up</li> <li> </li> </ul>	<p>Percentage of women participating training and mentorship of biosafety related issues for implementation compliance and enforcement of updated National Biosafety</p> <p> </p> <p>- number of women participating the trainings on monitoring and enforcement systems for follow-up</p> <p> </p>
<b>Component 4: Liability and redress</b>			
<p>4.1 National strategies and administrative framework with supportive institutional capacity established for the implementation of the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP).</p>	<p>4.1.1 Policy briefs are prepared for implementation of NKLSP.</p> <p>4.1.2 Institutional and Administrative guidelines on implementation of NKLSP prepared.</p> <p>4.1.3 Outreach materials and dissemination interventions among regulatory agencies, developers, legal persons, economists etc. about NKLSP developed.</p> <p> </p> <p> </p>	<ul style="list-style-type: none"> <li>- Ensure inclusion of gender issues in the institutional and administrative frameworks for the NKLSP</li> <li>- Ensure inclusion of gender dimensions in outreach materials on liability and redress</li> <li> </li> <li> </li> <li> </li> <li>- Encourage inclusion of women in the training and mentorship on adaptation of guidelines on Liability and Redress</li> <li> </li> </ul>	<ul style="list-style-type: none"> <li>- Levels of awareness and inclusion of gender related issues in the policy, institutional and administrative frameworks for the NKLSP</li> <li>-level of gender related issues in outreach materials on Liability and Redress</li> <li> </li> <li>- Number of Identifiable interventions on gender among regulatory agencies, legal persons, economists etc</li> </ul>

Outcome	Outputs	Gender Action	Indicator
<b>Component 5: Outreach and cooperation</b>			
<p>5.1 Biosafety Related education integrated and promoted in relevant national and State Level programmes.</p>	<p>5.1.1 Communication and awareness strategies are developed to ensure sustainable communication with concerned stakeholders.</p>	<ul style="list-style-type: none"> <li>- conduct awareness creation on the importance of inclusion of gender issues in biosafety</li> <li> </li> <li> </li> <li> </li> <li> </li> <li>- Encourage women participation on various biosafety related fora.</li> <li> </li> <li> </li> <li>- Build gender issues into the communication, PAEP strategies</li> <li> </li> <li> </li> <li>- Encourage women to share lessons of biosafety</li> <li> </li> <li>- Ensure gender related analysis of each guideline developed</li> <li> </li> </ul>	<ul style="list-style-type: none"> <li>- levels of awareness and inclusion of gender related issues in biosafety systems and their implementation at national level.</li> <li> </li> <li>- women participation in biosafety related fora</li> <li> </li> <li>- level of gender related issues into communication and</li> <li> </li> <li>PAEP strategies.</li> <li>- Number of women sharing lessons</li> <li> </li> <li>-level (number of issues included) of inclusion of gender issues in the developed guidelines</li> </ul>

Outcome	Outputs	Gender Action	Indicator
<p>5.2 Biosafety education at graduate and post graduate levels is strengthened and updated.</p>	<p>5.2.1 Stakeholder specific Educational and awareness materials on biosafety in different languages and modules developed for Tertiary and Non-Formal Education.</p>	<p>- Encourage inclusion of gender issues in stakeholder specific educational and awareness materials on Biosafety in different languages and modules for Tertiary and Non-Formal Education</p> <p>- Promote and encourage participation of women in peer-to-peer mentoring, advisory services and training on biosafety</p>	<p>Number of stakeholder specific educational and awareness materials on biosafety with gender issues incorporated</p> <p>- Proportion of women participating in peer-to-peer mentoring, advisory services and training on biosafety</p>
<p>5.3 South-South Cooperative measures to support sharing of best practices and regional approaches operationalized in the Indian Biosafety Framework</p>	<p>5.3.1 Biosafety newsletters are prepared and regularly distributed.</p> <p>5.3.2 The national Biosafety website and BCH is updated in line with the new unified web strategy of the CBD</p> <p>5.3.3 National, regional and international workshops are organized for targeted audience.</p>	<p>- ensure production of Biosafety publications including newsletters, surveys, design and update of the national biosafety website/BCH, consultation designs and implementation and workshops are gender sensitive and results are disseminated in a way that reaches men, women, youth, indigenous people and local communities</p>	<p>Ensure collection of disaggregated data on Outreach and information sharing programmes, and national/regional/international workshops includes men, women, youth, indigenous people and local communities</p>

