REQUEST FOR CEO ENDORSEMENT/APPROVAL

PROJECT TYPE: Full-sized Project
THE GEF TRUST FUND

Submission Date: 15th July 2011

PART I: PROJECT INFORMATION

GEFSEC PROJECT ID: 3751
GEF AGENCY PROJECT ID: 00388
COUNTRY(IES): India
PROJECT TITLE: Capacity Building on Biosafety for Implementation of the Cartagena Protocol in India - Phase II
GEF AGENCY(IES): UNEP, (select), (select)
OTHER EXECUTING PARTNER(S): Union Ministry of Enivronment and Forests, Government of India
GEF FOCAL AREA(s): Biodiversity
GEF-4 STRATEGIC PROGRAM(s): SP 6: Building Capacity for the Implementation of the Cartagena Protocol on Biosafety (see preparation guidelines section on exactly what to write)
NAME OF PARENT PROGRAM/UMBRELLA PROJECT: BIOSAFETY

Expected Calendar (mm/dd/yy)	
Milestones	**Dates**
Work Program (for FSPs only)	January 2009
Agency Approval date	August 2011
Implementation Start	September 2011
Mid-term Evaluation (if planned)	September 2013
Project Closing Date	August 2015

A. PROJECT FRAMEWORK (Expand table as necessary)

Project Objective: To strengthen the biosafety management system in Inida with special emphasis on Risk Assessmnet and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities.

Project Components	**Indicate whether Investment, TA, or STA[2]**	**Expected Outcomes**	**Expected Outputs**	**GEF Financing[1]**		**Co-Financing[1]**		**Total ($)**
				($) a	%	($) b	%	c=a+ b
Component I: Stocktaking Assessment								

1. Needs Assessment	TA	Updated information is consolidated to guide the planning of specific activities under this project.	•Baseline information to evaluate potential changes due to introduction of LMOs is compiled and updated. •Existing documentation is reviewed for compliance between the information needed under the prevailing regulatory system and the CPB. •A survey is conducted to identify the public institutions, facilities and laboratories to be up-graded to be national referral laboratory. •An assessment is carried out on the long term funding needed from GoI. •National consultation with all stakeholders and partners is carried to discuss results from this needs assessment study.	55,000	41	80,000	59	135,000
Component II: Strengthening Regulatory and Legal Framework								

2.1 Risk Assessment and Management	TA	A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk. By 2012, regulatory bodies have effective risk assessment and management strategies in place.	•Existing RA and RM procedure and guidelines are reviewed to confirm whether India is compliant with CPB obligations. •Crop-specific biology and ecology document is developed to assist dossier preparation. •Baseline data on presence of wild relatives is gathered for better risk management of LMOs. •Guidelines and procedures are developed for specific types of risk associated with specific traits. •LMOs are monitored by regulatory agencies after environmental release. •Indicators to measure gene flow and impact on non-targets are developed to assist in RA and RM	450,000	29	1,093,792.50	71	1,543,792.50
2.2 Socio-economic assessment		Socio-economic considerations are included in risk assessment	•Guidelines and methodologies are developed for socio-economic assessment of GM crops apart from Bt cotton. •Questionnaire is developed for conducting a socio-economic survey. •Guidelines are developed for risk benefit analysis	150,000	33	300,414.90	67	450,414.90

2.3 Handling, transport, packaging and identification of LMOs		A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB	•A feasibility study is carried out on measures to be taken for putting in place an 'identity preservation system' for handling of LMOs in agriculture. •To identify best practices suitable for India, a review is undertaken for strategies to sample, detect, quantify and certify LMOs from selected GM importing/exporting countries	165,000	29	400,414.90	71	565,414.90
Component III: Strengthening Institutional Capacity								
3.1 Institutional Capacity Building	TA	Institutions and staff capacity is enhanced for LMO detection	•A feasibility study is carried out on public private partnership for LMO detection. •Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMO in agriculture. •Methodology and procedures are developed for LMO detection. •Staff, irrespective of gender, is trained for LMO detection and maintenance of laboratory.	850,000	30	2,000,512.80	70	2,850,512.80
Component IV: Human Resource Development								

4.1 Training of Trainers	TA	Human resource is developed for strategic areas such risk evaluation. Enforcement mechanism at the ports of entry is strengthened with trained staff.	•Training modules/manuals are prepared for conducting/ evaluating risk assessment and management. •Training modules / manuals are prepared for monitoring field trials of GM crops and compliance evaluation. •Training modules/manuals are prepared for training of custom and plant quarantine officials for enhanced enforcement at the ports of entry.	360,000	29	901,352.10	71	1,261,352.10
Component V: Information dissemination for enhancing public awareness								

5.1 Information dissemination		Public awareness on biosafety issues, biosafety regulation and regional cooperation. is enhanced.	•Innovative outreach programs are developed for risk communication both through print and electronic media. •Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies. •Primers/ brochures/ booklets /FAQs and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc. •A mechanism is established to communicate regulatory decisions on LMOs to the public. •Biosafety newsletters are published regularly and distributed. •The national BCH is updated regularly. •National, regional and international workshops are organized for targeted audience.	325,000	37	550,512.80	63	875,512.80
Component VI: Project Management								
6.1 Establishing of a Project Coordinating and Monitoring Unit				260,000	34	498,000	66	758,000
Component VII: Project Monitoring and Evaluation								
7.1 Project Monitoring and Evaluation at Mid-term and project termination				45,000	41	65,000	59	110,000
Component VIII: Regional networking and cooperation								
8.1 Annual Meetings of National Project Coordinators under the implementation projects and regional activities to facilitate sharing of information and experience and promote regional cooperation.				67,273	38	110,000	62	177,273
Total Project Costs				**2,727,273**	**31**	**6,000,000**	**69**	**8,727,273**

[1] List the $ by project components. The percentage is the share of GEF and Co-financing respectively of the total amount for the component.

