UNEP GEF PIR Fiscal Year 15
(1 July 2014 to 30 June 2015)

1. PROJECT GENERAL INFORMATION

Project Title:	Capacity building on biosafety for implementation of the Cartagena Protocol in India-Phase II
Executing Agency:	Ministry of Environment, Forest & Climate Change (MoEF&CC), , Government of India
Project partners:	UNEP/GEF
Geographical Scope:	National

Participating Countries:	India

GEF project ID:	3751	**IMIS number*[1]:**	GFL/5060-2716-4C42
Focal Area(s):	Biodiversity	**GEF OP #:**	
GEF Strategic Priority/Objective:	SP 6 – Biosafety/SO3	**GEF approval date*:**	August 11, 2011
UNEP approval date:	May 3, 2012	**Date of first disbursement*:**	24/05/2012
Actual start date[2]:	May 29, 2012	**Planned duration:**	48 months
Intended completion date*:	May 28, 2016	**Actual or Expected completion date:**	May 28, 2016
Project Type:	Full-Sized Project (FSP)	**GEF Allocation*:**	2,727,273.00
PPG GEF cost*:	-	**PPG co-financing*:**	-
Expected MSP/FSP Co-financing*:	6,000,000.00	**Total Cost*:**	8,727,273.00
Mid-term review/eval. (planned date):	September 15, 2015	**Terminal Evaluation (actual date):**	May 02, 2016
Mid-term review/eval. (actual date):		**No. of revisions*:**	3
Date of last Steering Committee meeting:	March 16, 2015	**Date of last Revision*:**	01/07/2015
Disbursement as of 30 June 2015*:	1,079,297.15 USD	**Date of financial closure*:**	
Date of Completion[3]*:	May 2, 2016	**Actual expenditures reported as of 30 June 2015[4]:**	413,441.51 USD
Total co-financing realized as of 30 June 2015[5]:	4,429,789 USD	**Actual expenditures entered in IMIS as of 30 June 2015*:**	413,441.51 USD
Leveraged financing:[6]			

[1] Fields with an * sign (in yellow) should be filled by the Fund Management Officer
[2] Only if different from first disbursement date, e.g., in cases were a long time elapsed between first disbursement and recruitment of project manager.
[3] If there was a "Completion Revision" please use the date of the revision.
[4] Information to be provided by Executing Agency/Project Manager
[5] Projects which completed mid-term reviews/evaluations or terminal evaluations during FY15 should attach the completed co-financing table as per GEF format. See Annex 1
[6] See above note on co-financing

Project summary[7]	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). 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 17th 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. As of now Bt Cotton is the only crop approved for commercial use in the country covering an area of more than 90% of the total cotton cultivation area. In addition several other crops such as cotton, rice, castor, wheat, maize, tomato, groundnut, potato, sorghum, okra, brinjal, mustard, watermelon, papaya, sugarcane, rubber, banana, pigeon pea, Artemisia annua L. and chickpea 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. While several efforts have been made by the GOI towards capacity building within the country to strengthen the biosafety regulation and to create awareness regarding biosafety issues, the urgent need to intensify capacity building on identified priority areas through a focused programme was highlighted consequent to the Phase I Capacity Building Project on Biosafety which implemented by MoEF

[7] As in project document

	with the support of World Bank/GEF in 2007. In the above background, the UNEP-GEF Phase-II Capacity Building Project on Biosafety was developed by MoEF and approved by GEF on 11th August, 2011. The Phase II Project is conceptualized to supplement the ongoing biosafety capacity building initiatives in India integrate international experience and promote regional cooperation. The main focus of this project is to strengthen institutional capacity, develop human resource and enhance public awareness on biosafety to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities. The three thrust areas for capacity building are Risk Assessment and Management, Socio Economic Considerations Handling, Transport, Packaging and Identification of LMOs in agriculture. 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 GEF/UNEP-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.