**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;**

**improving women's participation and decision-making; and/or Yes**

**generating socio-economic benefits or services for women.**

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

Yes

#### **4. Private sector engagement**

**Will there be private sector engagement in the project?**

Yes

**Please briefly explain the rationale behind your answer.**

Public-Private Partnerships are essential for addressing sustainability issues due to the expanding global wealth and influence of the private sector. Additionally, many of the traditional development actors in the public and civil society sectors now recognize the increasing difficulty of tackling certain global problems in a unilateral manner. There are occasions when the private sector, often in partnership with government, civil society or both, can be better positioned to provide solutions because of its resources (financial and in-kind), innovation and management skills.

At the same time, the private sector is increasingly finding competitive benefits in embracing a more proactive and collaborative role in development. These benefits include risk mitigation, new market opportunities and increased value added. At the end of the day, it is the market (society, community) that determines the success of a company; consequently, this becomes an important driver for companies to contribute to society.

It is important to engage private sector with Government agencies so that they are quite aware of the regulatory requirements for bringing their innovative ideas into commercial products. Private sector also becomes a conduit for new technologies and tools including regulatory packages. The approach of

the project is to see a partnership that ensure, and support science and risk analysis based regulatory packages to support decision making in the delivery of modern biotechnology products.

The private sector will be engaged mainly through product developments and experience sharing on commodity management post approval including how they have been using new information to assist in development of regulatory packages, testing and monitoring of LMOs. The project intends to collaborate with private sector and work closely in the handling and management of non agriculture biotechnology products including animal vaccines, biosimilars, food and feed with LMOs.

### 5. Risks to Achieving Project Objectives

**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 (table format acceptable)**

No.	Risk	Priority	Risk Management Strategy
1.	Inadequate participation of the targeted stakeholders (especially at the State level) in the capacity building program.	Medium	To overcome this constraint, extensive efforts would be made to:  ? involve high level functionaries in this capacity building initiative.  ? Existing and mandated Central and State coordination mechanisms will be used.  ? stimulate interest from stakeholders to leverage support for the project.
2.	Inadequate participation of concerned ministries and agencies for mainstreaming biosafety	Medium	Efforts will be made to build on existing policies/programs of concerned ministries and agencies to have better integration and mutual acceptance.



3.	Sustainability of Capacity building programs on completion of the project is essential.	Medium	Measures to overcome the risk would include preparation of training modules and documents as an integral part of the institutional and human resource capacity building
4.	Change in national biosafety policies.	Low	While this risk is negligible, change in national policies may require reprioritization of some of the activities under the capacity building program. This can be identified during annual/mid-term project reviews and if required, the programs can be realigned with extant policies.

5.	Due to climate change impacts, public perception towards LMOs change, especially if LMOs perform better under climate change conditions	Medium	<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 <b>India</b>, the main projections under climate change suggest that seasons of heat, drought and rainfall will become more intense. These changes are likely</p> <p>to result in an increased frequency of extreme events, primarily floods during the monsoon (resulting in erosion, landslides, and crop failure) but in some cases also droughts.</p> <p>Temperatures in India are projected to increase by approximately 4°C by 2080-2099. Warming is stronger in annual minimum and maximum temperatures than in the average. Under all emissions pathways, the rise in annual minimum temperatures is around 18-21% higher than the rise in average temperatures. Considerable uncertainty characterizes projections of local long-term future precipitation trends in India, this uncertainty is compounded by a poor understanding of the relationship between El Niño Southern Oscillation and the monsoon, and the impact climate change may have on this relationship.[1]</p> <p>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. Based on the scenarios, 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 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 India capacity to effectively manage safe handling and use of LMOs in such cases.</p>
----	---	--------	--

