



# UNITED NATIONS ENVIRONMENT PROGRAMME

Programme des Nations Unies pour l'environnement    Programa de las Naciones Unidas para el Medio Ambiente  
 Программа Организации Объединенных Наций по окружающей среде    برنامج الأمم المتحدة للبيئة  
 联合国环境规划署



## PROJECT DOCUMENT

### SECTION 1: PROJECT IDENTIFICATION

- 1.1 Project title:** Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India – Phase II
- 1.2 Project number:** GFL/3751  
PMS: 00388
- 1.3 Project type:** FSP
- 1.4 Trust Fund:** GEF
- 1.5 Strategic objectives:**  
 GEF strategic long-term objective: BD3 Biosafety  
 Strategic programme for GEF IV: SP 6: Building Capacity for the Implementation of the Cartagena Protocol on Biosafety
- 1.6 UNEP priority:** Environmental Governance
- 1.7 Geographical scope:** National
- 1.8 Mode of execution:** External
- 1.9 Project executing organization:** Ministry of Environment and Forests, Government of India.
- 1.10 Duration of project:** 48 months  
 Commencing: September 2011  
 Completion: August 2015

<b>1.11 Cost of project</b>	<b>US\$</b>	<b>%</b>
Cost to the GEF Trust Fund	2,727,273	31.25
Co-financing		
Cash		
	900.000	10.31
<i>Sub-total</i>	9000.000	
In-kind		
Ministry of Environment & Forests, Government of India	5,100,000	58.44
<i>Sub-total</i>		
<b>Total</b>	<b>8,727,273</b>	<b>100</b>

## **1.12 Project summary:**

India is predominantly an agriculture-based country and ranks second worldwide in farm output. Agriculture and allied sectors like forestry, logging and fishing accounted for 16.6% of the GDP in 2007, employed 60% of the total workforce and despite a steady decline of its share in the GDP, is still the largest economic sector and plays a significant role in the overall socio-economic development of India. India's vast majority of people depend directly on agriculture and forestry for food security and livelihood. These sectors are also considered most vulnerable to the projected climate change. India's population is growing faster than its ability to produce agricultural commodities especially food crops. Population growth coupled with rapid industrialization is increasing the demand for food, feed, fibre and fuels many folds.

In the last decade, per unit productivity in food grains has plateaued and annual per capita availability is on the decline thereby requiring an urgent need for new technological interventions. In this context the Government of India (GOI) has recognized the potential of modern biotechnology to address poverty, food security and human health. India has made rapid progress in biotechnology research and development (R&D). As of now Bt Cotton is the only crop approved for commercial use in the country and several other crops are under various stages of field testing and evaluation. The impact of the release of living modified organisms (LMOs) on the sustainable use of biodiversity and human health continue to be a primary concern among many.

Recognizing the need for ensuring biosafety, the GOI has taken several steps to ensure safe use of LMOs. In terms of biosafety law and policies, India was one of the first in the developing world to enact a biosafety regulation in as early as 1989, 3 years before the CBD was adopted in 1992. The introduction of the biosafety rules in 1989 encompassed an implementation mechanism involving various committees at institutional, district, state and central levels. This was a pioneering step that was enabled by the Environment (Protection) Act, 1986. By 2007, a constellation of legislations cognate to biosafety regulations were developed. This included the Biological Diversity Act 2002, the Plant Quarantine Order, 2003, Food Safety and Standards Act, 2006, the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR), etc.

The GOI ratified the Cartagena Protocol on Biosafety (CPB) on 17<sup>th</sup> January 2003. Being a Party to the CPB, India is committed to meet its obligations on the transboundary movement of LMOs. Although, India is presently neither an importer nor an exporter of LMOs, there is an urgent need to strengthen the regulatory procedures and enforcement mechanisms with regard to transboundary movement of LMOs, in view of advancements in crop biotechnology at the national and global level.

In the above background, the Phase-II Capacity Building Project on Biosafety aims to strengthen the biosafety management system in India with special emphasis on Risk Assessment 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. The project has 8 components. It will begin with a stocktaking

assessment (Component 1), where updated information is consolidated to refine the project design and to assist in priority setting of project activities to ensure that all project outcomes are achieved. Component 2 aims to strengthen the legal and regulatory framework, whilst Component 3 will enhance institutional capabilities. Component 4 is designed to develop human resources and raising public awareness is undertaken under Component 5. Project management and Project monitoring and evaluation form Component 6 and 7. Promotion of regional cooperation, networking and sharing of experience is covered under Component 8.

This UNEP/GEF-funded Phase II project will build on the foundations of the previous GEF/WB project. The 9 outcomes of the project are expected to contribute to the project objective of enhancing the biosafety management capacity of India, which will in turn, contribute to the overarching goal of GEF to enable CPB Parties to comply with their international obligations under this legal instrument.

## TABLE OF CONTENTS

<b>SECTION 1: PROJECT IDENTIFICATION</b> .....	1
<b>ACRONYMS AND ABBREVIATIONS</b> .....	5
<b>SECTION 2: BACKGROUND AND SITUATION ANALYSIS (BASELINE COURSE OF ACTION)</b> .....	7
2.1. Background and context .....	7
2.2. Global significance.....	8
2.3. Threats, root causes and barrier analysis .....	9
2.4. Institutional, sectoral and policy context.....	10
2.5. Stakeholder mapping and analysis .....	12
2.6. Baseline analysis and gaps .....	13
2.7. Linkages with other GEF and non-GEF interventions .....	13
<b>SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)</b> .....	14
3.1. Project rationale, policy conformity and expected global environmental benefits.....	14
3.2. Project goal and objective.....	15
3.3. Project components and expected results.....	16
3.4. Intervention logic and key assumptions .....	16
3.5. Risk analysis and risk management measures.....	19
3.6. Consistency with national priorities or plans.....	19
3.7. Incremental cost reasoning.....	20
3.8. Sustainability.....	20
3.9. Replication.....	20
3.10. Public awareness, communications and mainstreaming strategy .....	22
3.11. Environmental and social safeguards .....	22
<b>SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS</b> .....	22
<b>SECTION 5: STAKEHOLDER PARTICIPATION</b> .....	25
<b>SECTION 6: MONITORING AND EVALUATION PLAN</b> .....	27
<b>SECTION 7: PROJECT FINANCING AND BUDGET</b> .....	28
7.1. Overall project budget .....	28
7.2. Project co-financing.....	28
7.3. Project cost-effectiveness .....	29
<b>APPENDICES</b> .....	30
Appendix 1: Budget by project components and UNEP budget lines .....	30
Appendix 2: Co-financing by source and UNEP budget lines.....	30
Appendix 3: Incremental cost analysis .....	30
Appendix 4: Results Framework .....	30
Appendix 5: Workplan and timetable .....	30
Appendix 6: Key deliverables and benchmarks .....	30
Appendix 7: Costed M&E plan .....	30
Appendix 8: Summary of reporting requirements and responsibilities .....	30
Appendix 9: Standard Terminal Evaluation TOR.....	30
Appendix 10: Decision-making flowchart and organogram .....	30
Appendix 11: Terms of Reference .....	30
Appendix 12: Co-financing commitment letters from project partners .....	30
Appendix 13: Endorsement letters of GEF National Focal Points .....	30
Appendix 14: Draft procurement plan.....	30
Appendix 15: Tracking Tool.....	<a href="#">29</a>

## ACRONYMS AND ABBREVIATIONS

APR	Annual Performance Report
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CCA	Common Country Assessment
CPB	Cartagena Protocol on Biosafety
CSIR	Council of Scientific and Industrial Research
DAE	Department of Atomic Energy
DBT	Department of Biotechnology
DGEF	Division of GEF Coordination
DGFT	Director General of Foreign Trade
DIP	Destructive Insects and Pests Act, 1914
DLC	District Level Committee
DST	Department of Science and Technology
EOU	Evaluation and Oversight Unit
EPA	Environment (Protection) Act, 1986
FAO	Food and Agriculture Organisation
FSSA	Food Safety and Standards Authority
FSSAI	Food Safety and Standards Authority of India
GDP	Gross Domestic Product
GE	Genetically Engineered
GEAC	Genetic Engineering Approval Committee
GEF	Global Environment Facility
GOI	Government of India
GTZ	Gesellschaft für Technische Zusammenarbeit
IBSC	Institutional Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICMR	Indian Council of Medical Research
IGOs	Inter-Governmental Organizations
LMOs	Living Modified Organisms
MEA	Ministry of External Affairs
MEC	Monitoring and Evaluation Committee
M&E	Monitoring and Evaluation
MoA	Ministry of Agriculture
MoEF	Ministry of Environment and Forests
MoHFW	Ministry of Health and Family Welfare
NBA	National Biodiversity Authority
NBAP	National Biodiversity Action Plan
nBCH	National Biosafety Clearing House
NBF	National Biosafety Framework
NBPGR	National Bureau of Plant Genetic Resources
NBRA	National Biotechnology Regulatory Authority
NEA	National Executing Agency
NEP	National Environment Policy
NFP	National Focal Point
NGO	Non-governmental Organisation
NPC	National Project Coordinator
NPD	National Project Director
NSC	National Steering Committee

PBS	Programme for Biosafety System
PCU	Project Coordination Unit
PIR	Project Implementation Review
PMMC	Project Management and Monitoring Committee
PPV&FRA	Protection of Plant Varieties and Farmers' Rights Act
R&D	Research and Development
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
SABP	South Asia Biosafety Program
SBB	State Biodiversity Board
SBCC	State Biotechnology Coordination Committee
SOPs	Standard Operating Procedures
UGC	University Grants Commission
UNDAF	United Nations Development Assistance Framework
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
USAID	United States Agency for International Development
WB	World Bank

## **SECTION 2: BACKGROUND AND SITUATION ANALYSIS (BASELINE COURSE OF ACTION)**

### **2.1. Background and context**

1. India is known for its rich heritage of biological resources, having already documented over 91,000 species of animals and 45000 species of plants. Nearly 6500 native plant species are still used prominently in indigenous healthcare systems. Thousands of locally adapted crop varieties, grown since ancient times and nearly 140 native breeds of farm livestock continue to thrive in its diversified farming systems. The country is recognized as one of the Vavilovian Centres of Origins and Diversity of Crop Plants having more than 300 wild ancestors and close relatives of cultivated plants are still growing and evolving under natural conditions.
2. Environment protection is enshrined in the Constitution of India. Article 48-A and Article 51-A (g) of the Directive Principles of State Policy in the Constitution of India state that “the State shall endeavour to protect and improve the environment and to safeguard the forests and wildlife in the country”, and it is a duty of every citizen “to protect and improve the national environment including forests, lakes, rivers and wildlife, and to have compassion for living creatures”.
3. India enacted the Environment (Protection) Act (EPA) in 1986, which is an umbrella legislation to enable Central Government to promulgate notifications and rules thereunder for regulating various activities for conservation of environment. Recognizing the need to regulate modern biotechnology products and processes, the GOI notified the ‘Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells’ in 1989 under the EPA, 1986.
4. The GOI acceded to the Convention on Biological Diversity (CBD) on 18 February 1994 and ratified the CPB on 17 January 2003. The Ministry of Environment and Forests (MoEF) is the nodal Ministry for implementing the obligations under the CPB in India.
5. As a Party to the CPB, 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.
6. Biotechnology has been identified as a “sunrise sector” and is expected to be the next key economic driver for the country after Information Technology. National Biotechnology Development Board was established way back in 1982 and in 1986, a separate Department of Biotechnology (DBT) was established under the Ministry of Science & Technology to support research endeavors in biotechnology. Apart from DBT, biotech research in the country is also supported by Indian Council of Agricultural Research (ICAR), Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), University Grants Commission and Private Sector Organizations.
7. Over a period of two decades, the country has built a strong infrastructure for biotechnology research in the public and private sectors, universities and research institutions. Extensive investment in R&D is resulting in development of newer products and processes. India has already commercialized the first transgenic crop i.e. Bt cotton in 2002. In a span of six years, the area under Bt cotton cultivation has

increased to approximately 7.0 million hectares, which is equivalent to 80% of the total area under cotton cultivation. In addition, several GM crops such as brinjal (eggplant), okra, rice, cauliflower, cabbage, tomato, potato, castor, groundnut, pigeon pea, mustard etc. developed through public and private institutions are under various stages of development and field testing. With the above developments, India is expected to be a key player in the export and import of LMOs in future. This new role will require India to comply with the requirements for safe handling and use of LMOs during their transboundary movement as per the obligations under the CPB.

8. Extensive efforts have been made towards capacity building within the country to address biosafety issues. The MoEF, DBT and Ministry of Agriculture (MoA) have organized several workshops for creating awareness regarding biosafety issues and regulatory requirements related to use of LMOs across the country.
9. With the support of World Bank/GEF, a capacity building project to enhance national capacity for implementing the National Biosafety Framework (NBF) related to the transboundary movement of LMOs was completed in June 2007. The experience gained from implementing the above WB/GEF 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.
10. 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, a GEF Phase II project on capacity building is being developed by MoEF.
11. This project proposal on further capacity building in 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.

## **2.2. Global significance**

12. The CPB, which was negotiated under the CBD, entered into force on 11 Sept. 2003 after Palau became the 50<sup>th</sup> country to ratify this international legally binding instrument to regulate the movement of LMOs across national borders. This marks a milestone in the history of international agreement to regulate the transboundary movement of products of biotechnology. The CPB is also the legal instrument which has the most rapid ratification, with 156 Parties (as of 25 March 2009); less than 6 years after its entry into force.
13. One of the operational principles of GEF is that it will be the catalyst to maximize global environmental benefits. Capacity building in biosafety to comply with CPB will ultimately contribute to global benefits through the conservation and sustainable use of India's mega biodiversity, ecosystems and habitats.



14. India being a major developer of LMOs, requires an efficient biosafety management system to ensure conservation and sustainable use of its mega biodiversity. Being one of the 17 mega diverse countries of the world, as also the centre of origin of food crops like eggplant, pigeon pea and cucumber, this project will help India in ensuring conservation and sustainable use of diverse genetic resources, thereby contributing to global environmental benefits both directly and indirectly.
15. This project aims to build not only capacity in various fields of biosafety management, but also aims to create a critical mass of the needed human resources, so that risks can be minimized and biotechnology can be utilised safely for achieving food security through agro-biotechnology practices which require less chemical input, minimal disturbance of the soil (no till cultivation) and better water conservation. These practices can contribute to environmental benefits with less chemical pollution in the atmosphere, less desertification, and better conservation of soil moisture. Drought and salt-tolerant crops can also be cultivated in traditionally non arable lands without additional burden to the environment.
16. After more than a decade of concerted effort in R&D in identified areas of modern biology and biotechnology, proven technologies have moved from the laboratories to field experiments and tests in India. These include transgenic plant research with emphasis on pest and disease resistance, nutritional quality, plant genome mapping, the development, validation and commercialization of diagnostic kits, biodiversity conservation and bio-prospecting. This rapid advancement of biotechnology R&D has made it necessary for India to ensure containment during field testing and safe movement of LMOs within the country. These measures are to advance biotechnology research and at the same time, prevent adverse impact on the sustainable use and conservation of biodiversity and on human health. As this project will enhance India's effort for safe application of agricultural biotechnology research, it will contribute to global agricultural biodiversity and ultimately to global benefits.

### **2.3. Threats, root causes and barrier analysis**

17. The threats and risks to the success of this project include poor coordination between line Ministries and implementing agencies at the national level, inadequate participation of targeted stakeholders (especially at the state level) in the capacity building program, lack of political will to institute changes through policies, regulatory regime and enforcement. Negative public opinion can also impede the progress of this project.
18. Risk mitigation strategies which can be adopted can include an inclusive approach to project design and implementation, so that greater ownership is created among key partners and line Ministries. This will not only address barriers to success, but will also ensure sustainability of the project beyond project life. This inclusive approach involving various sectors of society (media, farmers, students, home-makers, local communities, etc.) as well as through activities carried out under component V of this project i.e. on information dissemination for enhancing public awareness would ultimately help in informed feedback from public.

## 2.4. Institutional, sectoral and policy context

19. As mentioned above, the GOI in its Constitution clearly states that it is the duty of the state to protect and improve environment and to safeguard the forests and wildlife of the country. Reference to the environment has also been made in the Directive Principles of State Policy as well as the Fundamental Rights. In line with this the Environment Protection (EPA) Act, 1986 under the Ministry of Environment Forests (MoEF) provides a holistic framework for protection and improvement to the environment.

20. MoEF notified the “Rules for manufacture, use/import/ export & storage of hazardous micro organisms/ genetically engineered organisms or cells, 1989” (commonly known as Rules, 1989) as per powers conferred by Sections 6, 8 and 25 of Environment (Protection) Act, 1986. These rules are applicable to activities involving r-DNA technology in research, field trials and large scale use. The Rules, 1989 are implemented by the MoEF, the DBT and State Governments through six statutory committees formed under Rules, 1989 and such committees being (i) the Recombinant DNA Advisory Committee (RDAC); (ii) the Review Committee on Genetic Manipulation (RCGM); (iii) the Institutional Biosafety Committees (IBSC); (iv) the Genetic Engineering Approval Committee (GEAC), (v) the State Biotechnology Coordination Committees (SBCC), and (vi) the District Level Committees (DLC). As of now, there are about 400 IBSCs in various public and private sector organizations in the country. About 16 states have SBCCs and DLCs. The Rules, 1989 is supported by a series of guidelines for ensuring safety in biotechnology processes as given under:

- Recombinant DNA Safety Guidelines, 1990
- Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998
- Guidelines for generating preclinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999
- Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
- Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
- Guideline for the Monitoring of Confined Trials of Regulated, Genetically Engineered Plants, 2008
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008
- Protocols for Food and Feed Safety Assessment of GE crops, 2008

The rules and guidelines are available in electronic form at <http://www.igmoris.nic.in>; <http://dbtbiosafety.nic.in>; [http://www.envfor.nic.in/divisions/csurv/geac/geac\\_home.html](http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html)

21. The Biological Diversity Act 2002 has been enacted to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matter connected therewith. There are provisions of securing benefit sharing with local people, conservation and development, biological diversity heritage sites, protection and rehabilitation for threatened species and involvement of state government

institutions in the broad scheme of the implementation of the Biological Diversity Act through constitution of committees. The Act provides for setting up of a National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) by local bodies. Further, it has been mentioned that it is the duty of Central Government to undertake measures to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health.