Project status FY[8]	**Project Management and Monitoring Committee (PMMC)** The Project Management and Monitoring Committee (PMMC) constituted on February 2013, to address day to day procurement and project implementation issues have met three times during the period of July 1, 2014 to June 30, 2015 as below: ➢ September 14, 2014 --- 5th PMMC ➢ March 16, 2015 --- 6th PMMC ➢ June 23, 2015 --- 7th PMMC Till date seven meetings of the PMMC have been convened to review project progress and to accord various approvals related to activities such as TOR, for consultants, selection of consultants, award of contracts, revision in work plan, budget etc. on a quarterly basis. **Project Coordination Unit (PCU)** The PCU has been established at Biotech Consortium India Limited (BCIL) on August 2013, for a period of four years. The PCU is assisting NPC on a day to day basis for activities related to the project implementation. **Supervisory Mission** Dr. Alex O. Biney, Portfolio Manager, UNEP for Phase II Project on Biosafety, is tentatively planning to visit India for a supervisory mission and Mid-Term Review during the second week of September 2015 to review the progress of the project.

[8] Please add additional lines to keep prior year implementation status (if any)

He would be participating in discussions with NPD, NPC and PCU team. He would be evaluating the progress of the project in the four thrust areas.

National Steering Committee (NSC)
The third meeting of the NSC, which accords the necessary approvals related to annual work plan, budget and review of project progress, was held on March 16, 2015 at New Delhi, under the Chairmanship of Shri. Hem Pande Additional Secretary, MoEF&CC and National Project Director. The Members approved the annual work plan, budget and reviewed the progress of the project made so far subsequent to the second meeting of the NSC held on June 24, 2014.

Status of the Project Activities:
To initiate the project activities in a planned manner, implementation plans were prepared for each of the thrust areas i.e. risk assessment and risk management (RARM), socio-economic consideration (SECs) and handling, transport, packaging and identification (HTPI) and public awareness (PA). The status of implementation under each of the thrust areas is presented below:

THRUST AREA- I: RISK ASSESSMENT & RISK MANAGEMENT

The contract for undertaking activities related to Risk Assessment and Risk Management (RARM) was awarded to Centre for Environmental Risk Assessment (CERA) - ILSI research foundation, Washington, USA. The progress so far is as given under

a. **Preparation of a base paper:** An online survey on "GE Plants in product development pipeline in India" has been completed to understand the major crops and traits at various stages of product development cycle. The objective of the study was to assist in preparedness of the regulatory system to the products/traits in the pipeline.

b. **Preparation of CFT monitoring manual:** A course manual, "Monitoring Confined Field Trials of Regulated, GE Plants," and accompanying test questions have been drafted by CERA ILSI. This manual is designed to introduce confined field trials (CFTs) and their role in the development of new GE crop plants, the process by which CFTs are regulated in India, and the measures used to effectively manage potential environmental risks from CFTs.

c. **Training Workshops on Management of Confined Field Trials (CFTs) of Regulated GE Plants :** Two training workshops of two days duration each were organized at New Delhi (May 25-26, 2015) and Hyderabad (June 3-4, 2015) for members of monitoring teams; scientists from ICAR research institutions; scientists from State Agricultural Universities (SAUs) and state department of agriculture etc. participated in these workshops. After completion of training workshop, a post workshop survey and quiz were also organized. To encourage maximum participation in the survey and quiz, certificates were also distributed to participants who completed both quiz and survey.

d. **Preparation of ERA guidelines:** An expert committee under the chairmanship of Prof. C.R. Babu and Prof. K. Veluthambi as the co-chair has been constituted by MOEF&CC for formulation of guidelines for ERA of GE plants. Five meetings of the expert committee have been held so far. The committee has finalized the structure of the guidelines and the drafting has already been completed and reviewed during the 5th meeting. Guidelines are in final stages of completion. User's Guide and preparation of Risk Analysis Framework (RAF) are also near to completion.

e. **Visit to OGTR for understanding ERA process of GE plants:** A team of eight experts consisting of representatives of concerned ministries and members of regulatory committees, visited the Office of Gene Technology Regulator (OGTR) and other concerned agencies in Australia to understand the operational framework and risk analysis methodologies being followed in Australia. The five day visit was facilitated by CERA-ILSI. The officers from OGTR made detailed presentations on the Australian legislation, operations of national scheme, administrative system for handling and processing application, risk analysis and decision making, risk communication methods/approaches, monitoring and compliance etc. The visiting team had an opportunity to interact with Food Standards Australia New Zealand (FSANZ), Biosecurity Group of Department of Agriculture, Therapeutic Goods Administration, Australian Pesticide and Veterinary Medicine Authority and Commonwealth Scientific Research Organization (CSIRO).