6.	An outbreak of diseases (eg. COVID-19)	High	<p>India's situation is captured in the WHO incident reports. See <a href="https://cdn.who.int/media/docs/default-source/wrindia/situation-report/india-situation-report-96.pdf?sfvrsn=772d42d9_4">https://cdn.who.int/media/docs/default-source/wrindia/situation-report/india-situation-report-96.pdf?sfvrsn=772d42d9_4</a> As of 30 November 2021, India reported a total of 34,587,822 confirmed cases. Highest number of cases in a day were 414,188; reported on 7 May 2021 during the second wave. The Pandemic has had a severe impact on 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 supporting a strong biosafety regime will be communicated as part of the green recovery programme of country and building back better. Biosafety measures developed will also contribute to national biosecurity measures in managing future pandemics. 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 carrying out relevant activities via alternative working methods (e.g. video-conferences, telecommuting, recourse to national human resources and hybrid interventions ? virtual/face to face meetings among others). Any mitigation measure will have to be discussed between the implementing and the executing partners/agencies.</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 base 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 as applicable</p>
----	--	------	---

---

[1] <https://climateknowledgeportal.worldbank.org/country/india/climate-data-projections#:~:text=Temperatures%20in%20India%20are%20projected,2080%2D2099%20under%20the%20RCP8.&text=Warming%20is%20stronger%20in%20annual,the%20rise%20in%20average%20temperatures.>

## **6. 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.**

### **Institutional Structure**

MoEF&CC as the Nodal Ministry would be responsible for overall implementation of Phase-III Biosafety Project in association with UNEP/GEF and its identified stakeholders. National Project Director (NPD) would be designated from MoEF&CC who will be the key person for ensuring the implementation of project activities as per agreed Terms of Reference / Project Cooperation Agreement to be executed between MoEF&CC and UNEP. National Project Coordinator (NPC) would be designated from MoEF&CC who will be vested with the responsibility of day to day implementation of project activities through identification, engagement and execution of contracts/ agreements with concerned stakeholders. NPC would be participating in annual NPC meetings to be organized by UNEP for showcasing the progress and implementation of project activities at international forums. Project Steering Committee (PSC) would be constituted under the Chair of NPD, who will provide guidance on implementation of project objectives and this PSC would meet at least once in a year and approve work plans, budgets etc. Project Monitoring Committee (PMC) consisting of relevant inter-ministerial experts would be constituted under the Chair of NPD/NPC who will be primarily responsible for overseeing the progress of the project at regular intervals. PMC would meet at least once in a quarter and approve all contracts, payments, draft resource documents or outputs generated from time to time. Project Management Unit (PMU) consisting of Project Officers supported by Project Assistants would be engaged for ensuring the timely execution and implementation of project activities. PMU would be reporting to the NPC. In view of integration of Convention on Biological Diversity (CBD) and its two Protocols, efforts would be taken for Mainstreaming Biosafety activities across various sectors and international agreements like Aarhus Convention. The project will closely associate with other UNEP-Biosafety projects within the region.

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

**Is the Project consistent with the National Strategies and plans or reports and assesments under relevant conventions?**

Yes

**If yes, which ones and how: NAPAs, NAPs, ASGM NAPs, MIAs, NBSAPs, NCs, TNAs, NCSAs, NIPs, PRSPs, NPFE, BURs, INDCs, etc**

- National Biodiversity Strategy Action Plan (NBSAP)
- CBD National Report
- Cartagena Protocol National Report
- Nagoya Protocol National Report
- UNFCCC National Communications (NC)
- UNFCCC Biennial Update Report (BUR)
- UNFCCC National Determined Contribution
- UNFCCC Technology Needs Assessment
- UNCCD Reporting
- ASGM National Action Plan (ASGM NAP)
- Minamata Initial Assessment (MIA)
- Stockholm National Implementation Plan (NIP)
- Stockholm National Implementation Plan Update
- National Adaptation Programme of Action Update
- Others

National Biodiversity Strategies and Action Plan (NBSAP) under UNCBD

The following action points identified in National Biodiversity Action Plan (NBAP), 2008 and its Addendum 2014 provide some guidance on mainstreaming:

- ? Identify emerging areas for new legislation, based on better scientific understanding, economic and social development, and development of multilateral environmental regimes, in line with the NEP.
- ? Review the regulatory processes for LMOs so that all relevant scientific knowledge is considered, and ecological, health, and economic concerns are adequately addressed.
- ? Periodically review and update the national biosafety guidelines to ensure that these are based on current scientific knowledge.
- ? Ensure conservation of biodiversity and human health while dealing with LMOs in transboundary movement in a manner consistent with the multilateral biosafety protocol.
- ? Develop appropriate liability and redress mechanisms to internalize environment costs and address economic concerns in case of any damage to biodiversity
- ? Develop DNA-probe based technology for tracking of LMOs.
- ? Develop specific pilot gene banks for LMOs approved for undertaking research and commercial use.
- ? Develop capacity for risk assessment, management and communication on LMOs.
- ? Support pilot studies on use of biotechnology tools for conservation where appropriate.
- ? Develop specific complimentary capacity building measures based on national needs and priorities for the formulation and implementation of national rules and procedures for liability and redress to strengthen the establishment of baseline information and monitoring changes.
- ? Develop Protocols for monitoring products based on genetic use restriction technologies.
- ? Strengthen participatory appraisal techniques and encourage formation of local institution structures for planning and management of natural resources for ensuring participation of women.
- ? Develop a unified national system for regulation of all introductions and carrying out rigorous quarantine checks.
- ? Strengthening domestic quarantine measures to contain spread of IAS.

The new National Biotechnology Development Strategy (2015-2020) has identified biotechnology sector as a frontline area of science with immense potential to address sustainable socio-economic transformation. Major investments are proposed in identified thrust areas such as Pharmaceutical Biotechnology, Biotechnology in Healthcare, Food Biotechnology, Industrial and Microbial Biotechnology, Plant Biotechnology, Agriculture Biotechnology, Animal Biotechnology, Environmental Biotechnology, Marine Biotechnology, Nanobiotechnology, Biotechnology Regulation, Biotechnology Education is proposed through research and development (Basic and Translational),

institutional building, knowledge building and world class infrastructure with special focus on food and nutrition, advanced health care, bio-resource utilization/prospecting and bioremediation.

The Strategy specifically recognises that advances in gene discovery and genomics have led to the identification of several novel genes that provide excellent opportunities for effectively tackling problems of biotic/abiotic stresses, for enhancement of crop productivity, and for improvement of their nutritional quality. In the era of climate change, degradation of farmlands, increased soil salinity, drop in groundwater as well as pollution of surface water sources, more frequent droughts and so on; research and development in transgenic crops has been identified as a priority area. The Strategy provides special attention to bio-resources rich States spread across diverse ecosystems and nurtured by indigenous communities.

Under the National Action Plan on Climate Change, India has launched a dedicated National Mission on Sustainable Agriculture (NMSA) to define its strategies for climate mitigation and adaptation within the agriculture sector. The National Mission for Sustainable Agriculture (NMSA) has been formulated for enhancing agricultural productivity especially in rainfed areas focusing on integrated farming, water use efficiency, soil health management and synergizing resource conservation. The focus areas of NMSA include Dryland Agriculture, Risk Management, Access to Information and Use of Biotechnology. NMSA has identified the use of biotechnology in the following areas:

? Genetic engineering to convert C-3 crops to the more carbon responsive C-4 crops to achieve greater photosynthetic efficiency for obtaining increased productivity at higher levels of carbon dioxide in the atmosphere and to sustain thermal stresses.

? Development of strategies for low input sustainable agriculture by producing crops with enhanced water and nitrogen use efficiency which may also result in reduced emissions of greenhouse gases, and crops with greater tolerance to drought, high temperature, submergence and salinity stresses.

? Development of nutritional strategies for managing heat stress in dairy animals to prevent nutrient deficiencies leading to low milk yield and productivity.

? Development of salt tolerant and disease resistant freshwater fish and prawns

The National Report on Biosafety highlights the following areas as priority areas for further capacity building:

? Institutional capacity

- ? Human resources capacity development and training
- ? Risk assessment and other scientific and technical expertise
- ? Risk management
- ? Public awareness, participation and education in biosafety
- ? Information exchange and data management including participation in the Biosafety Clearing-House
- ? Scientific, technical and institutional collaboration at subregional, regional and international levels
- ? Technology transfer
- ? Identification of LMOs, including their detection
- ? Socio-economic considerations
- ? Implementation of the documentation requirements under Article 18.2 of the Protocol
- ? Measures to address unintentional and/or illegal transboundary movements of LMOs
- ? Scientific biosafety research relating to LMOs
- ? Taking into account risks to human health

Some of the highlighted issues shall inform the design of the project interventions.