Copy of the Biological Diversity Act, 2002 and Biological Diversity Rules, 2004 is available at <http://www.nbaindia.org/>.

22. The provisions of Plant Quarantine (Regulation of Import into India) Order 2003, issued under DIP (Destructive Insects and pests) Act, 1914, which came into force from April 1, 2004, are also applicable to import of transgenic seeds. The issuance of import permit of transgenic material is extremely important from the point of view of their potential impact on environment and on agriculture in the country. National Bureau of Plant Genetic Resources (NBPGR) has been designated as the Competent Authority to issue import permits for import of seeds by public and private sector agencies for research purposes after getting permission from DBT and MoEF as the case may be under Rules 1989.
23. The Food Safety and Standards Act, 2006 have been enacted to regulate manufacture, storage, distribution, sale and import of food including the genetically modified food. The Ministry of Health and Family Welfare is the administrative ministry for implementation of the Food Safety and Standards Authority (FSSA). The enforcement of the legislation will be through the State Commissioners for Food Safety and Panchayati Raj/municipal bodies. The Food Safety and Standards Act also takes into account the recommendations of *Codex Alimentarius Commission* related to food safety norms.
24. In the National Seeds Policy, 2002, a separate section (No. 6) on transgenic plant varieties states that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations and guidelines under the EPA, 1986. Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released in the market. After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act.
25. The Ministry of Commerce and Industry through Director General of Foreign Trade (DGFT) notified in April 2006, a new regulation for import of GM products by amending Schedule-I (Imports) of the ITC (HS) Classification of Export and Import items, under the Foreign Trade Policy (2004-09).
26. The National Environment Policy (NEP) adopted by MoEF in 2006 includes Section 5 on Substantive Reforms on living modified organisms (LMOs) that pose significant risks to ecological resources, and perhaps, human and animal health. The NEP 2006 seeks to achieve balance and harmony between conservation of natural resources and development processes and also forms the basic framework for the National Biodiversity Action Plan 2008. The policy proposes to include review or regulatory processes for LMOs to adequately address the ecological, health and economic concerns. It also lays major emphasis on environmental awareness, education and

information which is essential not only to harmonize patterns of individual behaviour with the requirements of environmental conservation but would also minimize the demands placed on the monitoring and enforcement regimes.

27. Recognising biotechnology as an important economic driver for future in the country, DBT has prepared the National Biotechnology Development Strategy, 2007. The stated vision of the strategy is to ensure responsible use of life sciences and biotechnology to promote balanced growth of all sections of society. The GOI is in the forefront of developing a sound biotech base in the country and accordingly a full fledged department of biotechnology pilots the multifarious development of biotechnology in addition to intervention and support by several other scientific departments.
28. As regards the regulation of biotechnology, the National Biotechnology Development Strategy, 2007 states that the National Biotechnology Regulatory Authority (NBRA) will be established as an “independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes”. DBT has been given the responsibility to set up the NBRA and until such time as the NBRA is fully functional, biotechnology regulation will continue under the existing framework.
29. The MoA has approved the “National Policy for Farmers, 2007”. The policy has laid emphasis on the need for genetic modification to incorporate genes which can help impart resistance to drought, salinity and other stresses in various crops. It has been indicated that the risks and benefits associated with GM crops be assessed in a credible and transparent manner. Training and awareness in agronomic management procedures in respect of GM crop varieties has been identified as a key element for maximizing the benefits for farmers.
30. As regards the status of GM crops in India, Bt cotton expressing *cryIAc* gene from *Bacillus thuringiensis* is the only GM crop approved for commercial cultivation. The approval was first accorded in 2002 to M/s Maharashtra Hybrid Seeds Company Ltd. As of now, six Bt cotton events containing single as well as stacked genes have been approved. Presently more than 25 private companies are involved in providing hybrid seeds to the farmers. For the first time, a Bt cotton variety developed by Central Institute of Cotton Research (CICR), Nagpur, a public research institution under ICAR has been introduced in 2008. Several public and private institutions are in the process of developing GM crops expressing different traits. The status of development of various GM crops in India is available at <http://www.igmoris.nic.in>.
31. MoEF is the national focal point for implementation of the CPB as well as the nodal ministry for implementation of the National Biosafety Framework (NBF). The Phase II Capacity Building Project on Biosafety would help in improved human and infrastructure resources for biosafety management to meet national challenges and is consistent with and supportive of the above national acts, policies and developments.

## **2.5. Stakeholder mapping and analysis**

32. MoEF, as the Competent National Authority for CPB and nodal agency for biosafety regulations in the country, will preside and coordinate with relevant ministries, agencies and other organizations at national level. It will work with UNEP/GEF to get stakeholders involved in a stepwise manner as follows:

- *Stakeholder identification:* Biosafety is a cross-cutting issue, which relates to several sectors, including environment, agriculture, health, science and technology, industry, trade, education and customs. The policy makers, scientists/technical experts from public and private sectors, researchers and technicians, legal experts, economists, interest groups, students, mass media and extension workers were identified as important stakeholders through a training needs assessment survey undertaken as part of the Phase I GEF/WB biosafety capacity building project. These stakeholders as identified in the above report (<http://www.envfor.nic.in/divisions/csurv/biosafety/default.htm>) will continue to play an important role in this Phase II project. In addition more stakeholders will be identified during the project cycle.
- *Stakeholders participation:* All identified stakeholders were involved in designing of this project, through a consultative stakeholder meeting convened by MoEF. This consultation also helped in identifying the potential project partners. As the first component of the project, a stocktaking exercise will be carried out and results will be discussed in a national consultation workshop, for setting priorities and refining the work plan of the project. Stakeholders will continue to be involved throughout the project cycle.
- *Information dissemination and consultation:* All relevant websites for information sharing including national Biosafety Clearing House (nBCH) will be updated regularly for use by stakeholders. The GEAC website is also being redesigned to make it more user-friendly. All project information will be disseminated through the above websites which will also serve as a platform for public feedback and participation. The progress of project will be shared through extensive circulation of a quarterly newsletter. Mechanisms for wider dissemination of public outreach material through various extension networks will be developed.

## 2.6. Baseline analysis and gaps

33. Baseline and needs analysis will be undertaken as a first component of this project, in conformity to the approved GEF Strategy for Financing Biosafety in GEF4. The stocktaking assessment will be carried out by government institutions and key partners. They will map out how to collect, consolidate and analyse the updated data to guide the fine-tuning of the project design, plan specific activities under this project, develop a detailed work plan and review existing legal documents for compliance between the information needed under the prevailing regulatory system and the CPB. The training needs assessment undertaken in the earlier biosafety project will also be taken into consideration. Additionally, the stocktaking assessment will also assist in determining the long term funding needed from the GOI to sustain biosafety activities after completion of this project. Incremental cost analysis is included in Appendix 3 (attached).

## 2.7. Linkages with other GEF and non-GEF interventions

34. Several capacity building activities such as organizing national and state level workshops/conferences/training programmes for various stakeholders have been undertaken in India since 2002, when the first GM crop was approved in the country under the aegis of concerned ministries/agencies such as MoEF, DBT, MoA, ICAR,

- ICMR etc. Each of these ministries/agencies particularly MoEF and DBT have allocated separate funds for strengthening biosafety management
35. India, as one of the 12 demonstration projects on NBF Implementation, completed a capacity building project funded by GEF and implemented by World Bank in 2007. The capacity building project helped in enhancing India's national capacity in order to implement the CPB. The development of national capacities in these areas was taken up to enhance the national capabilities for strengthening the legislative framework and operational mechanisms for biosafety management in India; enhance capacity for risk assessment and monitoring; establish the biosafety database system and Biosafety Clearing House Mechanism; and support a network for research, risk assessment, and monitoring. The final project report is available at <http://www.envfor.nic.in/divisions/csurv/biosafety/default.htm>.
  36. India also participated in the FAO project on 'Capacity Building of GM crops in Asia' in 2005.
  37. India is also one of the two countries presently participating in the South Asia Biosafety Program (SABP) which is an international development program initiated with funding from the United States Agency for International Development (USAID). The SABP is engaged in capacity building activities for technical training for food, feed and environmental safety assessment of GE plants.
  38. Coordination between these initiatives and the GEF-funded UNEP Phase II project on biosafety projects will be carried out at two levels, namely at the Executive Coordination level and at the national management team level. Since UNEP/GEF works closely with the key players of other capacity building initiatives in biosafety e.g. SABP, Programme for Biosafety System (PBS), Gesellschaft fur Technisohe Zusammenarbeit (GTZ), etc. under the Coordination Meetings for Governments and Organizations Implementing or Funding Biosafety Capacity Building Activities organized annually by the Secretariat of the CBD, coordination is also achieved at a higher management level.
  39. The Phase-II project through UNEP/GEF resources is conceptualized to build on the initiatives under the Phase I project and supplement the ongoing biosafety capacity building initiatives in India, integrate international experience and promote regional cooperation.

### **SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)**

#### **3.1. Project rationale, policy conformity and expected global environmental benefits**

40. 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 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 needs to be coupled with the national capacity to ensure biosafety 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.

41. As a Party to the CPB, 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 transboundary requirement of LMOs under the CPB.
42. This project conforms to the GEF policy as being the catalyst to maximize global environmental benefits. The project is within Strategic Objective 3 (*To safeguard Biodiversity*) in the Biodiversity focal area, and is relevant to Strategic Program 6: *Capacity Building for the Implementation of the Cartagena Protocol on Biosafety*. One of the aims of this project is to build capacity so that India can utilize agricultural biotechnology to address national food needs in a sustainable manner without harming its mega biodiversity and compromising the quality of the environment. Since this project ensures that the mega biodiversity of India will not be jeopardized at the expense of agricultural development, it is expected to yield global benefits through the conservation and sustainable use of biodiversity.
43. Additionally, the project will assist India, to build capacity to strengthen the biosafety management in the country. Strengthening the biosafety management system will be very important to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO related activities, and at the same time, allow the country to derive maximum benefits from biotechnology through increasing crop yields with more 'green' practices such as the reduction of pesticide use, less irrigation, less desertification and fewer chemicals to the soil. The ability to adopt these innovative agri-biotechnology practices safely will ultimately contribute to conservation of depleting natural resource (water) and reducing environmental degradation, which translate to global environmental benefits.

### **3.2. Project goal and objective**

44. The overarching goal of this project is to assist the GOI, as Party to the CPB, to build capacity to implement the CPB through activities at the national, sub regional and regional levels. It is also consistent with the "Program Document for GEF Support to Biosafety in GEF 4" approved in April 2008.
45. The project objective is to strengthen the biosafety management system in India with special emphasis on Risk Assessment and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure that adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities.



### 3.3. Project components and expected results

46. This project comprises eight components with expected results as described in Table 1 below:

**Table 1: Project components and expected results/outcomes**

<b>Project Components</b>	<b>Expected Results/Outcomes</b>
1. Stocktaking assessment	<ul style="list-style-type: none"><li>• Within the first eight months of project commencement, the project design will be fine tuned based on the updated information and needs assessment by the Project Coordinating Team under the supervision of the National Executing Agency (NEA).</li></ul>
2. Strengthening Regulatory and Legal Framework	<ul style="list-style-type: none"><li>• Within 48 months the legal framework consistent with CPB will be in place.</li><li>• Within 48 months parameters and methodologies for socio economic assessments will be in place.</li><li>• Within 42 months an operational administrative system for handling, transport, packaging and identification of LMOs will be in place.</li></ul>
3. Strengthening Institutional Capacity	<ul style="list-style-type: none"><li>• Within 48 months an institution with a network of 2-3 laboratories will be strengthened for LMO detection.</li></ul>
4. Human Resource Development	<ul style="list-style-type: none"><li>• Within 42 months at least 20 scientists will be trained in risk evaluation.</li><li>• Within 42 months at least three officials at every point of entry will be trained in enforcement of transboundary movement procedure.</li></ul>
5. Information Dissemination for Enhancing Public Awareness	<ul style="list-style-type: none"><li>• Within 48 months extent of feedback from target groups on biosafety issues, regulations and procedures will be increased up to 50%.</li></ul>
6. Project Management	<ul style="list-style-type: none"><li>• During project period, a Project Coordinating Unit would be operational.</li></ul>
7. Project Monitoring and Evaluation	<ul style="list-style-type: none"><li>• During project period, monitoring and evaluation will be ensured as per the GEF requirements</li></ul>
8. Regional Networking and cooperation	<ul style="list-style-type: none"><li>• During project period, participation in all NPC meetings will be ensured and by 2012, at least two events will be held to promote regional cooperation.</li></ul>

### 3.4. Intervention logic and key assumptions

47. The main objective of this project is to support India in implementing the CPB, by strengthening the biosafety management system in the country. This project will complement 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, and reduce environmental degradation. As reflected in the incremental cost analysis (Appendix 3), the baseline value of the planned activities to be carried out in this project is uneven, as it varies with the project component under consideration. A key assumption is that without GEF intervention, India will be unable to build the human and institutional capacities soon enough to ensure that its numerous indigenous LMOs from its national laboratories can be tested and released safely to the environment. Therefore the most important key intervention is capacity building in scientific, technical and administrative areas of biosafety. The intervention logic and key assumptions used are summarised in Table 2 (below). These interventions will result in expected outcomes as shown in the results framework (Annex A/Appendix 4).

**Table 2: Intervention logic and key assumptions**

<b>Intervention Logic</b>	<b>Key Assumptions</b>
1. Stocktaking assessment <ul style="list-style-type: none"> <li>Within the first eight months of project commencement, the project design will be fine tuned based on the updated information and needs assessment by the Project Coordinating Team under the supervision of the National Execution Agency (NEA).</li> </ul>	<ul style="list-style-type: none"> <li>➤ Response from all concerned line departments</li> <li>➤ Key respondents provide inputs</li> </ul>
2. Strengthening Regulatory and Legal Framework <ul style="list-style-type: none"> <li>Within 48 months a legal framework consistent with CPB will be in place.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Strong government commitment</li> <li>➤ Expertise available in carrying out SE assessments</li> </ul>
3. Strengthening Institutions <ul style="list-style-type: none"> <li>Within 48 months an institution with a network of 2-3 laboratories will be strengthened for LMO detection</li> </ul>	<ul style="list-style-type: none"> <li>➤ Build on experience gained in Phase I project</li> <li>➤ International guidance/expertise available</li> <li>➤ Training of trainers will mitigate risk due to staff attrition.</li> </ul>
4. Human Resource Development. <ul style="list-style-type: none"> <li>Within 42 months at least 20 scientists will be trained in risk evaluation</li> </ul>	<ul style="list-style-type: none"> <li>➤ Build on existing enforcement mechanisms e.g. quarantine and customs.</li> </ul>
5. Information dissemination for enhancing Public Awareness <ul style="list-style-type: none"> <li>Within 48 months, extent of feedback from target groups on biosafety issues, regulations and procedures will be increased upto 50%</li> </ul>	<ul style="list-style-type: none"> <li>➤ Strong government and private sector support for increasing public awareness</li> </ul>
6. Project Management	<ul style="list-style-type: none"> <li>➤ Build on experience gained in Phase 1 project</li> <li>➤ Availability of required</li> </ul>

	expertise for Project management
7. Project Monitoring and Evaluation	➤ Build on experience gained in Phase 1 project
8. Regional Networking and cooperation	➤ Build on ongoing regional cooperation activities

### 3.5. Risk analysis and risk management measures

48. Some of possible risk factors are listed in table below:

**Table 3: Risk analysis and mitigation strategies**

S. No.	Risk	Priority	Risk Mitigation Strategy
1.	Sustainability of capacity building programmes on completion of the project.	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. Further, a critical core of national experts would be available as a result of the involvement of network of experts and consultative approach in the project activities.
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: <ul style="list-style-type: none"> <li>- involve high level functionaries in this capacity building initiative.</li> <li>- stimulate interest from stakeholders to leverage support for the program.</li> </ul>
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/mid term project review and if required, the programs can be realigned with extant policies.

### 3.6. Consistency with national priorities or plans

49. 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 NEP (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, (2003). 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 complement the capacity requirements for the proposed National Biotechnology Regulatory Authority (NBRA). 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.

### 3.7. Incremental cost reasoning

50. The baseline, as determined by a training needs assessment under the earlier capacity building project on biosafety in 2006, will be supplemented with a new needs assessment report at the stocktaking exercise, as a first step of this project. The increment includes the activities proposed under this project proposal for the purpose of meeting the requirements of the CPB, to be financed through GEF contribution and national co-financing. An incremental cost analysis is described in Appendix 3 (attached).

### 3.8. Sustainability

51. The aim of this project is to assist India to strengthen its biosafety management system, with special focus on risk assessment and risk management, handling, transport, packaging and identification of LMOs, socio-economic considerations in decision making and increasing public awareness, in accordance with the CPB. This will also build on the foundations of the previous GEF-WB project on capacity building in biosafety, which was completed in 2007. Factors affecting sustainability have been considered in the planning of the project. The project is expected to be sustainable (a) financially, (b) institutionally, and (c) in terms of its environmental and development objectives.

- i. **Political:** Political commitment has been garnered in the fact that India is a party to the CPB. The political support is further reiterated in national policies such as NEP and National Biotechnology Development Strategy, commitment to set up a NBRA and taking up Phase II Capacity Building Project. The project aims to increase awareness among parliamentarians, government officials and judiciary on biotechnology and biosafety through information dissemination which will further facilitate political support.
- ii. **Financial sustainability:** The long term financial requirements to maintain biosafety activities in India are already under study. This project will further help the concerned ministries in the government to recognize the importance of biosafety issues particularly the obligations under the CPB and integrate the same in their plans, policies and strategies. This project will provide the GOI with validated financial figures for allocation in the national budget.
- iii. **Institutional and operational sustainability:** The national biosafety regulatory framework in India is operated by the MoEF and DBT through various statutory committees set up under Rules, 1989. These committees have expert members drawn from various public sector institutions across the country as well as representatives of concerned ministries, state governments and institutions. The

project activities have been planned in such a manner so as to involve a network of experts and use a consultative approach. In this way a critical core of national experts would be available at the end of the project and the movement of project staff will not adversely affect the operational sustainability of the system. Furthermore, it is proposed to clearly define and document the functions, responsibilities and working knowledge document of various stakeholders so that biosafety management can be carried out beyond the project life.