f. **Preparation of biology documents:**

The crop specific national institutions under ICAR have been engaged to prepare a series of biology documents for facilitating ERA process for eight crops viz. Chick Pea, Pigeon Pea, Sorghum, Papaya, Mustard, Rubber, Potato and Tomato. The following institutions were engaged:

i. Indian Institute of Pulses Research (IIPR), Kanpur for Chickpea and Pigeon Pea
ii. Directorate of Sorghum Research (DSR), Hyderabad for Sorghum
iii. Indian Institute of Horticultural Research (IIHR), Bangalore for Papaya
iv. Directorate of Rapeseed and Mustard Research (DRMR), Bharatpur for Mustard
v. Rubber Research Institute (RRI), Kottayam for Rubber
vi. Central Potato Research Institute (CPRI), Shimla for Potato
vii. Indian Institute of Vegetable Research (IIVR), Varanasi for tomato

Dr. O.P. Govila, Former Professor of Genetics, IARI and member, GEAC is the national consultant for assisting the national institutions in preparation of biology documents by reviewing the documents. A consultative process is being followed for finalization of the biology documents as per the following steps:

i. Review of draft biology documents being prepared by institutions by national consultant to confirm that the documents are in line with the suggested structure and intended purpose of risk assessment.
ii. Circulation of revised draft biology documents for comments/additional

information to State Agricultural Universities (SAUs), research institutions and private sector working on these crops.

iii. Forwarding the comments received to respective institutions for incorporation and submission of final draft.

iv. Review by CERA-ILSI, UNEP and national consultant

v. Consultative meetings with crop specific experts for finalization, if required.

vi. Formatting, editing and printing.

Biology documents of seven crops are under final stages of printing and ready for circulation after a series of consultation process. The biology document on Chickpea is under circulation for comments and is expected to be ready for printing in next few weeks.

THRUST AREA II: SOCIO-ECONOMIC CONSIDERATIONS

The activities related to socio-economic considerations for Genetically Modified Organisms (GMOs), have been assigned to Research and Information System for Developing countries (RIS). RIS has associated with following six national institutions for undertaking various project activities i.e. developing and validating questionnaires, conducting baseline surveys, organizing workshops and meetings for development of guidelines and methodologies etc.:

- Indian Agricultural Research Institute (IARI), New Delhi
- Gujarat Institute of Developmental Research (GIDR), Ahmedabad
- Institute of Social and Economic Change (ISEC), Bangalore
- National Academy of Agricultural Research and Management (NAARM), Hyderabad
- Tamil Nadu Agricultural University (TNAU), Coimbatore
- University of Agricultural Sciences (UAS), Raichur

Subsequent to signing of contracts with all partnering institutions, the first meeting was held on November 6, 2014 at New Delhi. The initial guidance document had been made by the RIS team within first four months from the commencement of the project. It captured the existing studies on socio-economic assessment of certain crops based on extensive literature review and analysis of available ex-ante and ex-post studies undertaken by various institutions and researchers across the crops and regions in India. It also encompassed analysis of available studies on cost-benefit analysis

RIS in collaboration with Institute of Social and Economic Change (ISEC) organized a two-day “Workshop on developing guidelines and methodologies for socio-economic assessment of LMOs” from December 11-12, 2014 at ISEC, Bangalore to discuss in detail the initial draft guidance document, selection of methodologies and questionnaire design. Principal Investigators (PIs) from all the partner institutions participated in this. In addition RIS invited couple of external experts. Based on the Workshop deliberations, the project partners are working on finalizing the design of the questionnaires for various stakeholders in respective sample survey locations based on selected crops and traits. The partner institutions have also started identifying two crops and two traits for use in the surveys and field work from the list provided by MoEF&CC.