[2] TA = Technical Assistance; STA = Scientific & Technical Analysis.

B. SOURCES OF CONFIRMED CO-FINANCING FOR THE PROJECT (expand the table line items as necessary)

Name of Co-financier (source)	*Classification*	*Type*	*Project*	*%**
Project Government Contribution	National Government	In-kind Cash	5,100,,000 900,000	85 15
GEF Agency(ies)	(select)	(select)	0	
Bilateral Aid Agency(ies)	(select)	(select)	0	
Multilateral Agency(ies)	(select)	(select)	0	
Private Sector	(select)	(select)	0	
NGO	(select)	(select)	0	
Others	(select)	(select)	0	
	(select)	(select)		
	(select)	(select)		
Total Co-financing			6,000,000	100%

* Percentage of each co-financier's contribution at CEO endorsement to total co-financing.

C. FINANCING PLAN SUMMARY FOR THE PROJECT ($)

	Project Preparation a	*Project B*	*Total c = a + b*	*Agency Fee*	*For comparison: GEF and Co-financing at PIF*
GEF financing	0	2,727,273	2,727,273	272,727	2,727,273
Co-financing	0	6,000,000	6,000,000		6,000,000
Total	0	8,727,273	8,727,273	272,727	8,727,273

D. GEF RESOURCES REQUESTED BY AGENCY(IES), FOCAL AREA(S) AND COUNTRY(IES)[1]

GEF Agency	*Focal Area*	*Country Name/ Global*	*(in $)*		
			Project (a)	*Agency Fee (b)[2]*	*Total c=a+b*
(select)	(select)				
(select)	(select)				
(select)	(select)				
Total GEF Resources					

[1] No need to provide information for this table if it is a single focal area, single country and single GEF Agency project.

[2] Relates to the project and any previous project preparation funding that have been provided and for which no Agency fee has been requested from Trustee.

E. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:

Component	*Estimated person weeks*	*GEF amount($)*	*Co-financing ($)*	*Project total ($)*
Local consultants*	220.70	165,500	776,000	941,500
International consultants*	94.0	376,000	4,000	380,000
Total	314.70	541,500	780,000	1,321,500

* Details to be provided in Annex C. [International consultancy is made up of $329,000 @ a rate of $700/day plus a travel allocation of $100/day amounting to $47,000]

F. PROJECT MANAGEMENT BUDGET/COST

Cost Items	*Total Estimated person weeks*	*GEF amount ($)*	*Co-financing ($)*	*Project total ($)*
Local consultants*[i]	253.33	190,000	148,000	338,000
International consultants*				
Office facilities, equipment, meetings, vehicles and communications*[ii]		65,000	312,000	377,000
Travel*[iii]			32,000	32,000
Others		5,000	6,000	11,000
Total		**260,000**	**498,000**	**758,000**

* Details to be provided in Annex C. ** For others, it has to clearly specify what type of expenses here in a footnote.

[i] Note: Budget covers cost of Project staff and consultancy support for project management and logistical support from designated agencies including travel costs as GEF Cost $194,000 and Cofinancing of $148,000 (in kind - $113,000 and cash - $35,000) - See Appendices 1 and 2

[ii] Note: Budget covers cost of Office premises, meetings, office supplies, equipment maintenance and communications as GEF Cost $65,000 and Cofinancing of $312,000 (in kind - $242,000 and cash -$70,000) - See Appendices 1 and 2 and Appendix 14

[iii] Note: *Budget under the Travel cost item is towards participation in annual meetings of project coordinators*

*****Note:*** *Others include expenses for project staff, administrative staff and sub contract to govt. agencies [Cash - $16,000; in kind $16,000].*

G. DOES THE PROJECT INCLUDE A "NON-GRANT" INSTRUMENT? yes ☐ no ☒

(If non-grant instruments are used, provide in Annex E an indicative calendar of expected reflows to your agency and to the GEF Trust Fund).

H. DESCRIBE THE BUDGETED M &E PLAN:

The project will follow UNEP standard monitoring, reporting and evaluation processes and procedures. Substantive and financial project reporting requirements are summarized in Appendix 1 & 2. Reporting requirements and templates are an integral part of the UNEP legal instrument to be signed by the executing agency and UNEP.

The project M&E plan is consistent with the GEF Monitoring and Evaluation policy. The Project Results Framework presented in Appendix 4 includes SMART indicators for each expected outcome as well as mid-term and end-of-project targets. These indicators along with the key deliverables and benchmarks included in Appendix 6 will be the main tools for assessing project implementation progress and whether project results are being achieved. The means of verification and the costs associated with obtaining the information to track the indicators are summarized in Appendix 7. Other M&E related costs are also presented in the Costed M&E Plan and are fully integrated in the overall project budget.