- iv. ***Environmental sustainability:*** One of the key objectives of this project is to build national capacity in risk assessment and risk management to ensure safe use of LMOs taking into account protection to biodiversity, environment and human health. Though all environmental impacts particularly long term effects will not be apparent immediately after the release of LMOs, the availability of state of the art technical tools and a strong regulatory and monitoring regime will help in mitigating the risks and ensuring environmental sustainability to a great extent.
- v. ***Regional/sub-regional cooperation:*** Regional/sub-regional cooperation with various countries in the region will be promoted by regional activities, such as inviting the participants from these countries to regional workshops on relevant issues as well as participation of experts in various events organized by them. Sharing of training activities as well as documentation developed under the project would help the countries who are in the process of implementing their national biosafety frameworks. Regional cooperation activities are integrated into the design of this project particularly component IIA, IV and V (see attached results based framework in Appendix 4).

### 3.9. Replication

- 52. An important component to this project is that throughout its development and its planned implementation, there has been a focus on replicating the project and disseminating information about the project, both within India and in neighbouring countries. These have built on the experiences and lessons from the NBF development project as well as the UNEP experience in managing the 8 demonstration projects on NBF Implementation. The experiences gained from the preparation of this proposal and its implementation will provide lessons for future projects on the implementation of regulations and policies, even in areas outside biosafety.
- 53. The ability for networking amongst stakeholders especially inter-departmental stakeholders to implement this project can be a model for cooperation in other similar situation such as in biodiversity conservation, ecosystems management and other multi stakeholder issues.
- 54. Technical tools such as guidelines for risk assessment, risk management, and monitoring, will be used continuously during the project cycle for field tests and these will be refined with time as more experience is gained from “learning by doing”. These valuable tools can also be shared between countries in the region.
- 55. The involvement and participation of all stakeholders including NGOs, IGOs and target groups in this project will increase understanding and awareness on biosafety issues. This approach will engender national stakeholder ownership, resulting in greater sustainability and replication for public participation and awareness, which has already been established throughout the preparation of this project.

56. Methods and modules for public education and awareness enhancement and participation in decision making can also be replicated for other projects on public empowerment, human rights, and national development. These can also be applied in neighboring countries.
57. The regional consultation activities proposed in this project will promote sub regional cooperation within Asian countries on biosafety, through sharing information on LMOs, conducting 'mock' applications within the region, harmonization of standards and regulations, as well as sharing of technical facilities for risk assessment and risk management and LMO detection. The annual meetings of the national project coordinators will further promote international cooperation through sharing of training resources, lessons and experiences among all biosafety implementation projects.

### **3.10. Public awareness, communications and mainstreaming strategy**

58. Public awareness and communication strategy is already mainstreamed into national developmental strategies and plans. This process which was initiated at the national level in 2002 was further enhanced under the previous GEF/WB capacity building project in biosafety. Public awareness, communications and education in biotechnology and biosafety are integral to Component V of this project.

### **3.11. Environmental and social safeguards**

59. Environmental safeguards are an integral part of this project. As the NEA of this project and also the NFP for the CBD and CPB, MoEF is mandated to ensure incorporation of environmental safeguards during the implementation of this project.
60. Social safeguards are incorporated into the project through empowering all citizens of India, irrespective of race, gender and creed. By establishing a mechanism to enable the public to access information on LMOs, social concerns will also be voiced and responded to. This project will endeavour to achieve gender balance. Project staff recruitment and project activities and training will not discriminate against any particular group or gender. Target groups like farmers will receive special attention in the development of awareness raising materials.
61. Developing procedures for socio-economic assessment is one of the key components which are expected to address issues concerning farmers and farming communities.

## **SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS**

62. The institutional arrangements for project supervision at the national level will be carried out 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. The Terms of Reference (TOR) for the NSC are as described in Appendix 11.
- 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. The Terms of Reference (TOR) for the NPD are as described in Appendix 11.
- iv. **National Project Coordinator (NPC):** A National Project Coordinator (NPC) will be appointed for day to day coordination of project activities. The NPC will report to the NPD and be responsible to ensure implementation of the project activities as set out in the project document. The NPC will also assist the NPD in discharging its functions as guided by NSC. The NPC will be responsible for the preparation of progress and financial reports of the project, as well as of the annual Project Implementation Report (PIR) for UNEP-GEF. The NPC will contribute to the mid-term review and is responsible for preparation of project terminal report, at the completion of the project. The NPC will also manage and work in close collaboration with the 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 Appendix 11.
- 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 provide the required operational and administrative support for project implementation. The PCU will be overseen by the NPC and essential staff and premises 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.



## SECTION 5: STAKEHOLDER PARTICIPATION

63. An inclusive approach to involve all stakeholders will be adopted throughout the project cycle. The stakeholder mapping and analysis as described in Section 2.5 will be the basis of identification of various stakeholder groups to be involved in different ways. Major stakeholders and proposed involvement is summarized below:

**Table 4: Major stakeholders and their participation**

Stakeholders	Type of involvement
<b>Decision makers/policy makers:</b> <ul style="list-style-type: none"> <li>Concerned ministries viz. MoEF, DBT, MoA, Ministry of Health and Family Welfare (MoHFW), Ministry of Finance (MoF), Ministry of External Affairs (MEA) etc.</li> <li>Relevant agencies and authorities viz. FSSAI, PPV&amp;FRA, ICMR, ICAR, CSIR, NBA, etc.</li> <li>Members of statutory committees viz. GEAC, RCGM, MEC and SBCCs.</li> </ul>	<ul style="list-style-type: none"> <li>Will be involved in project implementation as members of National Steering Committee to provide for the required inter-ministerial cooperation.</li> <li>Invited to take part in consultations and meetings on key issues at national, sub-regional and regional level. The relevant agencies would also be involved as resource persons in programmes on awareness raising.</li> </ul>
<b>Scientists/technical experts, researchers and technicians from public and private sectors including academic institutions</b>	<ul style="list-style-type: none"> <li>Will be invited to take part in consultations and workshops for training of trainers and awareness raising.</li> <li>Will be involved in developing training modules and working knowledge documents</li> <li>Will also be involved with developing outreach materials for different target groups.</li> </ul>
<b>Legal experts and economists</b>	<ul style="list-style-type: none"> <li>Will be invited for consultations on documents related to socio-economic assessment.</li> <li>Will be involved in developing training modules and working knowledge documents</li> <li>Will also be involved in developing outreach materials for different target groups.</li> </ul>
<b>Enforcement officials including Customs, Plant Quarantine, state agricultural departments, members of SBCCs, DLCs and IBSCs etc.</b>	<ul style="list-style-type: none"> <li>Will be invited to participate for training workshops.</li> <li>Will assist in post-release monitoring and enforcement at border controls.</li> </ul>
<b>Interest groups, teachers, students, mass media and extension workers</b>	<ul style="list-style-type: none"> <li>Will be invited to take part in awareness raising meetings</li> <li>They will also receive outreach material designed for the different target groups.</li> </ul>

--	--

## SECTION 6: MONITORING AND EVALUATION PLAN

64. The project will follow UNEP standard monitoring, reporting and evaluation processes and procedures. Substantive and financial project reporting requirements are summarized in Appendices 1 & 2. Reporting requirements and templates are an integral part of the UNEP legal instrument to be signed by the executing agency and UNEP.
65. 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.
66. 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.
67. The National 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.
68. 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.
69. 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.

70. A mid-term management review or evaluation will take place on September 2013 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.
71. 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.
72. 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.

## **SECTION 7: PROJECT FINANCING AND BUDGET**

### **7.1. Overall project budget**

73. The overall project budget is US\$ 8,727,273 comprising US\$ 2,727,273 from GEF. Details of budget according to UNEP budget lines are enclosed in Appendix 1&2.

### **7.2. Project co-financing**

74. The GOI will provide cash of US\$900,000 and US\$5,100,000 in kind co-financing amounting to a total of US\$ 6,000,000 as detailed in Table 5 below.

**Table 5: Project Financing**

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

### 7.3. Project cost-effectiveness

75. This project will be cost effective because it will build upon the foundations laid down by the other capacity building initiatives such as the national projects, WB-GEF ‘Capacity Building Project on Biosafety’, the FAO project on ‘Capacity Building of GM crops in Asia’, the South Asia Biosafety Program (SABP) and other projects. The various outputs from these earlier projects will be used for further refinement and development under this project, without the need to ‘re-invent the wheel’. Channels for public communication are already in place through the above efforts and can be used cost effectively through further expansion and replication.
76. The stocktaking exercise, as the mandatory first component of project preparation, will undertake a capacity needs and situation analysis. This will identify as well as ensure that only priority activities will be undertaken and gaps remaining from the previous initiatives are addressed.
77. Since the project emphasizes on inter-agency coordination and collaboration, duplication of efforts will be avoided, thus increasing cost effectiveness.
78. This project has included regional networking in its design. This is in-line with one of the key elements that constitute the foundations of the *GEF Strategy for Financing Biosafety*, namely “emphasize regional and sub-regional approached to the group of participating countries”. Regional cooperation is a cost effective method to share regional expertise and project outputs, such as outreach materials.
79. By emphasizing that a *team* rather than an individual manages the project via the PCU will mitigate staff attrition from the project. This is also a prudent and cost effective way of project management.
80. The project is also expected to be cost effective, as biosafety activities are already mainstreamed into national development plans and actions, and are implemented in a comprehensive and holistic manner, utilizing existing Government mechanisms.

## **APPENDICES**

- Appendix 1: Budget by project components and UNEP budget lines**
- Appendix 2: Co-financing by source and UNEP budget lines**
- Appendix 3: Incremental cost analysis**
- Appendix 4: Results Framework**
- Appendix 5: Workplan and timetable**
- Appendix 6: Key deliverables and benchmarks**
- Appendix 7: Costed M&E plan**
- Appendix 8: Summary of reporting requirements and responsibilities**
- Appendix 9: Standard Terminal Evaluation TOR**
- Appendix 10: Decision-making flowchart and organizational chart**
- Appendix 11: Terms of Reference**
- Appendix 12: Co-financing commitment letters from project partners**
- Appendix 13: Endorsement letters of GEF National Focal Points**
- Appendix 14: Draft procurement plan**
- Appendix 15: Tracking Tool**

### Appendix 3: Incremental Cost Analysis

1. Incremental cost analysis of this project is based on the GEF Operational Guidelines for the Application of Incremental Cost Principle<sup>1</sup> which were developed from the 1996 GEF policy paper on incremental cost<sup>2</sup>.
2. Incremental cost is estimated as the difference in scenarios between the “baseline” or “what would happen without GEF intervention” (where national activities are already being carried out to achieve the present project objectives for domestic benefit), and an “alternative” (where a series of additional activities will be carried out to contribute to global environmental benefit (GEB)). The activities to be carried out by this project proposal will result in that “alternative” scenario, the cost of which will be borne by GEF.
3. Recently, the term “baseline” is replaced by “business-as-usual”<sup>1</sup>. The baseline values described below were determined at the end of the earlier World Bank/GEF biosafety capacity building project. However, cognizant that baseline is dynamic and evolves with time; these will be re-evaluated after the stock taking analysis, as a mandatory first component of this project.

Project Component	Baseline or “Business as usual”	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
<b>1) Stocktaking Assessment</b>	12,000	55,000	43,000	<p>Comprehensive data on National capacity in biotech and biosafety are compiled and updated</p> <p>National RA procedures and documentation requirements for LMOs are reviewed for compliance to CPB</p> <p>Existing facilities are reviewed for strengthening in LMO detection</p>	<p>Updated comprehensive baseline information consolidated and validated.</p> <p>Strategic entry points for GEF intervention are identified</p> <p>GEF interventions are more cost effective.</p>
<b>2) Strengthening Regulatory and Legal Framework</b>					
2A) Risk Assessment and Management	150,000	450,000	300,000	A risk assessment system was already in place in India prior to being a Party to CPB.	Risk assessment (RA) and risk management (RM) system is improved through the strengthening of national legal instruments and capacity, together with better institutional structure.

Project Component	Baseline or “Business as usual”	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
				RA and RM procedures will be streamlined and updated for emerging technologies and products	<p>RA will be science-based according to agreed international principles and methods.</p> <p>RM and emergency response plans are in place to minimise damage to the environment and biodiversity.</p> <p>All decisions are made within CPB timelines</p>
2B) Socio Economic (SE) Assessment	10,000	150,000	140,000	Parameters and methodologies for SE assessment are in place to facilitate informed decision making to minimise any possible negative impact on farming communities	Minimising possible negative effects on farming community, will contribute to national and global food security and improved livelihood.
2C) Handling, transport, packaging and identification of LMOs	50,000	165,000	115,000	<p>Streamline export import procedures for LMOs</p> <p>Safe handling and transfer of LMOs within the country</p>	Facilitate international trade in line with CPB.
<b>3) Strengthening Institutional Capacity</b>	500,000	850,000	350,000	Institutional capacity for LMO detection will be strengthened for better enforcement and compliance	<p>Facilitate compliance to CPB during transboundary movement of LMOs</p> <p>Strengthened institution can serve as centre of excellence for the region.</p>
<b>4) Human Resource (HR) Development</b>	150,000	360,000	210,000	A few project staff was trained under the previous GEF World Bank Phase I project on Biosafety Implementation.	<p>Enhanced national capacity will expedite compliance with CPB</p> <p>The products of training can be utilised in other similar projects to achieve global benefits</p>



Project Component	Baseline or “Business as usual”	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
				Trained manpower will result in an effective and efficient biosafety management system.	The outcome of the project will cut across institutional and sectoral barriers to build not only on national but also regional capacity in key areas such as RA, RM etc
<b>5) Information Dissemination for enhancing Public Awareness</b>	100,000	325,000	225,000	<p>Outreach material will be translated into six regional and one national language for wider dissemination of information on biotechnology and biosafety information</p> <p>Upgraded national biosafety websites will be more user friendly</p> <p>Innovative training tools will be developed for continuous training beyond the project cycle</p>	<p>Innovative training tools and outreach materials can be utilized or replicated in other similar projects in the region</p> <p>Timely updating of nBCH and biosafety websites is an effective mechanism to share information with the international community</p>
<b>6) Project Management</b>	60,000	260,000	200,000	Enhanced national capacity in biosafety project implementation	The training in project management can be replicated in other similar projects to achieve global benefits
<b>7) Project Monitoring and Evaluation</b>	15,000	45,000	30,000	Enhanced national capacity in biosafety project implementation	Experience gained by project monitoring and evaluation can be replicated in other similar projects to achieve global benefits.
<b>8) Regional networking and cooperation</b>	25,000	67,273	42,273	<p>India is a member of SAARC</p> <p>Regional cooperation exists in areas other than biosafety</p>	<p>A cost effective method to pool regional resources.</p> <p>Sharing of experience in project implementation with other similar projects in this and other region will save scarce GEF resources</p>
<b>Total</b>	<b>1,072,000</b>	<b>2727273</b>	<b>1,610,273</b>		

<sup>1</sup>Available from <http://thegef.org/council/C.31/12>.

<sup>2</sup>Available from <http://thegef.org/council/C.7/Inf.5>.

## Appendix 4: Results Framework

### RESULTS-BASED FRAMEWORK for BIOSAFTY PHASE II, INDIA

#### Goal

The overarching goal of this project is in line with 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'. Through this objective of the GEF biosafety program Parties to the CPB will be assisted to build capacity 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.

#### Project Objective

This project aims to strengthen the biosafety management system in India with special emphasis on Risk Assessment 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.

**At the end of the Project, tools/instruments and strengthened human and institutional capacity will be developed which will be used to ensure that every intentional introduction into the environment is based on sound scientific risk assessment with socio economic considerations and clearly defined risk management and monitoring systems installed**

**The installed capacity would be verified by the guidance documents, training reports and data on reviews and monitoring of LMOs in India. This is based on the assumption that there will be strong political will, measures installed for sustainability, cooperation and collaboration by all the key stakeholders in the biosafety management process in India.**

Objectives	Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
<b>Component I Stocktaking Assessment</b>			
<b>Outcome:</b>			
1.1 Updated information is consolidated to guide the planning of specific activities under this project.	<ul style="list-style-type: none"> <li>Within the first eight months of project commencement, the project design will be fine tuned based on the updated information and needs assessment by the Project Coordinating Team under the supervision of the National Execution Agency (NEA).</li> </ul>	<ul style="list-style-type: none"> <li>A needs assessment report</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Delays in receiving the feedback from respondents</li> <li>Slow response from line departments</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Response from all concerned line departments</li> <li>Key respondents provide inputs</li> </ul>

	Objectives	Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
<b>Outputs:</b>				
1.1.1	Baseline information to evaluate potential changes due to introduction of LMOs is compiled and updated.	<ul style="list-style-type: none"> <li>Draft document prepared and presented for validation through consultations with stakeholders within six months of project commencement.</li> </ul>	<ul style="list-style-type: none"> <li>Validated base paper</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Difficulties in validation</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Availability of required information</li> </ul>
1.1.2	Existing documentation is reviewed for compliance between the information needed under the prevailing regulatory system and the CPB.	<ul style="list-style-type: none"> <li>Existing documentation for handling, packaging and transportation is reviewed for compliance by relevant regulatory agencies through consultations within the first six months of project commencement</li> </ul>	<ul style="list-style-type: none"> <li>Status report on documentation for handling, packaging and transportation is available</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Scattered documentation</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Willingness to share information</li> </ul>
1.1.3	A survey is conducted to identify the public institutions, facilities and laboratories to be upgraded to be national referral laboratory.	<ul style="list-style-type: none"> <li>Within six months a feasibility report on the needs and parameters for upgrading of national laboratory shall be prepared by NPC.</li> </ul>	<ul style="list-style-type: none"> <li>A survey report</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Delay in completion of survey within specified timeframe</li> <li>Requirements to follow bureaucratic procedures</li> <li>Lack of consensus on laboratory to be upgraded</li> </ul> <p><i>Assumptions</i></p> <ul style="list-style-type: none"> <li>Identified laboratories already have increased baseline from phase I project</li> <li>Cooperation from participating institutions</li> </ul>
1.1.4	An assessment is carried out on the long term funding needed from GoI.	<ul style="list-style-type: none"> <li>Techno Economic feasibility report from national/international experts within six months</li> </ul>	<ul style="list-style-type: none"> <li>Techno Economic feasibility report is available</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Changes in funding priorities</li> <li>Changes in government policies</li> <li>Lack of dedicated budget line for long term funding</li> </ul> <p><i>Assumption</i></p>