Each partner institution selected two crops and traits for the field survey. The crops and regions selected by the respective project partners is as shown in the following table

Institution	Crops	Traits	Location
GIDR	Castor and Groundnut	Fungus/Bacterial and Nitrogen Use	Gujarat
IARI	Mustard and Tomato	Insect Resistance and Delayed Ripening	Haryana and Punjab
TNAU	Brinjal and Maize	Insecticide Resistance and Herbicide Tolerance	Tamil Nadu
ISEC	Bt Cotton and Aerobic Paddy	Insect Resistance and Drought/salinity Tolerant	Karnataka
NAARM	Maize and Brinjal	Herbicide Tolerance and Insect Resistance	Telangana
UAS	Pigeon Pea and Black Gram	Insect Resistance and Fungal Resistance	Karnataka

A common questionnaire has been prepared for collection of information through surveys. This questionnaire will be used by all partner institutions for ensuring uniformity in data collection. As data is collected for different crops and different traits having a common questionnaire ensures that essential information that is relevant for understanding SE impacts is collected for the identified crops and traits. On the basis of the draft questionnaires, a common set of variables and parameters mentioned by each of the institutions will be prepared.

THRUST AREA III: HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

The activities under HTPI have been divided into three sub-components namely strengthening of institutions for LMO detection, Identity preservation and strengthening capacity of enforcement agencies.

Strengthening of institutional capacity for LMO Detection:

Subsequent to the completion of the stocktaking assessment of six labs during Phase-I of the stocktaking exercise by ScanBi Diagnostics in association with Dr. Lalitha Gowda, Chief Scientist, CFTRI, Mysore as the national and Dr. Murali Krishna from PCU, the final report submitted by ScanBi has been reviewed in the inter-ministerial meeting and recommended inviting proposals from all the six institutions and also suggested to audit three additional labs namely

- Export Inspection Council (EIC) Lab, Kochi
- Geo-Chem Laboratories Pvt. Ltd, Mumbai
- Punjab Biotechnology Incubator, Mohali

Subsequently, Dr. Lalitha Gowda and Dr. Murali Krishna visited the above three labs for stocktaking assessment and the final report submitted by Dr. Gowda was reviewed in the 7th PMMC held in June 23, 2014. PMMC recommended the following:

A. To provide financial support of Rs. 100 lakhs to NBPGR and Rs. 75 Lakhs to PBTI, EIA-Kochi and DFTCML each for strengthening their existing capacities as well as for procurement of equipments required for LMO detection.

B. Constitution of a Sub-Committee with Dr. Gowda as the Chair and the representatives of four institutions as Members of the Committee. The first meeting of the Sub-Committee for finalization of the equipments list is scheduled to be held in the first week of the July, 2015.

C. The Sub-Committee would finalize the list of common equipments required by all the four labs and procure the same through a common tendering process.

The Members of the PMMC also recommended the proposal submitted by Ms. Intertek-ScanBi Diagnostics for providing training to scientists and staff in aspects related to LMO detection in India and Sweden. A formal contracts needs to be signed between Intertek ScanBi Diagnostics and Biosafety Project, MoEF&CC

Identity Preservation

This component includes understanding of strategies and methodologies that are being followed to maintain Identity Preservation (IP) of various commodities such as basmati rice, soybean etc. followed by an estimation of the cost implications in terms of additional infrastructure, testing, maintenance, human resources, etc. to assess whether the existing IP systems for non GMO commodities can be applied for handling LMOs in India

The contract for documenting the identity preservation steps being followed for basmati rice has been assigned to All India Rice Exporters Association (AIREA). AIREA has already completed the farmer's survey covering approx. 20,000 farmers from 400 villages in four rice growing states of Punjab, Haryana, Delhi and Western Uttar Pradesh during Kharif 2014. Draft report on completion of farm survey has been submitted by AIREA and is under finalization.

The Members of the 7th PMMC also recommended the proposal submitted by Dr. P.K.Ghosh from Ms. Sompradip Publishers and Consultants for preparation of a feasibility study for implementing IP systems for LMOs in India. A formal contracts needs to be signed between Sompradip Publishers and Consultants and Biosafety Project, MoEF&CC

Strengthening of Enforcement Capacity

Being an emerging and scientifically advanced area, capacity building of enforcement personnel such as customs and plant quarantine officers are critical in implementing the requirements under Article 17 and 18 of the Protocol

Article 18 of the CPB requires parties to take measures to take measures for the safe handling, packaging and transportation including appropriate documentation of LMOs that are subject to transboundary movement. Whereas Article 17 calls for measures to prevent unintentional or illegal entry of LMOs.

This component has been divided into two parts namely (i) activities for strengthening the Plant Quarantine and (ii) activities for strengthening the

Customs.