The M&E plan will be reviewed and revised as necessary during the project inception workshop to ensure project stakeholders understand their roles and responsibilities vis-à-vis project monitoring and evaluation. Indicators and their means of verification may also be fine-tuned at the inception workshop. Day-to-day project monitoring is the responsibility of the project management team but other project partners will have responsibilities to collect specific information to track the indicators. It is the responsibility of the Project Director to inform UNEP of any delays or difficulties faced during implementation so that the appropriate support or corrective measures can be adopted in a timely fashion.

The Project Steering Committee will receive periodic reports on progress and will make recommendations to UNEP concerning the need to revise any aspects of the Results Framework or the M&E plan. Project oversight to ensure that the project meets UNEP and GEF policies and procedures is the responsibility to the Task Manager in UNEP-GEF. The Task Manager will also review the quality of draft project outputs, provide feedback to the project partners, and establish peer review procedures to ensure adequate quality of scientific and technical outputs and publications.

At the time of project approval, 75 percent of baseline data is available. Baseline data gaps will be addressed during the first year of project implementation. A plan for collecting the necessary baseline data is presented in Appendix 5. The main aspects for which additional information are needed are compiled information on evaluation of potential changes due to introduction of LMOs, review and cross-check of existing legal documents to comply with CPB obligations, survey to identify public institutions, facilities and laboratories to be up-graded and an assessment on long term funding needed from the GoI to maintain biosafety in the country.

Project supervision will take an adaptive management approach. The Task Manager will develop a project supervision plan at the inception of the project which will be communicated to the project partners during the inception workshop. The emphasis of the Task Manager supervision will be on outcome monitoring but without neglecting project financial management and implementation monitoring. Progress vis-à-vis delivering the agreed project global environmental benefits will be assessed with the Steering Committee at agreed intervals. Project risks and assumptions will be regularly monitored both by project partners and UNEP. Risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR. Key financial parameters will be monitored quarterly to ensure cost-effective use of financial resources.

A mid-term management review or evaluation will take place on October 2012 as indicated in the project milestones. The review will include all parameters recommended by the GEF Evaluation Office for terminal evaluations and will verify information gathered through the GEF tracking tools, as relevant. The review will be carried out using a participatory approach whereby parties that may benefit or be affected by the project will be consulted. Such parties were identified during the stakeholder analysis (see section 2.5 of the project document). The Project Steering Committee will participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented.

An independent terminal evaluation will take place at the end of project implementation. The Evaluation and Oversight Unit (EOU) of UNEP will manage the terminal evaluation process. A review of the quality of the evaluation report will be done by EOU and submitted along with the report to the GEF Evaluation Office not later than 6 months after the completion of the evaluation. The standard terms of reference for the terminal evaluation are included in Appendix 9. These will be adjusted to the special needs of the project.

The GEF tracking tools (Appendix 15) will be used and updated at mid-term and at the end of the project and will be made available to the GEF Secretariat along with the project PIR report. As mentioned above the mid-term and terminal evaluation will verify the information of the tracking tool.

PART II: PROJECT JUSTIFICATION: In addition to the following questions, please ensure that the project design incorporates key GEF operational principles, including sustainability of global environmental benefits, institutional continuity and replicability, keeping in mind that these principles will be monitored rigorously in the annual Project Implementation Review and other Review stages.

A. STATE THE ISSUE, HOW THE PROJECT SEEKS TO ADDRESS IT, AND THE EXPECTED GLOBAL ENVIRONMENTAL BENEFITS TO BE DELIVERED:

Although India had completed the United Nations Development Assistance Framework (UNDAF) process in 2000, where the elimination of human poverty and inequalities, and promotion of sustainable human development were identified as top national priorities, there is still much to be done. Poverty and inadequate sustainable development continue to contribute to environmental deterioration. The key environmental challenges facing the country presently are environmental degradation caused by rapid population growth, intensive agriculture, biodiversity loss, polluting industry, unplanned urbanization, uneven economic growth between urban and rural communities and poverty. All these impact negatively on the people-ecosystems relationship.

Biotechnology has been identified as a frontline area of science with immense potential to address poverty, food security and human health. After more than a decade of concerted effort in research and development (R&D) in identified areas of modern biology and biotechnology, India has derived rich dividends from this investment. Proven technologies at the laboratory level have been up-scaled and tested in demonstration field experiments. Initiatives have

been taken in diverse areas including transgenic plant research with emphasis on pest and disease resistance, nutritional quality, plant genome mapping, the development, validation and commercialization of diagnostic kits and vaccines for communicable diseases, food biotechnology, biodiversity conservation and bio-prospecting, setting up of micro-propagation parks and biotechnology-based development for rural areas, for women and for different States. However, this rapid advancement of biotechnology R&D in India has resulted in considerable concern about the national capacity to ensure safety. This concern is particularly with respect to containment during field testing and transboundary movement of LMOs and their impact on the sustainable use and conservation of biodiversity and on human health. These issues are further exacerbated by India being one of the 17 mega diverse regions of the world as well as the centre of origin of food crops like eggplant, pigeon pea, and cucumber. Therefore protection of its biodiversity is of utmost importance, as it contributes to global agricultural biodiversity and ultimately to global benefits.