Objectives		Objectively Verifiable Indicators	Means of Verification		Risk and Assumptions
1.1.5	National consultation with all stakeholders and partners is carried to discuss results from this needs assessment study.	<ul style="list-style-type: none"> <li>Final report on the draft outputs submitted by NPC.</li> </ul>	<ul style="list-style-type: none"> <li>Proceedings of national consultations</li> <li>Revised project designs</li> </ul>		<ul style="list-style-type: none"> <li>Strong government commitment</li> </ul> <p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Lack of consensus</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Clear recommendations will be obtained</li> </ul>
<b>Component II Strengthening Regulatory and Legal Framework</b>					
<b>A. Risk Assessment and Management</b>					
<b>Outcome:</b>					
2A.1	A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk.	<ul style="list-style-type: none"> <li>Within 48 months the legal framework consistent with CPB will be in place.</li> </ul>	<ul style="list-style-type: none"> <li>Government Notification</li> </ul>	Gazette	<p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Strong government commitment</li> </ul>
<b>Output:</b>					
2A.1.1	Existing RA and RM procedure and guidelines are reviewed to confirm whether India is compliant with CPB obligations	<ul style="list-style-type: none"> <li>Within 18 months review on compliance is completed and gaps identified by NPC</li> </ul>	<ul style="list-style-type: none"> <li>Report to National Steering Committee</li> <li>Report to GEAC</li> </ul>		<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Overlapping mandates among key agencies</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>To build on ongoing initiatives</li> </ul>
2A.1.2	Crop-specific biology and ecology document is developed to assist dossier preparation.	<ul style="list-style-type: none"> <li>Within 36 months complete biology documents of four crops such as okra, cabbage, cauliflower and pigeon pea are prepared by national experts</li> </ul>	<ul style="list-style-type: none"> <li>Biology documents for okra, cabbage, cauliflower and pigeon pea</li> </ul>		<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Availability of required information</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Dedicated institutions expected to have the information</li> </ul>
2A.1.3	Baseline data on presence	<ul style="list-style-type: none"> <li>Within 36 months inventory on wild</li> </ul>	<ul style="list-style-type: none"> <li>Inventory of wild relatives of</li> </ul>		<p><i>Risk</i></p>

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
	of wild relatives is gathered for better risk management of LMOs.	relatives of two crops such as okra and pigeon pea is available.	okra and pigeon pea	<ul style="list-style-type: none"> <li>Availability of required information</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>Dedicated institutions expected to have the information</li> </ul>
2A.1.4	Guidelines and procedures are developed for specific types of risk associated with specific traits.	<ul style="list-style-type: none"> <li>Within 42 months guidelines for risk assessment of at least one trait such as stacked genes are available</li> </ul>	<ul style="list-style-type: none"> <li>Guidelines for stacked genes</li> </ul>	<i>Assumptions</i> <ul style="list-style-type: none"> <li>Build on prevalent international experience</li> </ul>
2A.1.5	LMOs are monitored by regulatory agencies after environmental release.	<ul style="list-style-type: none"> <li>Within 30 months effective post release mechanism in place for monitoring of compliance</li> </ul>	<ul style="list-style-type: none"> <li>Monitoring reports submitted to the apex body GEAC.</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Unclear parameters to be monitored</li> <li>Lack of consensus on parameters to be monitored and frequency of monitoring</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>Resources will be available for monitoring</li> </ul>
2A.1.6	Indicators to measure gene flow and impact on non-targets are developed to assist in RA and RM.	<ul style="list-style-type: none"> <li>Within 36 months list of non target organisms and potential areas of gene flow are identified in different agro ecological zones.</li> </ul>	<ul style="list-style-type: none"> <li>Working knowledge document for measuring gene flow and impact on non-targets is available</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of consensus on indicators</li> </ul> <i>Assumptions</i> <ul style="list-style-type: none"> <li>Building on existing work already done in different agro ecological zones</li> </ul>
<b>2 B Socio-economic ( SE )assessment</b>				
<b>Outcome:</b>				
2B.1	Socio-economic assessment is considered.	<ul style="list-style-type: none"> <li>Within 48 months parameters and methodologies for socio economic assessments are in place</li> </ul>	<ul style="list-style-type: none"> <li>Decision documents of the apex regulatory authority</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Conflicts with other international obligations e.g. WTO</li> <li>Lack of consensus on methodologies</li> <li>Low priority accorded to SE considerations in decision making</li> </ul>

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
<b>Outputs:</b>				<i>Assumptions</i> <ul style="list-style-type: none"> <li>Expertise available in carrying out SE assessments</li> </ul>
2B.1.1	Questionnaire is developed for conducting a socio-economic survey.	<ul style="list-style-type: none"> <li>Within 30 months model questionnaires are available for the above traits.</li> </ul>	<ul style="list-style-type: none"> <li>Report of socio economic survey</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Effectiveness of survey reduced by lack of proper infrastructure and communication tools.</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>To build on the experience of Bt Cotton</li> </ul>
2B.1.2	Guidelines and methodologies are developed for socio-economic assessment of GM crops apart from Bt cotton.	<ul style="list-style-type: none"> <li>Within 36 months guidelines and methodologies are available for specific traits such as herbicide tolerance, insect resistance and biofortification.</li> </ul>	<ul style="list-style-type: none"> <li><i>Ex-ante</i> studies</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of consensus on parameters</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>To build on the experience of Bt Cotton</li> </ul>
2B1.3	Guidelines are developed for risk benefit analysis.	<ul style="list-style-type: none"> <li>Within 42 months cost benefit analysis guidelines are available.</li> </ul>	<ul style="list-style-type: none"> <li><i>Ex-ante</i> studies</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of adequate expertise in cost benefit analysis for transgenics</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>To build on the experience of Bt Cotton</li> </ul>
<b>2 C Handling, transport , packaging and identification of LMOs</b>				
<b>Outcome:</b>				
2C.1	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.	<ul style="list-style-type: none"> <li>Within 42 months an operational administrative system for handling, transport, packaging and identification of LMOs is in place</li> </ul>	<ul style="list-style-type: none"> <li>Establishment of an administrative system for handling, transport, packaging and identification of LMOs is in place.</li> <li>Government Gazette notification</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of consensus on institutional arrangement</li> <li>Poor inter-departmental coordination</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>Need has been recognised</li> </ul>
<b>Outputs:</b>				
2C.1.1	A feasibility study is carried out on measures to be taken for putting in place an	<ul style="list-style-type: none"> <li>Within 18 months a feasibility report for identity preservation (IP) system will be available for</li> </ul>	<ul style="list-style-type: none"> <li>Feasibility study report</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Gaps in information and experience</li> </ul>

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
2C.1.2	'identity preservation system' for handling of LMOs in agriculture.	commodities such as rice, soyabean and brinjal (eggplant)		<i>Assumption</i> <ul style="list-style-type: none"> <li>Build on IP experience of commodity exports such as Basmati Rice, tea etc</li> </ul>
	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.	<ul style="list-style-type: none"> <li>Within 24 months a certification and testing system in place.</li> </ul>	<ul style="list-style-type: none"> <li>Operational LMO certification and testing system</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of experience and national expertise</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>International guidelines and expertise available</li> </ul>
<b>Component III Strengthening Institutional Capacity</b>				
<b>Outcomes:</b>				
3.1	Institutions and staff capacity is enhanced for LMO detection	<ul style="list-style-type: none"> <li>Within 48 months an institution with a network of 2-3 laboratories is strengthened for LMO detection</li> </ul>	An efficient LMO detection institutional network is established	<i>Risk</i> <ul style="list-style-type: none"> <li>Lack of recognition of strengthened institution due to legal and policy changes</li> <li>Staff attrition</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>Training of trainers will mitigate above risks</li> </ul>
<b>Outputs:</b>				
3.1.1	A feasibility study is carried out on public private partnership (PPP) for LMO detection.	<ul style="list-style-type: none"> <li>Within 24 months of the project inception potential partnerships are identified.</li> </ul>	<ul style="list-style-type: none"> <li>MOUs/letters of intent between potential project partners</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Bureaucratic procedures to formalise MoUs</li> </ul> <i>Assumption</i> <ul style="list-style-type: none"> <li>Objective is in line with existing Government policies</li> <li>Several funding options are available for sustainability of PPP model</li> </ul>
3.1.2	Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMO in agriculture.	<ul style="list-style-type: none"> <li>Within 48 months improved infrastructure plans and equipment are available.</li> </ul>	<ul style="list-style-type: none"> <li>Key instruments are in place</li> </ul>	<i>Risk</i> <ul style="list-style-type: none"> <li>Delay in procurement of key instruments</li> </ul> <i>Assumptions</i> <ul style="list-style-type: none"> <li>Alternative procurement</li> </ul>



Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
				options could be explored • Build on experience gained in Phase I project.
3.1.3	Methodology and procedures are developed for LMO detection.	• Within 30 months sampling procedures and methodologies for LMO detection adopted for compliance	• Validated sampling procedures and methodologies for LMO detection are available	<i>Risk</i> • Difficulty in adopting international standards and procedures to local products <i>Assumption</i> • International guidance/expertise available
3.1.4	Staff, irrespective of gender, is trained for LMO detection and maintenance of laboratory.	• Within 42 months, 20 technicians are trained in LMO detection and operational maintenance of equipment	• Certifications of training	<i>Risk</i> • Staff attrition <i>Assumption</i> • Training of trainers • Timely recruitment to fill vacancies • Proper working documents are available
<b>Component IV: Human Resource (HR) Development</b>				
<b>Outcome:</b>				
4.1	Human resource is developed for strategic areas such risk evaluation.	• Within 42 months at least 20 scientists will be trained in risk evaluation	• Proceedings of training workshops	<i>Risk</i> • HR development unable to keep pace with technological advancements. <i>Assumption</i> • HR development is an integral part of National Biotechnology Strategy
<b>Outputs:</b>				
4.1.1	Training modules/manuals are prepared for conducting/evaluating risk assessment and management.	• Within 42 months at three training modules for environmental risk evaluation and management	▪ Training modules/manuals are available	<i>Risk</i> • Quality of training material and timeliness of delivery <i>Assumption</i> • Peer review by national and international experts
4.1.2	Training modules / manuals are prepared for monitoring	• Within 36 months a training manual and an e-learning	• Training manuals and e-learning modules are available	<i>Risk/Assumption</i> Same as above

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
Outcome: 4.2	field trials of GM crops and compliance evaluation.	module for monitoring field trials of GM crops and compliance evaluation are prepared.		
	Enforcement mechanism at the ports of entry is strengthened with trained staff.	<ul style="list-style-type: none"> <li>Within 42 months at least three officials at every point of entry will be trained in enforcement of trans boundary movement procedure</li> </ul>	<ul style="list-style-type: none"> <li>Certification of training</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Enforcement only at points of entry may be inadequate due to porous border</li> </ul> <p><i>Assumption</i></p> <ul style="list-style-type: none"> <li>Building on existing enforcement mechanisms e.g. quarantine and customs.</li> </ul>
Outputs: 4.2.1	Training modules/manuals are prepared for training of custom and plant quarantine officials for enhanced enforcement at the ports of entry.	<ul style="list-style-type: none"> <li>Within 42 months training manual and a working knowledge document for customs and plant quarantine officials for enforcement.</li> </ul>	<ul style="list-style-type: none"> <li>Training manual and working knowledge document are available</li> </ul>	<p><i>Risk/Assumption</i></p> <p>Same as above</p>
<b>Component V : Information dissemination for enhancing Public Awareness</b>				
Outcome: 5.1	Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced.	<ul style="list-style-type: none"> <li>Within 48 months extent of feedback from target groups on biosafety issues, regulations and procedures is increased upto 50%</li> </ul>	<ul style="list-style-type: none"> <li>Participants list in various awareness programmes</li> <li>Outreach products used as reference material</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Population that can be reached is limited due to the size of the country, time and funds constraints</li> <li>Strong anti-biotech NGOs</li> </ul> <p><i>Assumptions</i></p> <ul style="list-style-type: none"> <li>Strong government and private sector support for increasing public awareness</li> </ul>
	Outputs: 5.1.1	<ul style="list-style-type: none"> <li>Innovative outreach programs are developed for risk communication both through print and electronic media.</li> <li>Within 36 months outreach materials for print and electronic media are available for risk communication in English, Hindi and six regional languages with</li> </ul>	<ul style="list-style-type: none"> <li>Outreach material for risk communication in English, Hindi and six regional languages is available</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>Population that can be reached is limited due to the size of the country, time and funds constraints</li> </ul>

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
		public		<ul style="list-style-type: none"> <li>Quality of outreach material and timeliness of delivery</li> </ul> <i>Assumptions</i> <ul style="list-style-type: none"> <li>Strong government and private sector support for increasing public awareness</li> <li>Increasing public awareness will be part of a future long term communication strategy</li> </ul>
5.1.2	Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies.	<ul style="list-style-type: none"> <li>Within 36 months audio visual educational programmes on biosafety are available for students</li> </ul>	<ul style="list-style-type: none"> <li>Audio visual educational programme for students is available</li> </ul>	<i>Risk/Assumptions</i> Same as above
5.1.3	Primers/ brochures/ booklets/ FAQs and glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc.	<ul style="list-style-type: none"> <li>Within 24 months tailor made primers/brochures/booklets/FAQs are available in different languages</li> </ul>	<ul style="list-style-type: none"> <li>Country-wide circulation of awareness raising materials for various targeted audience</li> </ul>	<i>Risk/Assumptions</i> Same as above
5.1.4	A mechanism is established to communicate regulatory decisions on LMOs to the public.	<ul style="list-style-type: none"> <li>Regulatory decisions are deposited in National biosafety websites including national BCH within 15 days of decision making.</li> </ul>	<ul style="list-style-type: none"> <li>Records in national biosafety website and BCH</li> </ul>	<i>Risk/Assumptions</i> Same as above
5.1.5	Biosafety newsletters are published regularly and distributed.	<ul style="list-style-type: none"> <li>Quarterly newsletters are published and distributed</li> </ul>	<ul style="list-style-type: none"> <li>Quarterly newsletters published</li> </ul>	<i>Risk/Assumptions</i> Same as above
5.1.6	National, regional and international workshops are organized for targeted	<ul style="list-style-type: none"> <li>Workshop documents, list of participants and evaluation by participants in the workshops</li> </ul>	<ul style="list-style-type: none"> <li>Proceedings of the workshops</li> </ul>	<i>Risk/Assumptions</i> Same as above

Objectives		Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
audience.				
<p align="center">•</p> <p><b>COMPONENT VII – REGIONAL NETWORKING AND COOPERATION</b></p>				
<b>Outcome</b>				
8.1 Institutional mechanism for sharing information through networking and regional cooperation established	Regional cooperative measures strengthened through NPC meetings, regional/bilateral meetings/field missions undertaken to promote regional networking and cooperation	<ul style="list-style-type: none"> <li>• Within 48 months, at least four meetings held in which India shares experiences and a network established for sharing information within the region</li> </ul>	<ul style="list-style-type: none"> <li>• Workshop proceedings and NPC meeting reports</li> <li>• Mission reports on field visits and exchange trips with countries in the region</li> </ul>	<p><i>Risk</i></p> <ul style="list-style-type: none"> <li>• Different stages of development of biotechnology and biosafety instruments and measures could affect regional cooperative measures</li> <li>• Quality of outreach material and timeliness of delivery</li> <li>• Inability of different countries to take part in regional networking meetings</li> </ul> <p><i>Assumptions</i></p> <ul style="list-style-type: none"> <li>• Strong government interest to ensure cooperation through multilateral/bilateral agreements to support implementation of the Cartagena Protocol on Biosafety and related biosafety measures</li> </ul>
Outputs 8.1.1	Operational guidelines/manuals/Primers/brochures/newsletters and booklets and periodic update presentations are widely distributed to partner countries within the region.	<ul style="list-style-type: none"> <li>• Within 24 months tailor made biosafety documents are shared through regional networks and networking meetings including NPC meetings and relevant biosafety meetings in the region</li> <li>• At least two regional cooperation meetings held by India within 36 months of project implementation</li> </ul>	<ul style="list-style-type: none"> <li>• Resource materials developed to facilitate biosafety activities</li> <li>• NPC meeting reports including presentations made by India</li> <li>• Regional mailing lists and sharing services</li> </ul>	<p><i>Risk/Assumptions</i></p> <p>Same as above</p>

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]



## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 5: India Biosafety Implementation Project Workplan

[illegible]