**SDG: The project will also contribute and make inputs in meeting the following SDGs**

SDG 2 - End hunger, achieve food security and improved nutrition and promote sustainable agriculture

*By 2020, maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, as internationally agreed*

*Increase investment, including through enhanced international cooperation, in rural infrastructure, agricultural research and extension services, technology development and plant and livestock gene banks to enhance agricultural productive capacity in developing countries, least developed countries*

SDG 15: Protect, restore and promote sustainable use of terrestrial ecosystems



*By 2020, integrate ecosystem and biodiversity values into national and local planning, development processes, poverty reduction strategies and accounts*

*Mobilize and significantly increase financial resources from all sources to conserve and sustainably use biodiversity and ecosystems*

SDG 17: Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development

#### *Technology*

*Enhance North-South, South-South and triangular regional and international cooperation on and access to science, technology and innovation and enhance knowledge sharing on mutually agreed terms, including through improved coordination among existing mechanisms, at the United Nations level, and through a global technology facilitation mechanism*

*Promote the development, transfer, dissemination and diffusion of environmentally sound technologies to developing countries on favourable terms, including on concessional and preferential terms, as mutually agreed*

#### *Capacity Building*

*Enhance international support for implementing effective and targeted capacity-building in developing countries to support national plans to implement all the Sustainable Development Goals, including through North-South, South-South and triangular cooperation*

### **8. Knowledge Management**

**Outline the knowledge management approach for the Project, including, if any, plans for the Project to learn from other relevant Projects and initiatives, to assess and document in a user-friendly form, and share these experiences and expertise with relevant stakeholders.**

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 experience 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 Support 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 Union and State governmental sector, media, parliament, researchers, academia, farmers, women, the youth and local communities. Manuals and guidelines will be developed and published and made available for all the relevant stakeholders. The national BCH website, <http://in.biosafetyclearinghouse.net/>, will be updated periodically with new relevant information and made accessible via the Internet, mobile telephony, social media ? Facebook, twitter and YouTube. Communications sites will be used to disseminate information. Special publications, brochures, leaflets, posters, calendars on best practices on biosafety will be provided and disseminated through the relevant actors and stakeholders. On-line forums and webinars to discuss and share information will be used to facilitate inter-country and sub regional communication and networking. The project will also make available new information and communicate results through the quarterly Biosafety newsletters, TV, local and community radios and also through the news section of the Genetic Engineering Appraisal Committee (<http://www.geacindia.gov.in/biosafety-newsletter.aspx>). The project will also develop android based mobile applications as a platform for information sharing and knowledge management. The website of the Genetic Engineering Appraisal Committee ? <http://geacindia.gov.in/index.aspx> will be designated as a key repository of Biosafety information, decision and declarations to serve as a knowledge management repository on Biosafety for India.

## 9. 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 \*

PIF	CEO Endorsement/Approval	MTR	TE
Low			

#### Measures to address identified risks and impacts

Provide preliminary information on the types and levels of risk classifications/ratings of any identified environmental and social risks and potential impacts associated with the project (considering the GEF ESS Minimum Standards) and describe measures to address these risks during the project design.

No.	Risk	Priority	Risk Management Strategy
1.	Inadequate participation of the targeted stakeholders (especially at the State level) in the capacity building program.	Medium	To overcome this constraint, extensive efforts would be made to: <ul style="list-style-type: none"> <li>? involve high level functionaries in this capacity building initiative.</li> <li>? Existing and mandated Central and State coordination mechanisms will be used.</li> <li>? stimulate interest from stakeholders to leverage support for the project.</li> </ul>
2.	Inadequate participation of concerned ministries and agencies for mainstreaming biosafety	Medium	Efforts will be made to build on existing policies/programs of concerned ministries and agencies to have better integration and mutual acceptance.