As a Party to the CPB, Government of India (GoI) is committed to fully implement the obligations under CPB related to transboundary movements of LMOs. The GoI needs to ensure that biotechnology R&D is guided by a process of prudent decision making that safeguards both biodiversity and human health with adherence to the highest ethical standards. Since India already has several LMOs which are close to commercialization, India will soon be both an exporter and an importer of LMOs. This new role will require India to comply with the transboudary requirement of LMOs under the CPB. With the support of GEF/ World Bank, a capacity building project to enhance national capacity for implementing national biosafety framework (NBF) related to the transboundary movement of LMOs was completed successfully in June 2007. The experience gained from implementing the above GEF WB capacity building project highlighted the urgent need to intensify capacity building initiatives on identified priority areas through a focused program. Furthermore, since modern biotechnology is developing rapidly, there is a need for continuous sharing of best practices in biosafety regulation to ensure effective implementation of the CPB. India being a vast and diverse country, needs additional cooperation and financial resources for building capacity of its personnel for implementation of the various provisions of the CPB and harmonizing it with domestic and international biosafety regulations. To address these issues, the Ministry of Environment and Forests; the nodal Ministry for implementing the CPB is developing this GEF Phase II project on capacity building. This proposed capacity building project on biosafety is aimed at assisting India to fully implement her obligations as Party to the CPB related to the transboundary movement of LMOs. The phase-II project through GEF resources is conceptualized to supplement the ongoing biosafety capacity building initiatives in India, integrate international experience and promote regional cooperation. India being a major developer of LMOs, requires an efficient biosafety management system to ensure conservation and sustainable use of biodiversity, preserve unique eco-systems, reduce environmental degradation, and thereby contribute to global environmental benefits both directly and indirectly.

B. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH NATIONAL AND/OR REGIONAL PRIORITIES/PLANS:

This phase-II project is for building capacity in human and infrastructure resources for improved biosafety management to meet national challenges and goals identified by the Common Country Assessment (CCA) under the UNDAF process in India. This project is consistent with and supportive of the national priorities of India, its Tenth 5-year Plan and India's global commitments. This project will also facilitate the National Biodiversity Action Plan (NBAP) of 2008; support the National Biotechnology Development Strategy (2007), the National Environment Policy (2006), the National Seeds Policy (2005), the National Farmer's Policy (2007), the Food Safety and Standards Act (2006), the Biological Diversity Act (2002) and the Plant Quarantine Order, (2004). Details of the above regulations and policies can be accessed at http://www.envfor.nic.in, http://dbtbiosafety.nic.in, http://www.igmoris.nic.in, http://www.indbch.nic.in, http://mohfw.nic.in/, http://www.plantauthority.in/ and http://agricoop.nic.in/ Additionally, the project will facilitate the proposed establishment of a National Biotechnology Regulatory Authority (NBRA), as an effective single window clearance mechanism for all biotechnology products, to ease the multiple approval system for biotech products, practiced currently by the Department of Biotechnology (DBT) under Ministry of Science and Technology. As India is presently developing new policies, programs and regulations to meet new challenges posed by modern biotechnology, this project is timely and relevant as it will strengthen institutional mechanism, develop well trained human resources and infrastructure as well as establish a mechanism for easy access to relevant information. Therefore, this project is consistent with the national vision to use biotechnology as a vehicle to uplift the livelihood of its resource-poor population including women, improve human health and secure a clean and healthy environment.

C. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH GEF STRATEGIES AND STRATEGIC PROGRAMS:

The current project responds to the commitment under Article 22 of the CPB to provide support for capacity building for the effective implementation of the CPB. The project also meets the objective of GEF operational program on 'Focal Area Strategies and Strategic Programming for GEF-4 specifically in relation to strategic program 6: 'Building Capacity for the Implementation of the CPB, which itself is derived from the GEF strategy for financing Biosafety. The objective of the GEF biosafety program is "to help build the capacity of eligible countries to implement the Cartagena Protocol on Biosafety (CPB) through activities at the national, sub regional and regional levels". It is also consistent with the objectives of the "Program Document for GEF Support to Biosafety in GEF 4" which was approved by GEF Council in April 2008.

Finally the project activities confirm with the COP guidance to the GEF with respect to biosafety, in particular the key elements in the 'Updated Action Plan for Building Capacities for the Effective Implementation of the CPB (COP-MOP-3) which identifies institutional capacity building, human resource development and training, risk assessment and management, public awareness and education, identification of LMOs including detection, implementation of documentation requirements under Article 18 (2) and socio economic consideration as the key elements requiring concrete action for effective implementation of the Protocol.

D. JUSTIFY THE TYPE OF FINANCING SUPPORT PROVIDED WITH THE GEF RESOURCES.

The project will be financed by GEF grant funds under the Resource Allocation Framework (RAF) for biodiversity programs in India under the GEF-4 strategy, with co-financing of cash and in-kind from the national government. It is a technical assistance project and would help in strengthening the implementation of the obligations under CPB.

E. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES:

The project is in line with a number of ongoing capacity building initiatives under the aegis of various stakeholder Ministries / Departments which include; Ministry of Environment and Forests (MoEF), Department of Biotechnology (DBT), Ministry of Agriculture (MoA), Ministry of Commerce (MoC), Ministry of Health and Family Welfare (MoH&FW), Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR) and Central Institute of Cotton Research (CICR). The GoI intends to leverage GEF resources to complement their ongoing activities and facilitate effective implementation of the CPB. All efforts will be made to ensure synergy between the ongoing programs, avoid overlaps and optimize the available resources. Effective project oversight will be ensured through establishment of a National Steering Committee (NSC), chaired by the Secretary of MoEF, with members from relevant agencies. This NSC will review the project at least once a year, and will work closely with various ongoing initiatives carried out by other Ministries and stakeholders. Project management and coordination among different agencies will be carried out by the Project Coordination Unit (PCU) led by the National Project Coordinator (NPC) with technical support from the Project Management and Monitoring Committee. The National Project Director (NPD) will chair the PMMC (See Appendices 10 & 11 of UNEP Project Document).

F. DISCUSS THE VALUE-ADDED OF GEF INVOLVEMENT IN THE PROJECT DEMONSTRATED THROUGH INCREMENTAL REASONING :

India is emerging as a major developer of GM crops and is likely to be both an exporter and importer of LMOs in future. India's experience on the release of LMO is limited to Bt cotton. Therefore there is an urgent need to enhance the level of preparedness to meet the new challenges and to ensure adequate level of compliance during the transboundary movement of LMOs. This project will build upon the foundations laid by earlier initiatives e.g. the WB-GEF project 'Capacity Building Project on Biosafety', the FAO project on 'Capacity Building of GM crops in Asia' and other national projects. Because these were the initial initiatives in biosafety, they were limited to sensitization of various stakeholders on biosafety regulation and understanding the requirement for capacity building to meet the objective under CPB. The WB-GEF and FAO initiatives have already been completed. The ongoing national

capacity building initiative by itself would be unable to overcome the constraints in implementing the CPB. Cognizant of the wide range of biosafety issues that needs to be addressed as well as geographical region of this country, capacity building through national resources alone would be inadequate to implement an effective system that could keep pace with the rapid national and international development in modern technology. With India's adoption of a new set of guidelines for GE plants and food in June 2008, this project will augment the capacity building efforts required to implement these new guidelines. Limited resources, lack of experience and inadequate national expertise on issues specified in this project proposal are obstacles to India's fulfillment of her obligations as Party to the CPB. Therefore, suitable GEF financial support for this phase-II capacity building project on biosafety is critical. With GEF intervention, the baseline studies included in this project will provide guidance to activities, outputs and outcomes needed under each specific component of the project. This GEF-funded project will complement and reinforce the ongoing national capacity building initiatives, integrate international experience and promote regional cooperation with view to strengthen national capacity to fulfill commitments under CPB especially in critical areas such as risk assessment and management (RA&RM), handling, transport, packaging and identification of LMOs and socio economic consideration in decision making. The incremental reasoning would be even more evident after the 'Stocktaking Assessment' to be carried out under component 1 of this project.

G. INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS, THAT MIGHT PREVENT THE PROJECT OBJECTIVE(S) FROM BEING ACHIEVED AND OUTLINE RISK MANAGEMENT MEASURES:

S. No.	Risk	Priority	Risk Mitigation Strategy
1.	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 coupled with sustained national budgetary allocatioin on
2.	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. - stimulate interest from stakeholders to leverage support for the program.
3.	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 and mid term project review and if required, the programs can be realigned with extant policies without changing the primary objective of the current project.

H. EXPLAIN HOW COST-EFFECTIVENESS IS REFLECTED IN THE PROJECT DESIGN:

This project will be cost effective because:

- The project has been designed so as to ensure that all activities and components are not duplicative and directed to addressing gaps identified previously.
- The project will build upon the foundations laid by previous similar projects and national initiatives.
- The multi-agency NSC of this project will further ensure that all activities will be coordinated, reducing transaction cost.
- The 'Training Needs Assessment Survey' carried out during theWorld Bank-GEF capacity building initiative will augment the stock-taking exercise (Component 1) of this project.
- As part of the stocktaking assessment and project management, efforts would be made to leverage

participation from existing resources and institutional infrastructure to ensure wider outreach in various programmes.

- The project design provides for regional and sub regional approaches and also places emphasis on training of trainers which can be replicated throughout the country and the region[1].
- The project has adopted an issue-based approach in its capacity building, focusing on RA&RM, Handling, Transport, Packaging and Identification of LMOs, Socio-economic Considerations and Public Awareness. This approach will cut across institutional and sectoral barriers to build not only national but also regional capacity in these critical areas. This approach will also foster pooling of resources, promote international coordination and be cost effective.