Update on activities for strengthening the Plant Quarantine

In order to understand the existing procedures followed by Customs and Quarantine and the linkages between the two which is essential for assessing the training needs at various levels and for preparation of outreach material; Dr. Ranjini Warrier, Director along with officials from NBPGR has visited the Plant Quarantine Research Station at Rangpuri and the Air Cargo facilities at T3 of the IGI Airport wherein a detailed presentation was made by the Plant Protection and Quarantine (PPQ) officials.

Pursuant to the above field visit, a proposal has been received from NBPGR for training of PPQ officials. The proposal submitted by NBPGR has been reviewed by the Members of the PMMC and approved the same for organizing three training workshops for Plant Quarantine Officers and 4 workshops would be organized for Customs officials in four regional stations.

Technical support for organizing workshops for Customs officials would be provided by NBPGR whereas logistics support would be provided by NACEN. A proposed study tour to University of Murdoch, Australia to be undertaken by Plant Quarantine officials have been approved by PMMC.

The tentative dates for this study tour would be Sep 28, 2015 to Oct 03, 2015. A formal contract needs to be executed between NBPGR and Biosafety Project, MoEF&CC for organizing these training workshops.

THRUST AREA IV: PUBLIC AWARENESS

The activities related to the component on “Information dissemination to promote public awareness’’ involve undertaking development of various outreach material and their dissemination around the country with an objective to improve systems for public education, awareness, participation and access to biosafety information.

The following agencies have been engaged under Phase-II Biosafety Project for undertaking activities related to Public Awareness and the progress is as indicated below:

1. **Asia BioBusiness (ABB) Pte Ltd, Singapore** has been engaged for implementing activities related to risk communication on biosafety i.e., development of a risk communication strategy; preparing syllabus for training, modules for workshops on risk communication for policy makers and experts and providing assistance for organizing a regional workshop.

   A team of experts from ABB Pte Ltd visited India from January 5-9, 2015 for interactions with a range of stakeholder’s *viz.* regulators, policymakers, scientists, communication specialists, legal experts, industry, etc. These meetings were aimed towards:

   - Seeking further clarifications of project objectives
   - Identifying key issues to be considered in developing risk communication strategies
   - Identifying key targets for the risk communication trainings

- Identifying targets for the communication process

In order to meet the above objectives, meetings were organised with various focus groups as well as one to one interactions with individual experts.

Draft Risk Communication Strategy prepared by ABB Pte. Ltd has been communicated to various stakeholders for inputs and suggestions. Comments received from experts have been communicated to ABB Pte. Ltd for incorporation of the same and final Risk Communication strategy and training modules are awaited. It is proposed to organize two workshops at New Delhi and Hyderabad during the month of October 2015.

2. **CAB International (CABI), South Asia, New Delhi** has been engaged to develop primers/brochures./booklets/FAQs and other outreach material in 8 regional languages viz., English, Hindi, Bengali, Marathi, Gujarati, Tamil, Telugu and Oriya. The key deliverables assigned to them are :

- 8 brochures and their translation into 8 regional languages
- 1 primer and its translation into 8 regional languages
- 1 booklet on Frequently asked questions (FAQs) and its translation into 8 regional languages
- 1 glossary of terms and its translation into 8 regional languages
- Short animation (pictorial representation explaining the concepts of biosafety to non-experts) and its translation into 8 regional languages

3. **Indian Institute of Mass Communication (IIMC), New Delhi** has been engaged to organize four national and five regional level media workshops on biosafety, producing programmes for IIMC community radio 'Apna Radio' and broadcasting the same in regional community radios with the focus being on biosafety in agriculture sector an developing a quiz program on biosafety for the journalists.

IIMC has completed the conduct of 5 training workshops and remaining 4 workshops would be completed by August 2015. IIMC has also completed the formulation of quiz questions and this quiz would be aired in APNA Radio program. Interview for telecast in APNA Radio program with Prof. Ashiwini Pareek, JNU and Dr. Vinay Kumar, Digital Green has been completed and would be aired shortly.