3.	Sustainability of Capacity building programs on completion of the project is essential.	Medium	Measures to overcome the risk would include preparation of training modules and documents as an integral part of the institutional and human resource capacity building
4.	Change in national biosafety policies.	Low	While this risk is negligible, change in national policies may require reprioritization of some of the activities under the capacity building program. This can be identified during annual/mid-term project reviews and if required, the programs can be realigned with extant policies.

5.	Due to climate change impacts, public perception towards LMOs change, especially if LMOs perform better under climate change conditions	Medium	<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 <b>India</b>, the main projections under climate change suggest that seasons of heat, drought and rainfall will become more intense. These changes are likely</p> <p>to result in an increased frequency of extreme events, primarily floods during the monsoon (resulting in erosion, landslides, and crop failure) but in some cases also droughts.</p> <p>Temperatures in India are projected to increase by approximately 4°C by 2080-2099. Warming is stronger in annual minimum and maximum temperatures than in the average. Under all emissions pathways, the rise in annual minimum temperatures is around 18-21% higher than the rise in average temperatures. Considerable uncertainty characterizes projections of local long-term future precipitation trends in India, this uncertainty is compounded by a poor understanding of the relationship between El Niño Southern Oscillation and the monsoon, and the impact climate change may have on this relationship.[1]</p> <p>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. Based on the scenarios, 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 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 India capacity to effectively manage safe handling and use of LMOs in such cases.</p>
----	---	--------	--

6.	An outbreak of diseases (eg. COVID-19)	High	<p>India's situation is captured in the WHO incident reports and is among one of the highest currently in the world. See <a href="https://cdn.who.int/media/docs/default-source/wrindia/situation-report/india-situation-report-59.pdf?sfvrsn=fff0e451_4">https://cdn.who.int/media/docs/default-source/wrindia/situation-report/india-situation-report-59.pdf?sfvrsn=fff0e451_4</a> As at 15 March 2021, the confirmed cases of COVID-19 was 11,385,339 and 158,725. The Pandemic has had a severe impact on the country and is likely to slow down the impact on 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 supporting a strong biosafety regime will be communicated as part of the green recovery programme of country and building back better. Biosafety measures developed will also contribute to national biosecurity measures in managing future pandemics. 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 carrying out relevant activities via alternative working methods (e.g. video-conferences, telecommuting, recourse to national human resources and hybrid interventions ? virtual/face to face meetings among others). Any mitigation measure will have to be discussed between the implementing and the executing partners/agencies.</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 base 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 as applicable</p>
----	--	------	--

Per the guidance provided on the reviewed SRIF - Project is considered to be a low-risk project as the nature of the support is to build overall capacity of the government in implementing the Cartagena Protocol on Biosafety mainly in regulatory measures around LMOs. The project team will ensure safeguards principles are one of the key reference principles in the review and updated of policy briefs, risk management and liability and redress guidance. The proponents shall also ensure compliance to the Guiding Principles stated in the SRIF form of the GP 1-10 questions in the Section 3 of the SRIF Form.

[1] <https://climateknowledgeportal.worldbank.org/country/india/climate-data-projections#:~:text=Temperatures%20in%20India%20are%20projected,2080%2D2099%20under%20the%20RCP8.&text=Warming%20is%20stronger%20in%20annual,the%20rise%20in%20average%20temperatures.>

**Supporting Documents**

Upload available ESS supporting documents.

Title	Submitted
<b>Biosafety IndiaSRIF_PIFstage_updated</b>	
<b>BS India_SRIF</b>	