## Appendix 6: Key Deliverables and Benchmark

Key Deliverables (Outputs)	Benchmark
<b>COMPONENT 1: STOCKTAKING ASSESSMENT</b>	
<b>Objective</b> To assist India to update its information on status and capacity for biosafety management, including capacity in RA&RM, documentation and identification for compliance.	<ul style="list-style-type: none"> <li>➤ A gap analysis of country situation with regards to planning activities for biosafety management under the specified areas.</li> <li>➤ Status and strategy paper on requirements on RA&amp;RM, documentation and identification for compliance.</li> </ul>
<b>Outcome 1: Updated information is consolidated to guide the planning of specific activities under this project</b>	
<b>Outputs:</b> <ol style="list-style-type: none"> <li>1. Baseline information to evaluate potential changes due to introduction of LMOs is compiled and updated.</li> <li>2. Existing documentation is reviewed for compliance between the information needed under the prevailing regulatory system and the CPB</li> <li>3. A survey is conducted to identify the public institutions, facilities and laboratories to be up-graded to be national referral laboratory.</li> <li>4. An assessment is carried out on the long term funding needed from Gol.</li> <li>5. National consultation with all stakeholders and partners is carried to discuss results from this needs assessment study.</li> </ol>	<ol style="list-style-type: none"> <li>1. Draft document prepared and presented for validation through consultations with stakeholders within 4 months of project inception.</li> <li>2. Existing documentation for handling, packaging and transportation is reviewed for compliance by relevant regulatory agencies through consultations within the first 6 months of project commencement.</li> <li>3. A feasibility report on the needs and parameters for upgrading of national laboratory shall be prepared by NPC.</li> <li>4. Techno Economic feasibility report from national/international experts within 3 months.</li> <li>5. Final report on the draft outputs submitted by NPC.</li> </ol>
<b>COMPONENT 2: STRENGTHENING REGULATORY AND LEGAL FRAMEWORK</b>	
<b>Objective :</b> To assist India to strengthen biosafety regulatory framework that is consistent with CPB.	<ul style="list-style-type: none"> <li>➤ The legal framework consistent with CPB.</li> <li>➤ Guidelines and crop specific biology documents available for effective evaluation and management.</li> <li>➤ Parameters and methodologies for socioeconomic assessment will be available.</li> <li>➤ An operational administrative system for handling, packaging and identification of LMOs.</li> </ul>
<b>A. Risk Assessment and Management</b>	
<b>Outcome 2 A : A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk</b>	
<b>Outputs:</b> <ol style="list-style-type: none"> <li>1. Existing RA and RM procedure and guidelines are reviewed to confirm whether India is compliant with CPB obligations.</li> <li>2. Crop-specific biology and ecology document is developed to assist dossier preparation.</li> <li>3. Baseline data on presence of wild relatives is gathered for better risk management of LMOs.</li> <li>4. Guidelines and procedures are developed for specific types of risk associated with specific traits.</li> <li>5. LMOs are monitored by regulatory agencies after environmental release.</li> </ol>	<ol style="list-style-type: none"> <li>1. Project inception review on compliance is completed and gaps identified by NPC.</li> <li>2. Complete biology documents of four crops such as okra, cabbage, cauliflower and pigeon pea are prepared by national experts.</li> <li>3. Inventory on wild relatives of two crops such as okra and pigeon pea is available.</li> <li>4. Guidelines for risk assessment of at least one trait such as stacked genes are available.</li> <li>5. Effective post release mechanism in place for monitoring of compliance.</li> </ol>

Key Deliverables (Outputs)	Benchmark
6. Indicators to measure gene flow and impact on non-targets are developed to assist in RA and RM.	6. Non target organisms and potential areas of gene flow are identified in different agro ecological zones.
<b>B Socio-economic ( SE )assessment</b>	
<b>Outcome 2 B Socio-economic assessment are considered</b>	
<b>Outputs:</b> <ol style="list-style-type: none"> <li>1. Questionnaire is developed for conducting a socio-economic survey.</li> <li>2. Guidelines and methodologies are developed for socio-economic assessment of GM crops apart from Bt cotton.</li> <li>3. Guidelines are developed for risk benefit analysis.</li> </ol>	<ol style="list-style-type: none"> <li>1. Model questionnaires are available for the above traits.</li> <li>2. Guidelines and methodologies are available for specific traits such as herbicide tolerance, insect resistance and biofortification.</li> <li>3. Cost benefit analysis guidelines are available.</li> </ol>
<b>C Handling, transport , packaging and</b>	
<b>Outcome 2 C: 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.</b>	
<b>Outputs:</b> <ol style="list-style-type: none"> <li>1. 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.</li> <li>2. 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.</li> </ol>	<ol style="list-style-type: none"> <li>1. Project inception a feasibility report for identity preservation (IP) system will be available for commodities such as rice, soyabean and brinjal (eggplant).</li> <li>2. A certification and testing system in place.</li> </ol>
<b>COMPONENT 3: STRENGTHENING INSTITUTIONAL CAPACITY</b>	
<b>Objective</b> To assist India to establish a network of laboratories for detection of LMOs.	➤ Strengthen 2-3 institutions with infrastructure, equipment and trained manpower.
<b>Outcome 3: Institutions and staff capacity is enhanced for LMO detection</b>	
<b>Outputs:</b> <ol style="list-style-type: none"> <li>1. A feasibility study is carried out on public private partnership (PPP) for LMO detection.</li> <li>2. Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMO in agriculture.</li> <li>3. Methodology and procedures are developed for LMO detection.</li> <li>4. Staff, irrespective of gender, is trained for LMO detection and maintenance of laboratory.</li> </ol>	<ol style="list-style-type: none"> <li>1. Project inception potential partnerships are identified.</li> <li>2. Improved infrastructure plans and equipment are available.</li> <li>3. Sampling procedures and methodologies for LMO detection adopted for compliance.</li> <li>4. 20 technicians are trained in LMO detection and operational maintenance of equipment.</li> </ol>
<b>Component 4: HUMAN RESOURCE (HR) DEVELOPMENT</b>	
<b>Objective:</b> To assist India in enhancing human resource for RA, RM, LMO detection and enforcement.	➤ An effective pool of resource persons is available for risk assessment and management in line with CPB. ➤ Enhanced skills of present enforcement officers to check for compliance with conditions for approval of LMO release.

Key Deliverables (Outputs)	Benchmark
	➤ Enforcement procedures for transboundary movement of LMOS are strengthened.
<b>Outcome 4. 1: Human resource is developed for strategic areas such risk evaluation.</b> <b>Outcome 4.2: Enforcement mechanism at the ports of entry is strengthened with trained staff.</b>	
<b>Outputs:</b>  1. Training modules/manuals are prepared for conducting/ evaluating risk assessment and management. 2. Training modules / manuals are prepared for monitoring field trials of GM crops and compliance evaluation. 3. Training modules/manuals are prepared for training of custom and plant quarantine officials for enhanced enforcement at the ports of entry.	1. Training modules for environmental risk evaluation and management. 2. Training manual and an e-learning module for monitoring field trials of GM crops and compliance evaluation are prepared. 3. Training manual and a working knowledge document for customs and plant quarantine officials for enforcement.
<b>COMPONENT 5: INFORMATION DISSEMINATION FOR ENHANCING PUBLIC AWARENESS</b>	
<b>Objective:</b> To assist India to establish and consolidate systems for public education, awareness, participation and access to biosafety information.	➤ A communication strategy is in place. ➤ The public have access to biosafety information through print and electronic media. ➤ Awareness raising materials on biosafety are created and distributed.
<b>Outcome 5: Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced.</b>	
<b>Outputs:</b>  1. Innovative outreach programs are developed for risk communication both through print and electronic media. 2. Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies. 3. Primers/ brochures/ booklets /FAQs and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc 4. A mechanism is established to communicate regulatory decisions on LMOs to the public. 5. Biosafety newsletters are published regularly and distributed. 6. National, regional and international workshops are organized for targeted audience.	1. Outreach materials for print and electronic media are available for risk communication in English, Hindi and 6 regional languages with public. 2. Audio visual educational programmes on biosafety are available for students. 3. Tailor made primers/brouchers/booklets/FAQs are available in different languages. 4. Regulatory decisions are deposited in National biosafety websites including national BCH within 30 days of decision making. 5. Quarterly newsletters are published and distributed. 6. Workshop documents, list of participants and evaluation by participants in 10 workshops at national, regional and international levels.
<b>COMPONENT 8:REGIONAL NETWORKING AND COOPERATION</b>	
<b>Objective</b>  To facilitate regional cooperative measures through NPC meetings, regional/bilateral meetings/.field missions in the promotion of regional networking and cooperation	Peer review materials developed and shared to facilitate regional cooperation and networking in biosafety in the region



Key Deliverables (Outputs)	Benchmark
<p><b>Outputs</b></p> <p>Operational guidelines/manuals/Primers/ brochures/newsletters and booklets and periodic update presentations are widely distributed to partner countries within the region.</p>	<ol style="list-style-type: none"> <li>1. Within 24 months tailor made biosafety documents are shared through regional networks and networking meetings including NPC meetings and relevant biosafety meetings in the region</li> <li>2. Two regional cooperation meetings held by India within 36 months of project inception</li> </ol>

## Appendix 7: Costed M&E Plan

### Costed Results-Based Monitoring and Evaluation Framework

#### 1. Monitoring Framework and Budget

Objective / Outcome	Outcome / objective level indicator	Baseline Conditions	Mid point Target (as relevant)	End of Project Target	Means of Verification	Monitoring / sampling (frequency / size)	Location / Group	Responsibility	Time frame	Budget (Object of expenditure & cost)
<b>Component I Stocktaking Assessment</b>										
<b>Outcome 1</b> Updated information is consolidated to guide the planning of specific activities under this project	The project design will be fine tuned based on the updated information and needs assessment by the Project Coordinating Team under the supervision of the National Execution Agency (NEA).	Information available but scattered	Information will be consolidated and used	Needs assessment report would be used for sustainability of activities	A needs assessment report	NA	National Experts	NEA	First 8 months after project initiation	
<b>Component II Strengthening Regulatory and Legal Framework</b>										
<b>2 A. Risk Assessment and Management</b>										
<b>Outcome 2A.1</b> A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk	The legal framework consistent with CPB will be in place	Laws , policies and guidelines are in place	Gaps in the regulatory regime and inconsistencies with the CPB will be identified	Strengthened legal regime consistent with CPB	Government Gazette Notification	NA	Legal, technical experts and biotech product developers	National Execution Agency (NEA), PCMU and UNEP	Within 48 months	

## Appendix 7: Costed M&E Plan

Objective / Outcome	Outcome / objective level indicator	Baseline Conditions	Mid point Target (as relevant)	End of Project Target	Means of Verification	Monitoring / sampling (frequency / size)	Location / Group	Responsibility	Time frame	Budget (Object of expenditure & cost)
<b>2 B. Socio-economic (SE) assessment</b>										
<b>Outcome 2B.1</b> Socio-economic assessment are considered	Parameters and methodologies for socio economic assessments are in place	Limited experience with Bt Cotton	Model questionnaires on SE will be available	Parameters and methodologies for SE assessment, including guidelines for cost benefit analysis are in place	Decision documents of the apex regulatory authority	NA	Farmers and consumers	NEA and PCMU	Within 48 months	
<b>2 C. Handling, transport, packaging and identification of LMOs</b>										
<b>Outcome 2C.1</b> 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	An operational administrative system for handling, transport, packaging and identification of LMOs is in place	A basic administrative system exists but it is inadequate for handling, transport, packaging and identification of LMOs	A Feasibility report for identity preservation (IP) system will be available for commodities such as rice, soyabean and brinjal (eggplant)	An operational administrative system is in place including a certification and testing mechanism	<ul style="list-style-type: none"> <li>Establishment of an administrative system for handling, transport, packaging and identification of LMOs is in place</li> <li>Government Gazette notification</li> </ul>	NA	Importers, exporters and traders	NEA and concerned institutions	By 2012	
<b>Component III Strengthening Institutional Capacity</b>										
<b>Outcome 3</b> Institutions and staff capacity is enhanced for LMO detection	An institution with a network of 2-3 laboratories is strengthened for LMO detection	Laboratories for LMO detection exist however these institutions need further strengthening in terms of infrastructure and human resources	Short listing of potential partners in the network  Plans for infrastructure improvement are in place	Institution with a network of 2-3 laboratories is strengthened with improved infrastructure and at least 20 trained technicians	An efficient LMO detection institutional network is established	2 times during project cycle at mid term review and end of project	Partner institutions and laboratories in network	NEA	By 2012	

## Appendix 7: Costed M&E Plan

Objective / Outcome	Outcome / objective level indicator	Baseline Conditions	Mid point Target (as relevant)	End of Project Target	Means of Verification	Monitoring / sampling (frequency / size)	Location / Group	Responsibility	Time frame	Budget (Object of expenditure & cost)
<b>Component IV: Human Resource (HR) Development</b>										
<b>Outcome 4.1</b> Human resource is developed for strategic areas such risk evaluation.	At least 20 scientists will be trained in risk evaluation	Limited number of experts available  More focused training needed	Training manuals for environmental risk evaluation and management in place	20 Scientists will be trained	Proceedings of training workshops	2 times during project cycle at mid term review and end of project	Experts in RA & RM involved in technical and scientific advisory committees and biotech R & D developers	NEA	Within 36 months	
<b>Outcome 4.2</b> Enforcement mechanism at the ports of entry is strengthened with trained staff	At least 2 officials at every point of entry will be trained in enforcement of trans boundary movement procedure	Under phase I of GEF project, about 500 plant quarantine and custom officials sensitized.	Training manual and working knowledge document for custom and plant quarantine officials available	At least 2 officials at every point of entry will be trained in enforcement of trans boundary movement procedure	Certification of training	2 times during project cycle at mid term review and end of project	Exporters, importers and traders of LMOs	NEA	Within 36 months	
<b>Component V : Information dissemination for enhancing Public Awareness</b>										
<b>Outcome 5</b> Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced.	Extent of feedback from target groups on biosafety issues, regulations and procedures is increased upto 50%	Approximately 5,000 participants representing stakeholder groups viz. agricultural scientists, government officials, legal personnel, media, industry, school children and teachers, were sensitized under Phase I	Development of a risk communication strategy for various stakeholders	Outreach material for both in print and electronic form available for use by various stakeholders.  About 10,000 stakeholders representing key segments sensitized.	Participants list in various awareness programmes  Outreach products used as reference material	2 times during project cycle at mid term review and end of project	Key stakeholders	NEA	By 2012	

## Appendix 7: Costed M&E Plan

### 2. Cost of acquisition of essential baseline data during first year of project<sup>1</sup>:

The cost is estimated above to be US\$ 1.0 million inclusive of national consultants, and their travel to collect data. This has been reflected in the project cost.

### 3. Cost of project inception workshop (please include proposed location, number of participants):

The cost of project inception workshop is estimated to be about US\$ 30,000 (GEF `cost US\$ 13,000 and co-Finance at US\$ 17,000). This will be targeted to be combined with a 2-day National Consultation on findings of the stocktaking assessment to be held in New Delhi for about 100-150 participants representing all stakeholders, donors, and partnering capacity building agencies. Cost is factored into component 1.

### 4. Cost of Mid-Term Review/Evaluation:

The mid term review is expected to be a desk review carried out by 1-2 reviewers on a group of 4-5 projects at the same stage of implementation. The cost is estimated to be US\$ 5,000-10,000 per project.

### 5. Cost of Terminal Evaluation:

The terminal review is expected to be carried out on a group of projects at the same stage of implementation. There will be an initial desk review followed by in-country visits of selected countries carried out by 1-2 reviewers appointed by GEF Evaluation Office and UNEP Evaluation and Oversight Unit. The cost is estimated to be US\$ 30,000-40,000 per project.

### 6. Any additional M&E costs <sup>2</sup>:

None.

Total costs (this figure should be included in the consolidated project budget and in the Request for CEO endorsement/approval in the M&E budget line): **US\$ 45,000**

---

<sup>1</sup> Refer to detailed M&E work plan for additional information on what data will be collected and what activities will be undertaken. The data to be collected needs to be consistent with the indicators included in the table above.

<sup>2</sup> Please describe the activity and included the expected cost. Additional M&E costs could be related to the following: (i) Additional reviews and evaluation processes for phased and tranced projects; (ii) application & validation of tracking tools.

## Appendix 8 Reporting requirements

Reports	Due date	Format appended to legal instrument as	Responsibility of
Procurement plan (goods and services)	2 weeks before project inception meeting	N/A	NPC
Inception Report	1 month after project inception meeting	N/A	NPC
Expenditure report accompanied by explanatory notes	Quarterly on or before 30 April, 31 July, 31 October, 31 January	<b>Annex 11</b>	NPC
Cash Advance request and details of anticipated disbursements	Quarterly or when required	<b>Annex 7B</b>	NPC
Progress report	Half-yearly on or before 31 January	<b>Annex 8</b>	NPC
Audited report for expenditures for year ending 31 December	Yearly on or before 30 June	N/A	Executing partner to contract firm
Inventory of non-expendable equipment	Yearly on or before 31 January	<b>Annex 6</b>	NPC
Co-financing report	Yearly on or before 31 July	<b>Annex 12</b>	NPC
Project implementation review (PIR) report	Yearly on or before 31 August	<b>Annex 9</b>	NPC, TM, DGEF FMO
Minutes of steering committee meetings	Yearly (or as relevant)	N/A	NPC
Mission reports and “aide memoire” for executing agency	Within 2 weeks of return	N/A	TM, DGEF FMO
Final report	2 months of project completion date	<b>Annex 10</b>	NPC
Final inventory of non-expendable equipment		<b>Annex 9</b>	NPC
Equipment transfer letter		<b>Annex 10</b>	NPC
Final expenditure statement	3 months of project completion date	<b>Annex 11</b>	NPC
Mid-term review or Mid-term evaluation	Midway through project	N/A	TM or EOU (as relevant)
Final audited report for expenditures of project	6 months of project completion date	N/A	Executing partner to contract firm
Independent terminal evaluation report	6 months of project completion date	Appendix 9 to Annex 1	EOU

## APPENDIX 9 - STANDARD TERMINAL EVALUATION TERMS OF REFERENCE

### **Terminal Evaluation of the UNEP GEF project *Capacity Building on Biosafetly for Implementation of the Cartagena Protocol in India – Phase II***

#### **1. PROJECT BACKGROUND AND OVERVIEW**

##### **Project rationale**

The 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. 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. This 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.

*The objective was stated as:*

The project objective is to strengthen the biosafety management system in India with special emphasis on Risk Assessment and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure that adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities.

*The indicators given in the project document for this stated objective were:*

These are listed in the Results Framework (Annex 1) in the CEO Endorsement project document.

##### **Relevance to GEF Programmes**

This project conforms to the GEF policy as being the catalyst to maximize global environmental benefits. The project is within Strategic Objective 3 (*To safeguard Biodiversity*) in the Biodiversity focal area, and is relevant to Strategic Program 6: *Capacity Building for the Implementation of the Cartagena Protocol on Biosafety*. One of the aims of this project is to build capacity so that India can utilize agricultural biotechnology to address national food needs without harming its mega biodiversity and compromising the quality of the environment. Since this project ensures that the mega biodiversity of India will not be jeopardized at the expense of agricultural development, it is expected to yield global benefits through the conservation and sustainable use of biodiversity.

##### **Executing Arrangements**

*The implementing agency(ies) for this project was (were):*

UNEP

*The lead national agencies in the focal countries were:*

Union Ministry of Environment and Forests of India

**Project Activities**

The project comprised activities grouped in 6 components.