PART III: INSTITUTIONAL COORDINATION AND SUPPORT

A. INSTITUTIONAL ARRANGEMENT:

The institutional arrangements for project supervision at the national level will be carried out as indicated in the Organizational Chart (Appendix 10) as follows:

i. **National Executing Agency (NEA):** The MoEF, the national competent authority for CPB will be the National Executing Agency (NEA) for this project. The agency will work on behalf of GoI to manage the project and will take overall responsibilities for the implementation and execution of the project and achievements of its objectives. NEA will also provide the necessary scientific, technical, financial and administrative support to the project, working in close cooperation with relevant government agencies, the scientific community and other stakeholders.

ii. **National Steering Committee (NSC):** A National Steering Committee (NSC) will be constituted by the MoEF to advise and guide the implementation of the project. The committee will be chaired by Special Secretary/Additional Secretary, MoEF (Chairman of the GEAC) and the members will include senior representatives from concerned ministries/agencies with mandates relevant to the CPB, scientific experts, NGOs and a UNEP representative. It would meet at least once a year. Individual experts may be invited to provide inputs as appropriate to specific meetings. The NSC will oversee the project progress through receipt of half-yearly progress reports and make recommendations to UNEP on the need to revise any aspects of the Results Framework or the M&E plan. The NSC will participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan.

iii. **National Project Director (NPD):** A National Project Director (NPD) will be appointed by MoEF to provide overall supervision of the project. The Joint Secretary in charge of the biosafety subject matter in the ministry (also the national focal point for CPB), will be appointed as NPD of the project and would be responsible for managing the overall project, ensuring that all outcomes are achieved in a timely and cost-effective manner, in accordance to GEF and UNEP procedures. The NPD will oversee the NPC in the preparation of the annual Project Implementation Report (PIR); participate in the mid-term review and terminal evaluation. At the conclusion of the project, he/she is responsible for the completion of the project closure procedures including timely submission of all technical, financial and audit reports to UNEP.

iv. **National Project Coordinator (NPC):** A National Project Coordinator (NPC) will be appointed for day to day coordination of project activities. The NPC will ensure implementation of the project activities as set out in the project document. It would assist the NPD in discharging its functions as guided by NSC. The NPC will assist UNEP in the preparation of the annual Project Implementation Report (PIR), the mid-term and terminal evaluations, and the GEF Tracking Tool (Appendix 15) and is responsible for preparation of project terminal report, at the completion of the project. The NPC will also work in close collaboration with the National Project Coordinating Unit (PCU) as well as manage all other consultants and contractors appointed for the execution of the project. The TOR for the NPC team is in Appendix11

[1] Already India has received a visit by a delegation from the UNEP/GEF Biosafety Implementation Project for Bhutan to understudy the biosafety regulatory processes in India. The component on regional cooperation will be used to support this processes as an adaptive measure through such interactionsn to fine tune the Indian NBF

v. **Project Management and Monitoring Committee (PMMC):** A Project Management and Monitoring Committee (PMMC) will be constituted to provide technical support to NPD and NPC. The PMMC will be chaired by NPD and members will be NPC, experts from DBT and other relevant organizations.

vi. **Project Coordination Unit (PCU):** The Project Coordination Unit (PCU) will be contracted and located in a facilitating agency having experience in biotechnology and biosafety issues. The NEA has already started the process of selecting the facilitating agency which shall be in place by July 2010. The PCU will provide administrative and technical support to NPC in implementation of the project activities.

C. PROJECT IMPLEMENTATION ARRANGEMENT:

Project implementation will be as illustrated in Appendix 10. The project will be implemented by UNEP and managed at the country level by a National Project Coordinator (NPC), under the supervision of the National Project Director (NPD) under the overall guidance of the Naational Executing Agency. The National Steering Committee (NSC) will provide strategic guidance to ensure successful project implementation. Project implementation will be carried out through the Project Management and Monitoring Committee (PMMC) and the Project Coordination Unit (PCU). Progress in implementation will be monitored closely as reflected in the M&E plan (Appendix 7 of UNEP Project Document).

PART IV: EXPLAIN THE ALIGNMENT OF PROJECT DESIGN WITH THE ORIGINAL PIF:

The FSP has been prepared through a consultative process by seeking inputs from various stakeholder viz. government, scientists, public-sector institutions and NGOs on the approved PIF. A national consultation was organized on March 27-28, 2009 at New Delhi with potential project partners to discuss proposed activities under each component and the financial requirement. The key recommendations/suggestions that emerged from the two day consultation pertaining to each project component were consolidated and suitably incorporated in preparing the work plan and the final project design.

The final project design in CEO endorsement template and the UNEP Project Document is the same as the original PIF with respect to objectives, components, activities, global environment benefits, co-financing and GEF grant requested. However, the intra-allocation of funds under various components has been reappropriated based on the detailing of activities and outputs from the stakeholder consultation.

Component	**GEF financing in approved PIF**	**Proposed GEF financing in CEO endorsement**
I. Stocktaking Assessment	30,273	55,000
II. Strengthening Regulatory and Legal Framework		
2.1 Risk Assessment and Management	650,000	450,000
2.2 Socio-economic assessment	150,000	150,000
2.3 Handling, transport, packaging and identification of LMOs	350,000	165,000
III. Strengthening Institutional Capacity	850,000	850,000
IV. Human Resource Development.	250,000	360,000
V. Information dissemination for enhancing Public Awareness	150,000	325,000
VI. Project Management	150,000	260,000
VII. Project monitoring and evaluation	147,000	45,000
VIII. Regional networking and cooperation		67,273
TOTAL	**2,727,273**	**2,727,273**

PART V: AGENCY(IES) CERTIFICATION

This request has been prepared in accordance with GEF policies and procedures and meets the GEF criteria for CEO Endorsement.