4. **Biotech Consortium India Limited (BCIL), New Delhi** has been engaged to prepare a biosafety resource toolkit containing five brochures as indicated below:
   a. Regulatory framework for Genetically Engineered plants in India
   b. Cartagena Protocol on Biosafety: An overview
   c. Confined field trials of Genetically Engineered plants
   d. Frequently asked questions about Genetically Engineered plants
   e. Accessing Information/Databases: Useful resources for safety

	assessment of genetically modified organisms Draft brochures of all the above documents have been completed by BCIL and are under finalization. In addition, booklets for students on basics of biotechnology and biosafety are also under preparation. As a parallel exercise, BCIL is also implementing the following activities: I. Hindi translation of the text of CPB and Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress has been completed for wider circulation. II. A quarterly Biosafety Newsletter is being prepared and circulated to about 10,000 stakeholders on a quarterly basis. Till now 14 issues were published and circulated from July 2011, which provides information on the project activities, developments under the CPB, new publications related to emerging issues and upcoming events related to biosafety and CPB. On another note, a Communication Workshop on Agricultural Biotechnology and Invitational Media Workshop on Communicating Food Science and Agricultural Biotechnology was organized by MoEF&CC in collaboration with International Food Information Council (IFIC) Foundation, USA, IIMC and BCIL organized on November 19 and 20, 2014 respectively. The objective of the workshops was to improve public understanding of science based communications in agricultural biotechnology for the policy makers, members of the regulatory committees, scientists and media practitioners. The workshop on agricultural biotechnology was attended by 67 participants mainly comprising policy makers, members of regulatory committee's viz., Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC) and scientists. The workshop for media personnel was attended by 35 participants mainly comprising of journalists, communication specialists from Department of Biotechnology, Department of Science and Technology and the Department of Communication Research of IIMC. Guidance documents prepared by IFIC Foundation i.e. "Food Biotechnology: A Communicator's Guide to Improving Understanding" and "Improving Public Understanding Guidelines: for Communicating Emerging Science on Nutrition, Food Safety and Health", for journalists, scientists and other communicators were circulated to the participants of the workshop.

Project status FY[9]	The Project activities under various thrust areas have been initiated by identification of appropriate consultants/ agencies after setting up of PCU which was made operational in August 2013. The contract for activities related to RARM has been assigned to CERA-ILSI, Washington, USA through involvement of various national agencies and experts at various stages.

[9] Progress made during current reporting period (one paragraph stating key changes since previous reporting period)

	The contract for undertaking activities related to Socio-economic considerations have been assigned to RIS and six other National Institutions have further collaborated with RIS for effective implementation of activities related to SEC. The Stocktaking assessment activities related to LMO detection under HTPI component has been completed by ScanBi Diagnostics, Sweden. The proposal submitted by Intertek-ScanBi for providing training to Scientists and staff have been approved by PMMC and a formal contract would be signed shortly. Activity related to documenting Identity Preservation (IP) steps being followed for basmati rice in India has been completed by AIREA through a farm survey involving 20000 farmers and the draft report has been received and is under review. The contract for preparing a feasibility study for implementing IP systems in LMOs in India would be awarded to Ms. Sompradip Publishers and Consultants, New Delhi. The proposal submitted by them has been approved by PMMC in its 7th meeting. Activities related to strengthening enforcement capacities (Plant quarantine and Customs) would be assigned to NBPGR and a total of 7 training workshops for Plant Quarantine and Customs officials would be organized jointly by NBPGR and NACEN. Activities related to Public awareness is being implemented through various agencies namely ABB Pte. Ltd, IIMC, CABI and BCIL. The National Steering Committee (NSC) and Project Management and Monitoring Committee (PMMC) have been constituted and are meeting at regular intervals to accord the necessary approvals from time to time.

Planned contribution to strategic priorities/targets[10]	GEF strategic long-term objective: BD3 - Strategic programme for GEF IV: SP 6: Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. The Indian Biosafety 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. The project has 8 components. The 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

[10] For Full Size Projects this information is found in the front page of the project Executive Summary; for Medium-Sized Projects the information appears in the MSP brief cover page.

	this legal instrument.

2. PROJECT OBJECTIVE

State the global environmental objective(s) of the project[11]

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 "Programme Document for GEF Support to Biosafety in GEF 4" approved in April, 2008.

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.