1. Stocktaking Assessment
2. Strengthening Regulatory and Legal Framework
3. Strengthening Institutional Capacity
4. Human Resource Development
5. Information Dissemination for enhancing Public Awareness
6. Project Management

**Budget**

At project inception the following budget prepared:

	<u>GEF</u>	<u>Co-funding</u>
Project preparation funds:	\$2,727,273	\$6,000,000
GEF Full Size Grant		

**TOTAL (including project preparation funds):**

\$8,727,273

Co-funding sources: Project Government Contribution (In-kind)

Anticipated: \$6,000,000



**APPENDIX 9**  
**TERMS OF REFERENCE FOR THE EVALUATION**

**1. Objective and Scope of the Evaluation**

The objective of this terminal evaluation is to examine the extent and magnitude of any project impacts to date and determine the likelihood of future impacts. The evaluation will also assess project performance and the implementation of planned project activities and planned outputs against actual results. The evaluation will focus on the following main questions:

1. Did the project help to {} among key target audiences (international conventions and initiatives, national level policy-makers, regional and local policy-makers, resource managers and practitioners).
2. Did the outputs of the project articulate options and recommendations for {}? Were these options and recommendations used? If so by whom?
3. To what extent did the project outputs produced have the weight of scientific authority and credibility necessary to influence policy makers and other key audiences?

**Methods**

This terminal evaluation will be conducted as an in-depth evaluation using a participatory approach whereby the UNEP/DGEF Task Manager, key representatives of the executing agencies and other relevant staff are kept informed and consulted throughout the evaluation. The consultant will liaise with the UNEP/EOU and the UNEP/DGEF Task Manager on any logistic and/or methodological issues to properly conduct the review in as independent a way as possible, given the circumstances and resources offered. The draft report will be circulated to UNEP/DGEF Task Manager, key representatives of the executing agencies and the UNEP/EOU. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary or suggested revisions.

The findings of the evaluation will be based on the following:

1. A desk review of project documents including, but not limited to:
  - (a) The project documents, outputs, monitoring reports (such as progress and financial reports to UNEP and GEF annual Project Implementation Review reports) and relevant correspondence.
  - (b) Notes from the Steering Group meetings.
  - (c) Other project-related material produced by the project staff or partners.
  - (d) Relevant material published on the project web-site: {}.
2. Interviews with project management and technical support including {}**NEED INPUT FROM TM HERE**
3. Interviews and Telephone interviews with intended users for the project outputs and other stakeholders involved with this project, including in the participating countries and international bodies. The Consultant shall determine whether to seek additional information and opinions from representatives of donor agencies and other organizations. As appropriate, these interviews could be combined with an email questionnaire.

4. Interviews with the UNEP/DGEF project task manager and Fund Management Officer, and other relevant staff in UNEP dealing with {relevant GEF focal area(s)}-related activities as necessary. The Consultant shall also gain broader perspectives from discussions with relevant GEF Secretariat staff.
5. Field visits<sup>1</sup> to project staff

### Key Evaluation principles.

In attempting to evaluate any outcomes and impacts that the project may have achieved, evaluators should remember that the project's performance should be assessed by considering the difference between the answers to two simple questions “*what happened?*” and “*what would have happened anyway?*”. These questions imply that there should be consideration of the baseline conditions and trends in relation to the intended project outcomes and impacts. In addition it implies that there should be plausible evidence to **attribute** such outcomes and impacts **to the actions of the project**.

Sometimes, adequate information on baseline conditions and trends is lacking. In such cases this should be clearly highlighted by the evaluator, along with any simplifying assumptions that were taken to enable the evaluator to make informed judgements about project performance.

## 2. Project Ratings

The success of project implementation will be rated on a scale from ‘highly unsatisfactory’ to ‘highly satisfactory’. In particular the evaluation shall **assess and rate** the project with respect to the eleven categories defined below:<sup>2</sup>

### A. Attainment of objectives and planned results:

The evaluation should assess the extent to which the project's major relevant objectives were effectively and efficiently achieved or are expected to be achieved and their relevance.

- *Effectiveness*: Evaluate how, and to what extent, the stated project objectives have been met, taking into account the “achievement indicators”. The analysis of outcomes achieved should include, *inter alia*, an assessment of the extent to which the project has directly or indirectly assisted policy and decision-makers to apply information supplied by biodiversity indicators in their national planning and decision-making. In particular:
  - Evaluate the immediate impact of the project on {relevant focal area} monitoring and in national planning and decision-making and international understanding and use of biodiversity indicators.
  - As far as possible, also assess the potential longer-term impacts considering that the evaluation is taking place upon completion of the project and that longer term impact is expected to be seen in a few years time. Frame recommendations to enhance future project impact in this context. Which will be the major ‘channels’ for longer term impact from the project at the national and international scales?
- *Relevance*: In retrospect, were the project's outcomes consistent with the focal areas/operational program strategies? Ascertain the nature and

---

<sup>1</sup> Evaluators should make a brief courtesy call to GEF Country Focal points during field visits if at all possible.

<sup>2</sup> However, the views and comments expressed by the evaluator need not be restricted to these items.

significance of the contribution of the project outcomes to the {relevant Convention(s)} and the wider portfolio of the GEF.

- *Efficiency*: Was the project cost effective? Was the project the least cost option? Was the project implementation delayed and if it was, then did that affect cost-effectiveness? Assess the contribution of cash and in-kind co-financing to project implementation and to what extent the project leveraged additional resources. Did the project build on earlier initiatives, did it make effective use of available scientific and / or technical information. Wherever possible, the evaluator should also compare the cost-time vs. outcomes relationship of the project with that of other similar projects.

## B. Sustainability:

Sustainability is understood as the probability of continued long-term project-derived outcomes and impacts after the GEF project funding ends. The evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, e.g. stronger institutional capacities or better informed decision-making. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes. The evaluation should ascertain to what extent follow-up work has been initiated and how project outcomes will be sustained and enhanced over time.

Five aspects of sustainability should be addressed: financial, socio-political, institutional frameworks and governance, environmental (if applicable). The following questions provide guidance on the assessment of these aspects:

- *Financial resources*. Are there any financial risks that may jeopardize sustenance of project outcomes? What is the likelihood that financial and economic resources will not be available once the GEF assistance ends (resources can be from multiple sources, such as the public and private sectors, income generating activities, and trends that may indicate that it is likely that in future there will be adequate financial resources for sustaining project's outcomes)? To what extent are the outcomes of the project dependent on continued financial support?
- *Socio-political*: Are there any social or political risks that may jeopardize sustenance of project outcomes? What is the risk that the level of stakeholder ownership will be insufficient to allow for the project outcomes to be sustained? Do the various key stakeholders see that it is in their interest that the project benefits continue to flow? Is there sufficient public / stakeholder awareness in support of the long term objectives of the project?
- *Institutional framework and governance*. To what extent is the sustenance of the outcomes of the project dependent on issues relating to institutional frameworks and governance? What is the likelihood that institutional and technical achievements, legal frameworks, policies and governance structures and processes will allow for, the project outcomes/benefits to be sustained? While responding to these questions consider if the required systems for accountability and transparency and the required technical know-how are in place.
- *Environmental*. Are there any environmental risks that can undermine the future flow of project environmental benefits? The TE should assess whether certain activities in the project area will pose a threat to the sustainability of the project outcomes. For example; construction of dam in a protected area could inundate a

sizable area and thereby neutralize the biodiversity-related gains made by the project; or, a newly established pulp mill might jeopardise the viability of nearby protected forest areas by increasing logging pressures; or a vector control intervention may be made less effective by changes in climate and consequent alterations to the incidence and distribution of malarial mosquitoes.

**C. Achievement of outputs and activities:**

- Delivered outputs: Assessment of the project's success in producing each of the programmed outputs, both in quantity and quality as well as usefulness and timeliness.
- Assess the soundness and effectiveness of the methodologies used for developing the technical documents and related management options in the participating countries
- Assess to what extent the project outputs produced have the weight of scientific authority / credibility, necessary to influence policy and decision-makers, particularly at the national level.

**D. Catalytic Role**

Replication and catalysis. What examples are there of replication and catalytic outcomes? Replication approach, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated or scaled up in the design and implementation of other projects. Replication can have two aspects, replication proper (lessons and experiences are replicated in different geographic area) or scaling up (lessons and experiences are replicated within the same geographic area but funded by other sources). Specifically:

- Do the recommendations for management of {project} coming from the country studies have the potential for application in other countries and locations?

If no effects are identified, the evaluation will describe the catalytic or replication actions that the project carried out.

**E. Assessment monitoring and evaluation systems.**

The evaluation shall include an assessment of the quality, application and effectiveness of project monitoring and evaluation plans and tools, including an assessment of risk management based on the assumptions and risks identified in the project document. The Terminal Evaluation will assess whether the project met the minimum requirements for 'project design of M&E' and 'the application of the Project M&E plan' (see minimum requirements 1&2 in *Annex 4* to this Appendix). GEF projects must budget adequately for execution of the M&E plan, and provide adequate resources during implementation of the M&E plan. Project managers are also expected to use the information generated by the M&E system during project implementation to adapt and improve the project.

**M&E during project implementation**

- *M&E design.* Projects should have sound M&E plans to monitor results and track progress towards achieving project objectives. An M&E plan should include a baseline (including data, methodology, etc.), SMART indicators (see Annex 4) and data analysis systems, and evaluation studies at specific times to assess results. The time frame for various M&E activities and standards for outputs should have been specified.
- *M&E plan implementation.* A Terminal Evaluation should verify that: an M&E system was in place and facilitated timely tracking of results and progress

towards projects objectives throughout the project implementation period (perhaps through use of a logframe or similar); annual project reports and Progress Implementation Review (PIR) reports were complete, accurate and with well justified ratings; that the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs; and that projects had an M&E system in place with proper training for parties responsible for M&E activities.

- *Budgeting and Funding for M&E activities.* The terminal evaluation should determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

**F. Preparation and Readiness**

Were the project's objectives and components clear, practicable and feasible within its timeframe? Were the capacities of executing institution and counterparts properly considered when the project was designed? Were lessons from other relevant projects properly incorporated in the project design? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities), enabling legislation, and adequate project management arrangements in place?

**G. Country ownership / driveness:**

This is the relevance of the project to national development and environmental agendas, recipient country commitment, and regional and international agreements. The evaluation will:

- Assess the level of country ownership. Specifically, the evaluator should assess whether the project was effective in providing and communicating biodiversity information that catalyzed action in participating countries to improve decisions relating to the conservation and management of the focal ecosystem in each country.
- Assess the level of country commitment to the generation and use of biodiversity indicators for decision-making during and after the project, including in regional and international fora.

**H. Stakeholder participation / public awareness:**

This consists of three related and often overlapping processes: information dissemination, consultation, and "stakeholder" participation. Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the GEF-financed project. The term also applies to those potentially adversely affected by a project. The evaluation will specifically:

- Assess the mechanisms put in place by the project for identification and engagement of stakeholders in each participating country and establish, in consultation with the stakeholders, whether this mechanism was successful, and identify its strengths and weaknesses.
- Assess the degree and effectiveness of collaboration/interactions between the various project partners and institutions during the course of implementation of the project.
- Assess the degree and effectiveness of any various public awareness activities that were undertaken during the course of implementation of the project.

**I. Financial Planning**

Evaluation of financial planning requires assessment of the quality and effectiveness of financial planning and control of financial resources throughout the project's lifetime.

Evaluation includes actual project costs by activities compared to budget (variances), financial management (including disbursement issues), and co- financing. The evaluation should:

- Assess the strength and utility of financial controls, including reporting, and planning to allow the project management to make informed decisions regarding the budget and allow for a proper and timely flow of funds for the payment of satisfactory project deliverables.
- Present the major findings from the financial audit if one has been conducted.
- Identify and verify the sources of co- financing as well as leveraged and associated financing (in co-operation with the IA and EA).
- Assess whether the project has applied appropriate standards of due diligence in the management of funds and financial audits.
- The evaluation should also include a breakdown of final actual costs and co-financing for the project prepared in consultation with the relevant UNEP/DGEF Fund Management Officer of the project (table attached in *Annex 1* to this Appendix Co-financing and leveraged resources).

**J. Implementation approach:**

This includes an analysis of the project's management framework, adaptation to changing conditions (adaptive management), partnerships in implementation arrangements, changes in project design, and overall project management. The evaluation will:

- Ascertain to what extent the project implementation mechanisms outlined in the project document have been closely followed. In particular, assess the role of the various committees established and whether the project document was clear and realistic to enable effective and efficient implementation, whether the project was executed according to the plan and how well the management was able to adapt to changes during the life of the project to enable the implementation of the project.
- Evaluate the effectiveness and efficiency and adaptability of project management and the supervision of project activities / project execution arrangements at all levels (1) policy decisions: Steering Group; (2) day to day project management in each of the country executing agencies and {lead executing agency}.

**K. UNEP Supervision and Backstopping**

- Assess the effectiveness of supervision and administrative and financial support provided by UNEP/DGEF.
- Identify administrative, operational and/or technical problems and constraints that influenced the effective implementation of the project.

The *ratings will be presented in the form of a table*. Each of the eleven categories should be rated separately with **brief justifications** based on the findings of the main analysis. An overall rating for the project should also be given. The following rating system is to be applied:

HS	= Highly Satisfactory
S	= Satisfactory
MS	= Moderately Satisfactory
MU	= Moderately Unsatisfactory
U	= Unsatisfactory
HU	= Highly Unsatisfactory

**3. Evaluation report format and review procedures**

The report should be brief, to the point and easy to understand. It must explain; the purpose of the evaluation, exactly what was evaluated and the methods used. The report must highlight any methodological limitations, identify key concerns and present evidence-based findings, consequent conclusions, recommendations and lessons. The report should be presented in a way that makes the information accessible and comprehensible and include an executive summary that encapsulates the essence of the information contained in the report to facilitate dissemination and distillation of lessons.

**The evaluation will rate the overall implementation success of the project and provide individual ratings of the eleven implementation aspects as described in Section 1 of this TOR. The ratings will be presented in the format of a table with brief justifications based on the findings of the main analysis.**

Evidence, findings, conclusions and recommendations should be presented in a complete and balanced manner. Any dissident views in response to evaluation findings will be appended in an annex. The evaluation report shall be written in English, be of no more than 50 pages (excluding annexes), use numbered paragraphs and include:

- i) An **executive summary** (no more than 3 pages) providing a brief overview of the main conclusions and recommendations of the evaluation;
- ii) **Introduction and background** giving a brief overview of the evaluated project, for example, the objective and status of activities; The GEF Monitoring and Evaluation Policy, 2006, requires that a TE report will provide summary information on when the evaluation took place; places visited; who was involved; the key questions; and, the methodology.
- iii) **Scope, objective and methods** presenting the evaluation's purpose, the evaluation criteria used and questions to be addressed;
- iv) **Project Performance and Impact** providing *factual evidence* relevant to the questions asked by the evaluator and interpretations of such evidence. This is the main substantive section of the report. The evaluator should provide a commentary and analysis on all eleven evaluation aspects (A – K above).
- v) **Conclusions and rating** of project implementation success giving the evaluator's concluding assessments and ratings of the project against given evaluation criteria and standards of performance. The conclusions should provide answers to questions about whether the project is considered good or bad, and whether the results are considered positive or negative. The ratings should be provided with a brief narrative comment in a table (see *Annex 1* to this Appendix);
- vi) **Lessons (to be) learned** presenting general conclusions from the standpoint of the design and implementation of the project, based on good practices and successes or problems and mistakes. Lessons should have the potential for wider application and use. All lessons should 'stand alone' and should:
  - Briefly describe the context from which they are derived
  - State or imply some prescriptive action;
  - Specify the contexts in which they may be applied (if possible, who when and where)

- vii) **Recommendations** suggesting *actionable* proposals for improvement of the current project. In general, Terminal Evaluations are likely to have very few (perhaps two or three) actionable recommendations.

*Prior to each recommendation*, the issue(s) or problem(s) to be addressed by the recommendation should be clearly stated.

A high quality recommendation is an actionable proposal that is:

1. Feasible to implement within the timeframe and resources available
2. Commensurate with the available capacities of project team and partners
3. Specific in terms of who would do what and when
4. Contains results-based language (i.e. a measurable performance target)
5. Includes a trade-off analysis, when its implementation may require utilizing significant resources that would otherwise be used for other project purposes.

- viii) **Annexes** may include additional material deemed relevant by the evaluator but must include:

1. The Evaluation Terms of Reference,
2. A list of interviewees, and evaluation timeline
3. A list of documents reviewed / consulted
4. Summary co-finance information and a statement of project expenditure by activity
5. The expertise of the evaluation team. (brief CV).

TE reports will also include any response / comments from the project management team and/or the country focal point regarding the evaluation findings or conclusions as an annex to the report, however, such will be appended to the report by UNEP EOU.

Examples of UNEP GEF Terminal Evaluation Reports are available at [www.unep.org/eou](http://www.unep.org/eou)

### **Review of the Draft Evaluation Report**

Draft reports submitted to UNEP EOU are shared with the corresponding Programme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff are allowed to comment on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks feedback on the proposed recommendations. UNEP EOU collates all review comments and provides them to the evaluators for their consideration in preparing the final version of the report.

### **4. Submission of Final Terminal Evaluation Reports.**

The final report shall be submitted in electronic form in MS Word format and should be sent to the following persons:

Segbedzi Norgbey, Chief,  
UNEP Evaluation and Oversight Unit  
P.O. Box 30552-00100  
Nairobi, Kenya  
Tel.: +(254-20)762-4181  
Fax: +(254-20)762-3158



Email: [Segbedzi.Norgbey@unep.org](mailto:Segbedzi.Norgbey@unep.org)

With a copy to:

Maryam Niamir-Fuller,  
Director  
UNEP/Division of GEF Coordination  
P.O. Box 30552-00100  
Nairobi, Kenya  
Tel: +(254-20)762-4166  
Fax: +(254-20)762-4041/2  
Email: [Maryam.Niamir-Fuller@unep.org](mailto:Maryam.Niamir-Fuller@unep.org)

{Name}

Task Manager

{Contact details}

The Final evaluation will also be copied to the following GEF National Focal Points.

{Insert contact details here}

The final evaluation report will be published on the Evaluation and Oversight Unit's web-site [www.unep.org/eou](http://www.unep.org/eou) and may be printed in hard copy. Subsequently, the report will be sent to the GEF Office of Evaluation for their review, appraisal and inclusion on the GEF website.