Agency Coordinator, Agency name	Signature	Date *(Month, day, year)*	Project Contact Person	Telephone	Email Address
Dr. Maryam Niamir-Fuller, Director, UNEP Division. of GEF Coordination, PO Box 30552 Nairobi, Kenya.		June 03, 2010	*Alex Owusu-Biney,*	+254 20 7624066	Alex.Owusu-Biney@unep.org

ANNEX A: PROJECT RESULTS FRAMEWORK

SEE APPENDIX 4 OF UNEP PROJECT DOCUMENT

ANNEX B1: RESPONSES TO PROJECT REVIEWS (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF)

Comments from Scientific and Technical Advisory Panel (STAP)	**Responses to Comment**
To clarify in the subsequent project documents whether the focus is on agricultural LMOs for each component.	Noted. Emphasis on agricultural LMOs has been incorporated into project document.
To take into consideration adaptation of established systems from other countries and regions to the circumstances of India regarding some of the proposed biosafety measures viz. • Baseline data on the presence of wild relatives of LMOs (2.1); • Sampling and testing (2.3); Further, it has been suggested that keeping in view, the time frame and budget proposed, it may be more realistic to take a risk based approach and focus on wild relatives of LMOs that are most likely to be develop in or introduced to India. In the context of sampling and testing, the same may be considered as a sub component of the identity preservation system and review of strategies in countries with similar circumstances would be useful to identify best practices to adopt in India. Further, it needs to be clarified that the review will focus on agricultural system and not the medical, environmental and other industrial biotechnology sector.	Noted and incorporated. Regarding the baseline data on the presence of wild relatives of LMOs, as suggested, the focus would be on wild relatives of LMOs that are most likely to be developed or introduced to India such as okra and rice. Regarding the sampling and testing, as suggested a review of strategies in countries with similar circumstances to identify best practices has been included. However, the review has still been kept separate, instead of being a sub component of the identity preservation system feasibility study. Because this study would build on primarily existing systems in India for non-GM products such as basmati rice, whereas the sampling and testing systems need to be developed for both in-house and imported products. It has already been indicated that the whole project is focused only on LMOs in agriculture.
German Council Members	**Responses to Comment**
To clarify the relation between the project aiming to implement the CPB with its limited scope with regard to the range of GMOs and related activities covered and the projects objective to support the Indian GMO regulatory system aiming to cover all GMOs and related activities.	Whereas the primary aim of the project is to implement the CPB, the activities covered include strengthening of Indian GMO regulatory system to be consistent with CPB. The project aims to cover both imported and in-house developed LMOs to ensure capacity building for handling both imports and exports from the country.
The project should be developed on the basis of on an independent evaluation of the former WB-GEF biosafety project to take into account lessons learnt, to fill remaining gaps, to build upon reached aims and to avoid repeated funding of comparable activities. Especially with regard to the activities related to the risk evaluation procedure and to GMO detection, the relation between the two projects should be clarified.	The lessons learnt from the former WB GEF project have been taken into account. Concerns with respect to filling the remaining gaps, and avoid repeated funding of comparable activities has been taken care. Activities related to risk evaluation procedure and GMO detection would be built on preliminary capacity created under the first project.

Comments from Scientific and Technical Advisory Panel (STAP)	Responses to Comment
It appears to be problematic that the project "will facilitate the proposed establishment of a National Biotechnology Regulatory Authority" while the respective legislative process and consultations are still ongoing. Especially when the concept of the NBRA has raised considerable controversies within the public and scientific debate since it has been suggested in 2004. The GEF-funded biosafety project should not aim at taking national policy decisions into a specific direction but it - or parts of it - should be developed after these decisions have been taken in order to support their implementation.	The project in no way is involved in facilitating the proposed establishment of NBRA. The inclusion of above statement is primarily for the information and also to emphasize that the capacity building and outreach created under the project will be used by the new system, if it comes into force, as per the decisions of GoI.
It should be indicated if a private partner has already been identified to carry out the feasibility study for LMO detection as indicated in 3.1 and what amount of co-financing is expected.	The private partner has not been identified as of now and the same would be done at later date in accordance with the appointment procedures of GoI. The amount of co-financing has been reflected in the budget sheets.
It may be indicated if it is also planned to support the participation of the public in biosafety decision making (ref. to CPB, Article 23), because currently the fifth component concentrates on public information only.	Component V concentrates primarily on development of systems for public awareness. There is a system of seeking feedback on various issues through regulatory websites in India. Increased public awareness will help in strengthening the public feedback mechanism.