**Part III: Approval/Endorsement By GEF Operational Focal Point(S) And GEF Agency(ies)**

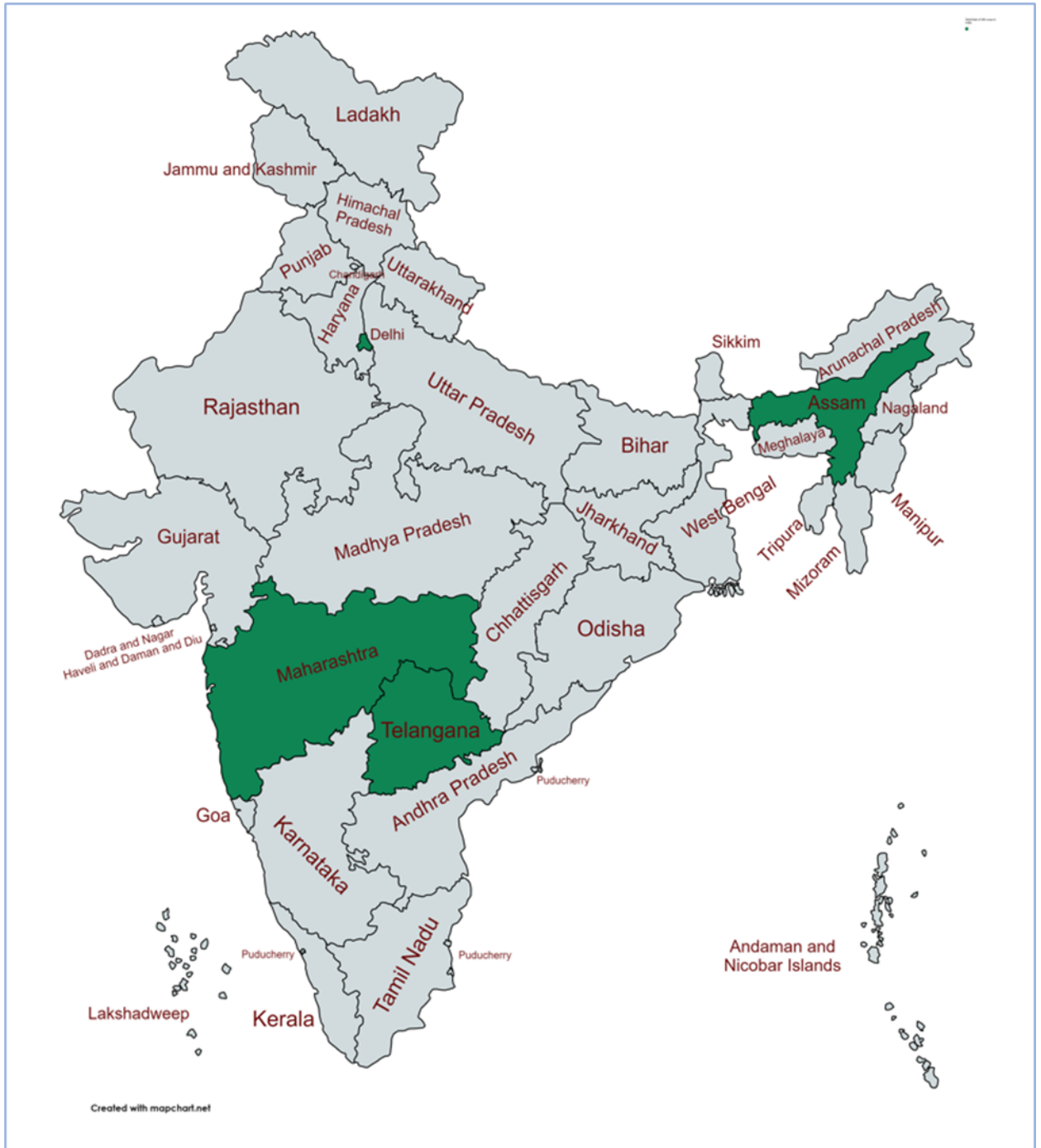
**A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT (S) ON BEHALF OF THE GOVERNMENT(S): (Please attach the Operational Focal Point endorsement letter with this template).**

<b>Name</b>	<b>Position</b>	<b>Ministry</b>	<b>Date</b>
Richa Sharma	Joint Secretary and GEF Operation Focal Point	Ministry of Environment, Forest and Climate Change	3/11/2020



**ANNEX A: Project Map and Geographic Coordinates**

Please provide geo-referenced information and map where the project intervention takes place



The project will be implemented in India: for activities related to State level engagement at pilot scale, States will be shortlisted based on results of stock taking assessment. States with active biotechnology

programmes for development and use of LMOs and where field trials have been permitted in the recent past are highlighted in the map.

The tools and interventions envisaged in the proposed project will be tailor made to address State specific needs, ecosystems and environments. The final selection of targeted States will be based on the results of the Stocking taking assessment under Component 1.