#### **5. Resources and schedule of the evaluation**

This final evaluation will be undertaken by an international evaluator contracted by the Evaluation and Oversight Unit, UNEP. The contract for the evaluator will begin on ddmmyyy and end on ddmmyyy (# days) spread over # weeks (# days of travel, to {country(ies)}, and # days desk study). The evaluator will submit a draft report on ddmmyyy to UNEP/EOU, the UNEP/DGEF Task Manager, and key representatives of the executing agencies. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary revisions. Comments to the final draft report will be sent to the consultant by ddmmyyy after which, the consultant will submit the final report no later than ddmmyyy.

The evaluator will after an initial telephone briefing with EOU and UNEP/GEF conduct initial desk review work and later travel to {country(ies)} and meet with project staff at the beginning of the evaluation. Furthermore, the evaluator is expected to travel to {country(ies)} and meet with representatives of the project executing agencies and the intended users of project's outputs.

In accordance with UNEP/GEF policy, all GEF projects are evaluated by independent evaluators contracted as consultants by the EOU. The evaluator should have the following qualifications:

The evaluator should not have been associated with the design and implementation of the project in a paid capacity. The evaluator will work under the overall supervision of the Chief, Evaluation and Oversight Unit, UNEP. The evaluator should be an international expert in {} with a sound understanding of {} issues. The consultant should have the following minimum qualifications: (i) experience in {} issues; (ii) experience with management and implementation of {} projects and in particular with {} targeted at policy-influence and

decision-making; (iii) experience with project evaluation. Knowledge of UNEP programmes and GEF activities is desirable. Knowledge of {specify language(s)} is an advantage. Fluency in oral and written English is a must.

**6. Schedule Of Payment**

The consultant shall select one of the following two contract options:

**Lump-Sum Option**

The evaluator will receive an initial payment of 30% of the total amount due upon signature of the contract. A further 30% will be paid upon submission of the draft report. A final payment of 40% will be made upon satisfactory completion of work. The fee is payable under the individual Special Service Agreement (SSA) of the evaluator and **is inclusive** of all expenses such as travel, accommodation and incidental expenses.

**Fee-only Option**

The evaluator will receive an initial payment of 40% of the total amount due upon signature of the contract. Final payment of 60% will be made upon satisfactory completion of work. The fee is payable under the individual SSAs of the evaluator and is **NOT** inclusive of all expenses such as travel, accommodation and incidental expenses. Ticket and DSA will be paid separately.

In case, the evaluator cannot provide the products in accordance with the TORs, the timeframe agreed, or his products are substandard, the payment to the evaluator could be withheld, until such a time the products are modified to meet UNEP's standard. In case the evaluator fails to submit a satisfactory final product to UNEP, the product prepared by the evaluator may not constitute the evaluation report.

*Annex 1 to Appendix 9: OVERALL RATINGS TABLE*

Criterion	Evaluator's Summary Comments	Evaluator's Rating
<b>A. Attainment of project objectives and results (overall rating)</b> Sub criteria (below)		
A. 1. Effectiveness		
A. 2. Relevance		
A. 3. Efficiency		
<b>B. Sustainability of Project outcomes (overall rating)</b> Sub criteria (below)		
B. 1. Financial		
B. 2. Socio Political		
B. 3. Institutional framework and governance		
B. 4. Ecological		
<b>C. Achievement of outputs and activities</b>		
<b>D. Monitoring and Evaluation (overall rating)</b> Sub criteria (below)		
D. 1. M&E Design		
D. 2. M&E Plan Implementation (use for adaptive management)		
D. 3. Budgeting and Funding for M&E activities		
<b>E. Catalytic Role</b>		
<b>F. Preparation and readiness</b>		
<b>G. Country ownership / drivenness</b>		
<b>H. Stakeholders involvement</b>		
<b>I. Financial planning</b>		
<b>J. Implementation approach</b>		
<b>K. UNEP Supervision and backstopping</b>		

**RATING OF PROJECT OBJECTIVES AND RESULTS**

Highly Satisfactory (HS): The project had no shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Satisfactory (S): The project had minor shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Satisfactory (MS): The project had moderate shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Unsatisfactory (MU): The project had significant shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Unsatisfactory (U) The project had major shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Highly Unsatisfactory (HU): The project had severe shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Please note:** Relevance and effectiveness will be considered as critical criteria. The overall rating of the project for achievement of objectives and results **may not be higher** than the lowest rating on either of these two criteria. Thus, to have an overall satisfactory rating for outcomes a project must have at least satisfactory ratings on both relevance and effectiveness.

### **RATINGS ON SUSTAINABILITY**

A. Sustainability will be understood as the probability of continued long-term outcomes and impacts after the GEF project funding ends. The Terminal evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, i.e. stronger institutional capacities, legal frameworks, socio-economic incentives /or public awareness. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes.

#### Rating system for sustainability sub-criteria

On each of the dimensions of sustainability of the project outcomes will be rated as follows.

Likely (L): There are no risks affecting this dimension of sustainability.

Moderately Likely (ML). There are moderate risks that affect this dimension of sustainability.

Moderately Unlikely (MU): There are significant risks that affect this dimension of sustainability

Unlikely (U): There are severe risks that affect this dimension of sustainability.

According to the GEF Office of Evaluation, all the risk dimensions of sustainability are deemed critical. Therefore, overall rating for sustainability will not be higher than the rating of the dimension with lowest ratings. For example, if a project has an Unlikely rating in any of the dimensions then its overall rating cannot be higher than Unlikely, regardless of whether higher ratings in other dimensions of sustainability produce a higher average.

### **RATINGS OF PROJECT M&E**

Monitoring is a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing project with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds. Evaluation is the systematic and objective assessment of an on-going or completed project, its design, implementation and results. Project evaluation may involve the definition of appropriate standards, the examination of performance against those standards, and an assessment of actual and expected results.

The Project monitoring and evaluation system will be rated on ‘M&E Design’, ‘M&E Plan Implementation’ and ‘Budgeting and Funding for M&E activities’ as follows:

Highly Satisfactory (HS): There were no shortcomings in the project M&E system.

Satisfactory(S): There were minor shortcomings in the project M&E system.

Moderately Satisfactory (MS): There were moderate shortcomings in the project M&E system.

Moderately Unsatisfactory (MU): There were significant shortcomings in the project M&E system.

Unsatisfactory (U): There were major shortcomings in the project M&E system.

Highly Unsatisfactory (HU): The Project had no M&E system.

“M&E plan implementation” will be considered a critical parameter for the overall assessment of the M&E system. The overall rating for the M&E systems will not be higher than the rating on “M&E plan implementation.”

All other ratings will be on the GEF six point scale.

GEF Performance Description	Alternative description on the same scale
HS = Highly Satisfactory	Excellent
S = Satisfactory	Well above average
MS = Moderately Satisfactory	Average
MU = Moderately Unsatisfactory	Below Average
U = Unsatisfactory	Poor
HU = Highly Unsatisfactory	Very poor (Appalling)

*Annex 2 to Appendix 9: Co-financing and Leveraged Resources*

Co financing (Type/Source)	IA own Financing (mill US\$)		Government (mill US\$)		Other* (mill US\$)		Total (mill US\$)		Total Disbursement (mill US\$)	
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
- Grants										
- Loans/Concessional (compared to market rate)										
- Credits										
- Equity investments										
- In-kind support										
- Other (*)										
-										
-										
-										
-										
-										
<b>Totals</b>										

*Co-financing (basic data to be supplied to the consultant for verification)*

\* Other is referred to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

***Leveraged Resources***

Leveraged resources are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector. Please briefly describe the resources the project has leveraged since inception and indicate how these resources are contributing to the project's ultimate objective.

**Table showing final actual project expenditure by activity to be supplied by the UNEP Fund management Officer. (insert here)**

*Annex 3 to Appendix 9***Review of the Draft Report**

Draft reports submitted to UNEP EOU are shared with the corresponding Programme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff provide comments on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks agreement on the findings and recommendations. UNEP EOU collates the review comments and provides them to the evaluators for their consideration in preparing the final version of the report. General comments on the draft report with respect to compliance with these TOR are shared with the reviewer.

**Quality Assessment of the Evaluation Report**

All UNEP GEF Mid Term Reports are subject to quality assessments by UNEP EOU. These apply GEF Office of Evaluation quality assessment and are used as a tool for providing structured feedback to the evaluator.

The quality of the draft evaluation report is assessed and rated against the following criteria:

<b>GEF Report Quality Criteria</b>	<b>UNEP EOU Assessment</b>	<b>Rating</b>
A. Did the report present an assessment of relevant outcomes and achievement of project objectives in the context of the focal area program indicators if applicable?		
B. Was the report consistent and the evidence complete and convincing and were the ratings substantiated when used?		
C. Did the report present a sound assessment of sustainability of outcomes?		
D. Were the lessons and recommendations supported by the evidence presented?		
E. Did the report include the actual project costs (total and per activity) and actual co-financing used?		
F. Did the report include an assessment of the quality of the project M&E system and its use for project management?		
<b>UNEP EOU additional Report Quality Criteria</b>	<b>UNEP EOU Assessment</b>	<b>Rating</b>
G. Quality of the lessons: Were lessons readily applicable in other contexts? Did they suggest prescriptive action?		
H. Quality of the recommendations: Did recommendations specify the actions necessary to correct existing conditions or improve operations ('who?' 'what?' 'where?' 'when?'). Can they be implemented? Did the recommendations specify a goal and an associated performance indicator?		
I. Was the report well written? (clear English language and grammar)		
J. Did the report structure follow EOU guidelines, were all requested Annexes included?		
K. Were all evaluation aspects specified in the TORs adequately addressed?		
L. Was the report delivered in a timely manner		

**GEF Quality of the MTE report = 0.3\*(A + B) + 0.1\*(C+D+E+F)**

**EOU assessment of MTE report = 0.3\*(G + H) + 0.1\*(I+J+K+L)**



**Combined quality Rating = (2\* 'GEF EO' rating + EOU rating)/3**

The Totals are rounded and converted to the scale of HS to HU

Rating system for quality of terminal evaluation reports

A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1, and unable to assess = 0.

**GEF Minimum requirements for M&E*****Minimum Requirement 1: Project Design of M&E<sup>3</sup>***

All projects must include a concrete and fully budgeted monitoring and evaluation plan by the time of Work Program entry (full-sized projects) or CEO approval (medium-sized projects). This plan must contain at a minimum:

- SMART (see below) indicators for project implementation, or, if no indicators are identified, an alternative plan for monitoring that will deliver reliable and valid information to management
- SMART indicators for results (outcomes and, if applicable, impacts), and, where appropriate, corporate-level indicators
- A project baseline, with:
  - a description of the problem to address
  - indicator data
  - or, if major baseline indicators are not identified, an alternative plan for addressing this within one year of implementation
- An M&E Plan with identification of reviews and evaluations which will be undertaken, such as mid-term reviews or evaluations of activities
- An organizational setup and budgets for monitoring and evaluation.

---

<sup>3</sup> <http://gefweb.org/MonitoringandEvaluation/MEPoliciesProcedures/MEPTools/meptstandards.html>

## ***Minimum Requirement 2: Application of Project M&E***

- Project monitoring and supervision will include implementation of the M&E plan, comprising:
- Use of SMART indicators for implementation (or provision of a reasonable explanation if not used)
- Use of SMART indicators for results (or provision of a reasonable explanation if not used)
- Fully established baseline for the project and data compiled to review progress
- Evaluations are undertaken as planned
- Operational organizational setup for M&E and budgets spent as planned.

**SMART INDICATORS** GEF projects and programs should monitor using relevant performance indicators. The monitoring system should be “SMART”:

1. **Specific:** The system captures the essence of the desired result by clearly and directly relating to achieving an objective, and only that objective.
2. **Measurable:** The monitoring system and its indicators are unambiguously specified so that all parties agree on what the system covers and there are practical ways to measure the indicators and results.
3. **Achievable and Attributable:** The system identifies what changes are anticipated as a result of the intervention and whether the result(s) are realistic. Attribution requires that changes in the targeted developmental issue can be linked to the intervention.
4. **Relevant and Realistic:** The system establishes levels of performance that are likely to be achieved in a practical manner, and that reflect the expectations of stakeholders.
5. **Time-bound, Timely, Trackable, and Targeted:** The system allows progress to be tracked in a cost-effective manner at desired frequency for a set period, with clear identification of the particular stakeholder group to be impacted by the project or program.

*Annex 5 to Appendix 9*

***List of intended additional recipients for the Terminal Evaluation (to be completed by the IA Task Manager)***

Name	Affiliation	Email
Aaron Zazueta	GEF Evaluation Office	azazueta@thegef.org
<b>Government Officials</b>		
<b>GEF Focal Point(s)</b>		
<b>Executing Agency</b>		
<b>Implementing Agency</b>		
Carmen Tavera	UNEP DGEF Quality Assurance Officer	

## Appendix 10: Decision-making flowchart and organizational chart

### National Steering Committee

Chair – Special Secretary/Additional Secretary, MoEF, who is the Chairperson, GEAC

Vice chair - Concerned Joint Secretary, MoEF who is also the National Focal Point of CPB and National Project Director

Members – Officers/Advisors of the rank of Joint Secretary from DBT, MOA, DGFT, DEA, FSSAI, MEA, representatives from research institutions, representative of industry association and farmer's organizations.

Member Secretary - Director, Incharge of biosafety, who is also the Member Secretary, GEAC and National Project Coordinator

### National Project Director

(JS, MoEF)

### Project Management and Monitoring Committee

Chair: National Project Director  
Members: National Project Coordinator, representative from DBT and one or two other experts

### National Project Coordinator

(Director, MoEF)

### Project Coordination Unit

(to be located in a facilitating agency)

## 1. APPENDIX 11: TERMS OF REFERENCE

### Terms of Reference for:

- **National Executing Agency (NEA)**
- **National Steering Committee (NSC)**
- **National Project Director (NPD)**
- **National Project Coordinator (NPC)**
- **Project Management and Monitoring Committee (PMMC)**
- **Project Coordinating Unit (PCU)**

a) The **National Executing Agency (NEA)**, in addition to other duties given to it by the National Government, will:

- Establish the National Steering Committee (NSC);
- Appoint a National Project Director (NPD) and a National Project Coordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NSC, working in close co-operation with relevant government agencies, the scientific community and other stakeholders.

b) The **National Steering Committee (NSC)** will be constituted by MoEF to advise and guide the implementation of the project. It would meet at least once a year. The functions of NSC are to:

- Provide overall policy advice on the execution of the project;
- Oversee the progress of project execution to ensure that its objectives will be met by the end of the project;
- To review annual work plan, progress report and other key issues in implementation;
- Make recommendations to UNEP when revision of Results Framework, work plan or M&E plan are needed;
- Mobilise necessary expertise, as needed for proper execution of the National Project outputs;
- Catalyse inter-ministerial and broader stakeholder support towards achieving the objectives of the project.

c) **National Project Director (NPD):**

The NPD will be appointed by NEA to provide overall supervision of the project. The Joint Secretary in charge of the Biosafety Unit within MoEF will be appointed as the NPD of the project. The NPD will carry out the following tasks

- To act as Convener of the NSC;
- Manage the overall Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Responsible for review, monitoring and clearance of work plan;
- Approve the of selection of consultant and subcontracting agencies;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the NSC;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Oversee overall resource allocation and where relevant submit proposals for budget revisions to the NSC and UNEP;
- Ensure submission of regular progress, financial reports, and terminal report at project completion;
- Oversee the preparation of annual Project Implementation Review (PIR) and GEF Tracking Tools by NPC.

- Participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan.
- Ensure the project is in conformity with objectives of the CPB;
- Any other task as decided by the NEA.

**d) The National Project Coordinator (NPC)**

The NEA will appoint a NPC for day to day coordination of implementation of project activities. The NPC will report to the NPD and NSC on all project activities

- Coordinate, the planning, management and execution of the project activities as set out in the project document and as guided by NSC;
- Assist the NPD in discharging its functions;
- Preparation of detailed annual work plans consistent with the envisaged outputs and objectives of the Project Document that incorporates the work plans prepared by all the implementing partners;
- Manage the project budget in line with the approved work plans;
- Coordinating selection of subcontractors and consultants and supervise PCU;
- Technical review of the TOR as well as reports prepared by sub-contractors and consultants.
- Supervise the timely preparation and submission of quarterly and annual progress reports, work plans, budgets, and financial reports by all the executing partners to UNEP and the NSC;
- Coordinating with line ministries, state governments, institutions and project partners involved in the project execution;
- Reviewing project budget revisions and all other administrative arrangements required under GOI and UNEP procedures;
- Work with UNEP to prepare the annual Project Implementation Review (PIR) and the GEF Tracking Tool
- Preparation of the terminal report and other project closure procedures at project completion;
- Participate in the mid-term review and develops, in consultation with NPD and UNEP, and develop a management response to the evaluation recommendations along with an implementation plan.
- Provide administrative inputs to the project and monitoring arrangements as per GOI/UNEP procedures;
- Attend workshops and consultations as appropriate;
- Support resource mobilization efforts and development of partnerships;
- Support in replication of project lessons through sharing of information with UNEP and other countries at regional and sub regional levels.
- Any other task assigned.

**e) Project Management and Monitoring Committee (PMMC)**

The PMMC will be chaired by NPD and members would be NPC, experts from DBT and other relevant organisations such as ICAR, NBPGR etc. The PMMC would meet at least once in two months and provide technical support to the NPD and NPC as indicated below:

- Assist in the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the project outputs;
- Provide advice on the work plans and budgets.

**f) Project Coordination Unit (PCU)**

The PCU will be contracted and located in a facilitating agency having experience in biotechnology and biosafety issues. The criteria of selection would also include experience in similar assignments

earlier. Funds will also be channelized through the facilitating agency selected for the purpose. The PCU will carry out the following tasks:

- To provide administrative and technical support to NPC in implementation of the project activities;
- Assist the NPC in ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in organizing of NSC and PMMC meetings;
- Assist in drafting Terms of Reference for national project consultants and experts as per the advice of PMMC;
- Assist in preparation of detailed work plan and budget under the guidance of the NPC;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Assist the NPC in the preparation and submission to UNEP and the NSC, of regular progress and financial reports;
- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact;
- Will propose cost estimates for accounting, budget revisions as needed and prepare requests for disbursement in a timely fashion to ensure that funds are available when needed for project activities;
- Will maintain detailed records of all expenditures incurred in accordance with GoI and UNEP procedures;
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines.