ANNEX C: CONSULTANTS TO BE HIRED FOR THE PROJECT USING GEF RESOURCES

Position Titles	*$/ person week**	*Estimated person weeks***	*Tasks to be performed*
For Project Management			
Local			
Project Staff	750	253.33	• To provide administrative and technical support and inputs for project implementation
International			
Justification for Travel, if any: *Country-wide travel for national consultations, workshops, etc.			
For Technical Assistance			
Local ***			
Senior Consultant/Scientist	750	14	To provide technical support and inputs for implementation of outcome 1 • Base paper preparation for review of crops and traits under development, need for biology documents, information on non-target and beneficiary organisms in different agro ecological zones and the status of available guidelines. • Identification of gaps in existing documents with respect to India's obligations under Articles 8, 10 and 18 (2) of CPB. • Identification of requirements for operationalizing a state of the art referral lab for the detection of LMOs • Assessment of long term funding requirements to sustain the national referral laboratory and its associated network of laboratories • Assessment and inputs for final project design.

Senior Consultants/Scientist(s)	750	65	To provide technical support and inputs for implementation of outcome 2 • Preparation and review of crop-specific biology and ecology documents of okra, cabbage, cauliflower and pigeon pea. • Collection of baseline data on the presence of wild relatives of okra and pigeon pea • Preparation of guidelines for specific types of risk associated with specific traits. • Assessment of roles and responsibilities of various agencies for post release monitoring and development of guidance document for post release monitoring • Preparation of inventories of non target organisms with reference to specific traits/crops in different agroecological zones
Environmentalist and expert in social issue	750	29	To provide technical support and inputs for implementation of outcome 3 • Preparation of questionnaire for conducting a socio-economic survey • Preparation of guidelines and methodologies for SE assessment and risk benefit analysis.
Senior Consultant/Scientist	750	26	To provide technical support and inputs for reviewing strategies for sampling, detection, quantification and certification of LMOs and identification of institutions to be responsible for certification and testing of LMOs.
Senior Consultant/Scientist	750	29	To provide technical support and assistance for • Accreditation of laboratories as per the international norms for detection and verification of LMO in agriculture. • Preparation of sampling procedures and methodologies for LMO detection
Senior Consultant/Scientist	750	29	To provide technical support and inputs for preparation of training modules/manuals for conducting environmental risk assessment and risk management

Communication experts	750	28.7	To provide technical support and inputs preparation of a risk communication strategy and for implementation of a public awareness strategy
International ***			
Senior LMO Detection Consultant	3500	3	To provide technical support and inputs for undertaking survey to identify the public institutions, facilities and laboratories that need to be up-graded as national referral laboratory
Senior Consultant(s)	3500	50	To provide technical support and inputs for • Preparation of a base paper on the status of conformity of existing procedures and guidelines with Article 15, 16 and Annex III of CPB. • Preparation of ERA guidelines and procedures for assessing risks associated with stacking of genes expressing multiple traits • For identification and development of indicators for impact on non target organisms
Environmentalist and experts in social issues	3500	8	To provide technical support and inputs for drafting guidelines and methodologies for SE assessment and for risk benefit analysis
Senior consultants	3500	6	To provide technical support and inputs for reviewing strategies for sampling, detection, quantification and certification of LMOs and identification of institutions to be responsible for certification and testing of LMOs.
Senior consultants	3500	11	To provide technical support and inputs for carrying out feasibility studies for LMO detection through public private partnership (PPP) and also prepare methodologies and procedures for the same. Also to assist in accreditation of laboratories as per the international norms for detection and verification of LMO in agriculture
Senior consultants/scientists	3500	5	To provide technical support and inputs for preparation of training modules/manuals for conducting/ evaluating risk assessment and management
Communication experts	3500	11	To provide for assistance and inputs by sharing experience in risk communication and in awareness raising for public outreach

Justification for Travel, if any: International air travel to India and back, plus addition travel within India, on a needs basis. Travel is budgeted for at $100/day per each consultancy group which comes to $47,000, this allocation is set aside for travel related to the planned international consultancies

* Provide dollar rate per person week. ** Total person weeks needed to carry out the tasks. *** India plans to set up a team of technical experts which will be constituted as cross sectoral teams to provide technical assistance for the targeted activities

ANNEX D: STATUS OF IMPLEMENTATION OF PROJECT PREPARATION ACTIVITIES AND THE USE OF FUNDS

NA

A. EXPLAIN IF THE PPG OBJECTIVE HAS BEEN ACHIEVED THROUGH THE PPG ACTIVITIES UNDERTAKEN. NA

B. DESCRIBE FINDINGS THAT MIGHT AFFECT THE PROJECT DESIGN OR ANY CONCERNS ON PROJECT IMPLEMENTATION, IF ANY: NA

C. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES AND THEIR IMPLEMENTATION STATUS IN THE TABLE BELOW: NA

Project Preparation Activities Approved	*Implementation Status*	*GEF Amount ($)*				*Co-financing ($)*
		Amount Approved	*Amount Spent To date*	*Amount Committed*	*Uncommitted Amount**	
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
Total						

* Any uncommitted amounts should be returned to the GEF Trust Fund. This is not a physical transfer of money, but achieved through reporting and netting out from disbursement request to Trustee. Please indicate expected date of refund transaction to Trustee.

ANNEX E: CALENDAR OF EXPECTED REFLOWS

Provide a calendar of expected reflows to the GEF Trust Fund or to your Agency (and/or revolving fund that will be set up)

NA