**HEM PANDE**

Joint Secretary

Tel: 011-24362551

Fax: 011-24360894

[hempande@nic.in](mailto:hempande@nic.in)



भारत सरकार  
पर्यावरण एवं वन मंत्रालय  
GOVERNMENT OF INDIA  
MINISTRY OF ENVIRONMENT & FORESTS

D. O. No. C-12021/1/2009 CS III

Dated: 27<sup>th</sup> January 2011

Dear

*Dr Maryam,*

This is with reference to UNEP/ GEF FSP titled "Capacity Building on Bio-safety for Implementation of the Cartagena Protocol in India – Phase II". This is to kindly confirm that the co-financing for this FSP is USD 6 million (comprising of USD 5.1 m in kind and USD 0.9 m in cash) from the Ministry of Environment and Forests, Government of India for the project implementation phase.

Warm regards,

Yours sincerely,

(Hem Pande)

Dr Maryam Niamir-Fuller  
GEF Executive Coordinator and Director  
Division of GEF Coordination  
UNEP, Nairobi



जहाँ है हरियाली।  
वहाँ है खुशहाली।।

पर्यावरण भवन, सी.जी.ओ. कॉम्प्लेक्स, लोदी रोड, नई दिल्ली - 110 003  
PARYAVARAN BHAWAN, C.G.O. COMPLEX, LODHI ROAD, NEW DELHI - 110 003



**Dr Maryam Niamir-Fuller**

Director, Division of GEF Coordination  
UNEP, P O Box 30552  
Nairobi, Kenya



भारत सरकार  
पर्यावरण एवं वन मंत्रालय  
GOVERNMENT OF INDIA  
MINISTRY OF ENVIRONMENT & FORESTS  
D. O. No. 4(2)/10/2007 - IC & SD.1  
Date: 16<sup>th</sup> July 2008

**Subject: Endorsement for 'Capacity Building on Bio-safety for Implementation of the Cartagena protocol - Phase II'**

In my capacity as GEF Operational Focal Point for India, I confirm that the above project proposal (a) is in accordance with the government's national priorities and the commitments made by India under the relevant global environmental conventions and (b) has been discussed with relevant stakeholders, including the global environmental convention focal points, in accordance with GEF's policy on public involvement.

Accordingly, I am pleased to endorse the above proposal for GEF consideration and approval through UNEP. If approved, this proposal will be prepared and implemented by the Ministry of Environment and Forests, Government of India, UNEP along with other partners.

I understand that the total GEF financing being requested for this project is USD 3 million from India's GEF 4 RAF allocation for biodiversity focal area including the Agency fee (10%) to UNEP for project cycle management services associated with this project.

With warm regards,

Yours sincerely,

  
(Sudhir Mital)

Joint Secretary &  
GEF Operational Focal Point India

Copy to:

- Mr. M. Prasad, Joint Secretary, DEA, North Block, New Delhi
- Mr. A K Goyal, Joint Secretary, Ministry of Environment and Forests, Gol, new Delhi
- Dr FeeChon Chong-Low, Regional Coordinator for Biosafety (Asia), UNEP/ DGEF - Biosafety Unit, Bangkok, Thailand



जहाँ है हरियाली।  
वहाँ है खुशहाली।।

पर्यावरण भवन, सी.जी.ओ. कॉम्प्लेक्स, लोदी रोड, नई दिल्ली - 110 003  
PARYAVARAN BHAWAN, C.G.O. COMPLEX, LODHI ROAD, NEW DELHI - 110 003

## APPENDIX 14: PROCUREMENT PLAN FOR EQUIPMENT FOR CAPACITY BUILDING FOR IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSEATY IN INDIA – PART II

Component	Description	Costs US\$	Proposed dates for procurement as per work plan
2	Office Supplies for Project Coordination Unit spread over 3 years: - Computers, printers, photocopier	4X \$2,500 = \$10,000	Q1, Year 1; Q1, Year 2; Q1, Year 3
3	Laboratory Equipment for monitoring and enforcement (Activities under output 3.1.2): - Real-time PCR equipment - Laminar flow cabinet - Micro Centrifuge - Gel casting equipment - Electrophoresis apparatus - Hybridization oven - Electrophoresis Power Pack - Camera to record DNA separation - Computers, printers - Necessary tools, materials and reagent	25,000 10,000 3,000 1,000 3,000 2,000 1,000 1,000 3,000 31,000	Q3 and Q4, Year 2
6	Non laboratory Purchase	22,000	Q1 and Q2, Year 3

<sup>i</sup> Unit cost per laboratory to assist network of laboratories to the referral laboratory (4 laboratories)



## Tracking Tool for Biodiversity Projects in GEF-4 and GEF-5

### Objective 3:

#### Build Capacity for the Implementation of the Cartagena Protocol on Biosafety (CPB)

**Objective:** To measure progress in achieving the impacts and outcomes established at the portfolio level under the biodiversity focal area.  
**Rationale:** Project data from the GEF-4 and GEF-5 project cohort will be aggregated for analysis of directional trends and patterns at a portfolio-wide level to inform the development of future GEF strategies and to report to GEF Council on portfolio-level performance in the biodiversity focal area.  
**Structure of Tracking Tool:** Each tracking tool requests background and coverage information on the project and specific information required to track portfolio level indicators in the GEF-5 strategy.  
**Guidance in Applying GEF Tracking Tools:** GEF tracking tools are applied three times: at CEO endorsement, at project mid-term, and at project completion.  
**Submission:** The finalized tracking tool will be cleared by the GEF Agencies as being correctly completed.  
**NOTE:** Please complete sections I, II, III for GEF-4 and sections I and II for GEF-5.

**Important:** Please read the Guidelines posted on the GEF website before entering your data

I. General Data	Please indicate your answer here	Notes
Project Title	Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India - Phase II	
GEF Project ID	3751	
Agency Project ID	ADDIS 00388	
Implementing Agency	UNEP	
Project Type	FSP	FSP or MSP
Country	India	
Region	SAR	
Date of submission of the tracking tool	June 30, 2011	Month DD, YYYY (e.g., May 12, 2010)
Name of reviewers completing tracking tool and completion date		Completion Date
Planned project duration	4	Years
Actual project duration		Years
Lead Project Executing Agency (ies)	Ministry of Environment and Forests	
Date of Council/CEO Approval		Month DD, YYYY (e.g., May 12, 2010)
GEF Grant (US\$)	2,727,273	
Cofinancing expected (US\$)	6,000,000	

### II. For each question please identify any intended actions that will improve performance of the biosafety framework.

Issue	Please select your score from drop down menu	Scoring Criteria	Comment	Next Steps
<b>Biosafety Policy</b> 1) Has a biosafety policy been developed and is it being fully implemented?	3	<p>0: A stand alone biosafety policy does not exist</p> <p>1: A stand alone biosafety policy has been produced</p> <p>2: A stand alone biosafety policy has been produced and has been formally adopted by the government</p> <p>3: A legally approved biosafety strategy has been incorporated into broader sectoral policies (e.g. agriculture, biotechnology, science and technology, health, etc) and is being enforced</p> <p>4: A biosafety policy is implemented through a multi-year Action Plan that involves more than one sector of Government or society.</p>	<p><b>Comment:</b></p> <p>Biosafety issues integrated into National Seed Policy 2002 and National Biotechnology Development Strategy, 2007</p>	<p><b>Next Steps:</b></p> <p>To strengthen the implementation and synergy in policy issues.</p>
<b>Biosafety Regulatory Regime</b> 2) Has a regulatory regime been developed and does it have full legal force?	3	<p>0: A regulatory regime has not been developed</p> <p>1: Interim measures for biosafety decision making, including some modification of existing regulations, have been put in place.</p> <p>2: A regulatory regime has been developed and adopted but does not yet have full legal force</p> <p>3: The regulatory regime has full legal force, is operational and linked to the administrative system -i.e. used for decisions</p>	<p><b>Comment:</b></p> <p>Environment Protection Act 1986 provides the framework legislation under which notifications and rules are developed as the biosafety regulatory regime pivoted around the "Rules for manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms, 1989"</p> <p>See also <a href="http://dbtbiosafety.nic.in">http://dbtbiosafety.nic.in</a></p>	<p><b>Next Steps:</b></p> <p>The proposed project will further enhance human and material capacity to equip India in meeting its obligations to the Cartagena Protocol on Biosafety</p>
<b>Administrative System</b>				

3) Is an administrative system in place and fully operational?	3	<p><b>0:</b> Focal Points and National Competent Authorities not appointed nor available via BCH</p> <p><b>1:</b> All Focal Points and National Competent Authorities appointed, and roles &amp; responsibilities stated and available on BCH</p> <p><b>2:</b> Procedures for handling requests have been designed, legally adopted, and made available to the public.</p> <p><b>3:</b> Requests have been received, processed, and decisions communicated to the BCH. Appeal procedures designed and operational.</p> <p><b>4:</b> Administrative system fully supported by national budget allocation or alternative (non-donor) system of revenue generation</p>	<p><b>Comment:</b>  <a href="http://moef.gov.in">http://moef.gov.in</a> provides linkages and details on requests and clearances</p>	<p><b>Next Steps:</b>  Further capacity to be built including measures to ensure public input and enhanced risk assessment capacity to assist decision making</p>
<b>Risk Assessment and Decision-making</b>				
4) Are risk assessment procedures employed and contributing to decision-making?	2	<p><b>0:</b> No risk assessment is applied to LMOs</p> <p><b>1:</b> Sectoral risk assessment dossiers are required to accompany LMO requests</p> <p><b>2:</b> Risk assessment/risk management system involves case-by-case analyses by scientific experts that provide recommendations to decision-making bodies. Composition and responsibilities of the decision-making bodies clearly stated and publicized.</p> <p><b>3:</b> Decisions on LMOs are integrated across sectors (e.g. take into account risks to human health)</p>	<p><b>Comment:</b>  Applications on a case by case procedure. Procedural manuals developed to facilitate decision making</p>	<p><b>Next Steps:</b>  To further enhance capacity</p>
<b>Follow-up and Monitoring</b>				
5) Does an operational follow-up and monitoring system exist?	2	<p><b>0:</b> No system for follow-up and monitoring exists</p> <p><b>1:</b> Institutional and human capacity in place to follow-up and monitor, including Risk Management for field-trials and post-release</p> <p><b>2:</b> Compliance mechanisms for Risk Management established</p> <p><b>3:</b> Liability and redress mechanisms in place</p> <p><b>4:</b> Decisions, risk management plans, a</p>	<p><b>Comment:</b>  Pre and post release monitoring mechanisms have been put in place for risk management through state agricultural universities and state agriculture departments</p>	<p><b>Next Steps:</b>  Further capacity to be built for ensuring robust post release surveillance</p>
<b>Public awareness, education and participation awareness</b>				
6) Is information on LMOs made available to public?	3	<p><b>0:</b> Little or no official information on LMOs available to the general public</p> <p><b>1:</b> Information on LMOs generally available in at least one national language</p> <p><b>2:</b> Information on LMOs generally available in at least one national language and is kept updated</p> <p><b>3:</b> Information on LMOs is used for awareness-raising campaigns</p> <p><b>4:</b> Survey results on levels of public aw</p>	<p><b>Comment:</b> Extensive awareness programmes organized throughout the country</p>	<p><b>Next Steps:</b>  Awareness and sensitization to be enhanced targeting multiple stakeholders in different languages.</p>
<b>Education</b>				
7) Has coursework and training on biosafety been integrated into higher education?	4	<p><b>0:</b> No modern biotechnology and biosafety available in the formal (i.e. technical, academic, extramural) education system.</p> <p><b>1:</b> Basic modern biotechnology and biosafety information included in the curricula at technical and college levels.</p> <p><b>2:</b> Dedicated short-term courses on biosafety available for government staff at technical schools and higher education institutions.</p> <p><b>3:</b> National association for biosafety established</p> <p><b>4:</b> Undergraduate and graduate degree programs offering concentrations and/or degree programs on modern biotechnology, including biosafety</p>	<p><b>Comment:</b>  Several undergraduate and graduate programs on going in the country</p>	<p><b>Next Steps:</b>  The current project will produce materials to facilitate the ongoing programs</p>
<b>Participation</b>				
8) Has the public been engaged in LMO decision-making?	2	<p><b>0:</b> Little or no direct involvement of public in LMO decision-making</p> <p><b>1:</b> Access to information includes other mechanisms in addition to the BCH (i.e. radio and television programs, newspapers columns, blogs, etc.).</p> <p><b>2:</b> Mechanism for public involvement in LMO decision-making established</p> <p><b>3:</b> Evidence of level of public involvement in LMO decision-making available via BCH or other means</p> <p><b>4:</b> Regular open consultation meetings held on biosafety</p>	<p><b>Comment:</b>  Mechanisms for public engagement in decision making established</p>	<p><b>Next Steps:</b>  This will be further strengthened in the new project</p>

	22	TOTAL SCORE
	32	TOTAL POSSIBLE

**III. For GEF-4 ONLY: Strategic Program 6: Building capacity for the implementation of the Cartagena Protocol on Biosafety Tracking Tool**

Issue	Please select your score from drop down menu	Scoring Criteria	Comment	Next Steps
<b>National Coordination Mechanism</b> <i>1) Is there a National Coordination Mechanism to assist with the design and implementation of a national IAS strategy? (This could be a single "biosecurity" agency or an interagency committee).</i>		<b>0:</b> National Coordination Mechanism does not exist <b>1:</b> A national coordination mechanism has been established <b>2:</b> The national coordination mechanism has legal character and responsibility for development of a national strategy <b>3:</b> The national coordination mechanism oversees implementation of IAS National Strategy	<b>Comment:</b>	<b>Next Steps:</b>
		<b>Bonus point:</b> Contingency plans for IAS emergencies exist and are well coordinated <b>0:</b> NO <b>1:</b> Yes		
<b>IAS National Strategy Development and Implementation</b> <i>2) Is there a National IAS strategy and is it being implemented?</i>		<b>0:</b> IAS strategy has not been developed <b>1:</b> IAS strategy is under preparation or has been prepared and is not being implemented <b>2:</b> IAS strategy exists but is only partially implemented due to lack of funding or other problems <b>3:</b> IAS strategy exists, and is being fully implemented	<b>Comment:</b>	<b>Next Steps:</b>
<b>Policy Framework to Support IAS Management</b> <i>3) Has the national IAS strategy lead to the development and adoption of comprehensive framework of policies, legislation, and regulations across sectors.</i>		<b>0:</b> IAS policy does not exist <b>1:</b> Policy on invasive alien species exists (Specify sectors in comment box if applicable) <b>2:</b> Principle IAS legislation is approved (Specify sectors in comment box if applicable. It may be that harmonization of relevant laws and regulations to ensure more uniform and consistent practice is most realistic result.) <b>3:</b> Subsidiary regulations are in place to implement the legislation (Specify sectors in comment box if applicable) <b>4:</b> The regulations are under implementation and enforced for some of the main priority pathways for IAS (Specify sectors in comment box if applicable) <b>5:</b> The regulations are under implementation and enforced for all of the main priority pathways for IAS (Specify sectors in comment box if applicable)	<b>Comment:</b>	<b>Next Steps:</b>
<b>Prevention</b>				



4) Have priority pathways for invasions been identified and actively managed and monitored?		<p><b>0:</b> Priority pathways for invasions have not been identified.</p> <p><b>1:</b> Priority pathways for invasions have been identified using risk assessment procedures as appropriate</p> <p><b>2:</b> Priority pathways for invasions are being actively managed and monitored to prevent invasions (In comment section please specify methods for prevention of entry: quarantine laws and regulation, database establishment, public education, inspection, treatment technologies (fumigation, etc) in the comment box.)</p> <p><b>3:</b> System established to use monitoring results from the methods employed to manage priority pathways in the development of new and improved policies, regulations and management approaches for IAS</p>	Comment:	Next Steps:
<b>Early Detection</b> 5) Are detection, delimiting and monitoring surveys conducted on a regular basis?		<p><b>0:</b> Detection surveys[1] of aggressively invasive species (either species specific or sites) are not regularly conducted due to lack of capacity, resources, planning, etc</p> <p><b>1:</b> Detection surveys (observational) are conducted on a regular basis</p> <p><b>2:</b> Detection and delimiting surveys[2] (focusing on key sites: high risk entry points or high biodiversity value sites) are conducted on a regular basis</p> <p><b>3:</b> Detection, delimiting and monitoring</p>	Comment:	Next Steps:
		<p><b>Bonus point:</b> Data from surveys is collected in accordance with international standards and stored in a national database.</p> <p>0: NO</p> <p>1: Yes</p>		
		<p><b>Bonus point:</b> Detection surveys rank IAS in terms of their potential damage and detection systems target the IAS that are potentially the most damaging to globally significant biodiversity</p> <p>0: NO</p> <p>1: Yes</p>		
<b>Assessment and Management: Best practice applied</b> 6) Are best management practices being applied in project target areas?		<p><b>0:</b> Management goal and target area undefined, no acceptable threshold of population level established</p> <p><b>1:</b> Management goal and target area has been defined and acceptable threshold of population level of the species established</p> <p><b>2:</b> Four criteria are applied to prioritize species and infestations for control in the target areas: a) current and potential extent of the species; b) current and potential impact of the species; c) global value of the habitat the species actually or potentially infests; and d) difficulty of control and establishing replacement strategies.</p> <p><b>3:</b> Eradication, containment, control and</p>	Comment:	Next Steps:
		<p><b>Bonus point:</b> Monitoring system (ongoing surveys) established to determine characteristics of the IAS population, and the condition of the target area.</p> <p>0: NO</p> <p>1: Yes</p>		
		<p><b>Bonus points:</b> Funding for sustained and ongoing management and monitoring of the target area is secured.</p> <p>0: NO</p> <p>3: Yes</p>		
		<p><b>Bonus point:</b> Objective measures indicate that the restoration of habitat is likely to occur in the target area.</p> <p>0: NO</p> <p>1: Yes</p>		
		<b>TOTAL SCORE</b>		
	29	<b>TOTAL POSSIBLE</b>		

[1] Detection survey: survey conducted in an attempt to determine if IAS are present.  
 [2] Delimiting survey: survey conducted to establish the boundaries of an area considered to be infested or free from a pest.  
 [3] Monitoring survey: survey to verify the characteristics of a pest/IAS.