Please provide a narrative of progress made towards meeting the project objective(s). ***Describe any significant environmental or other changes (results) attributable to project implementation.*** *Also, please discuss any major challenges to meet the* ***objectives*** *or specific project* ***outcomes*** *(not more than 300 words)*

As there were some delays in the initiation of the activities due to administrative procedures, several activities have been started in parallel with the involvement of multiple institutions/ agencies. Even though activities related to RARM, SEC and PA were progressing well, there was delay in initiation of activities related to Strengthening Enforcement Capacities. However, the activities related to strengthening enforcement capacities have been initiated after repeated follow ups with various international and national agencies. The activities related to training of plant quarantine officials would be undertaken by NBPGR and trainings for customs officials would be undertaken by NACEN with technical support from NBPGR. It is expected that due to initiation of enforcement activities, the project would be completed in time as per agreed time lines.

Please provide a narrative of progress towards the stated GEF Strategic Priorities and Targets if identified in project document [12]*(not more than 200 words)*

[11] Or immediate project objective

[12] Projects that did not include these in original design are encouraged to the extent possible to retrofit specific targets.

3. RATING PROJECT PERFORMANCE AND RISK

*Based on inputs by the Project Manager, the **UNEP Task Manager**[13] will make an overall assessment and provide ratings of:*
(i) Progress towards achieving the project objective(s)- see section 3.1
(ii) Implementation progress – see section 3.2

Section 3.3 on Risk should be first completed by the Project Manager. The UNEP Task Manager will subsequently enter his/her own ratings in the appropriate column.

3.1 Progress towards achieving the project objective (s)

Project objective and Outcomes	Description of indicator[14]	Baseline level[15]	Mid-term target[16]	End-of-project target	Level at 30 June 2015	Progress rating [17]
Objective[18]:	**Objectives have outcomes which have indicators and its mentioned below**					

[13] For joint projects and where applicable ratings should also be discussed with the Task Manager of co-implementing agency.
[14] Add rows if your project has more that 3 key indicators per objective or outcome.
[15] Depending on selected indicator, quantitative or qualitative baseline levels and targets could be used (see Glossary included as Annex 1).
[16] Many projects did not identify Mid-term targets at the design stage therefore this column should only be filled if relevant.
[17] Use GEF Secretariat required six-point scale system: Highly Satisfactory (HS), Satisfactory (S), Marginally Satisfactory (MS), Marginally Unsatisfactory (MU), Unsatisfactory (U), and Highly Unsatisfactory (HU). See Annex 2 which contains GEF definitions.
[18] Add rows if your project has more than 4 objective-level indicators. Same applies for the number of outcome-level indicators.

Project objective and Outcomes	Description of indicator[14]	Baseline level[15]	Mid-term target[16]	End-of-project target	Level at 30 June 2015	Progress rating [17]
Outcome 1: 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	Stocktaking assessment has been completed through ScanBi Diagnostics. Nine National Institutions were audited for assessing their LMO detection capacities Crops and traits which are under various stages of product development pipeline completed through CERA-ILSI	S

Project objective and Outcomes	Description of indicator[14]	Baseline level[15]	Mid-term target[16]	End-of-project target	Level at 30 June 2015	Progress rating [17]
Outcome 2: Outcome 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	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	Baseline survey on compliance with Article 15, 16 and Annex III of the CPB has been prepared and is under review. Identifying the gaps between existing system and country obligations under Article 8, 10 and 18 (2) of CPB would be assigned to NBPGR. Proposal accepted and contract needs to be signed. Draft ERA guidelines have been prepared through Expert Committee Preparation of biology documents for 6 crops have been completed and 2 are in various stages of consultative process	S

Project objective and Outcomes	Description of indicator[14]	Baseline level[15]	Mid-term target[16]	End-of-project target	Level at 30 June 2015	Progress rating [17]
Outcome 2B.1 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	RIS with support of 6 other institutions have initiated the activities. Model Questionnaires on SE are ready and surveys initiated.	S
Outcome 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	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 basmati rice and soybean	An operational administrative system is in place including a certification and testing mechanism	AIREA has completed the survey with 20000 farmers documenting IP steps followed for basmati rice. Feasibility report would be assigned to Sompradip Publishers & Consultants.	
Outcome 3: 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 needs 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	4 labs identified for strengthening LMO detection facilities. Training of 20 staff in India and 8 in Sweden on LMO detection with support of Intertek-ScanBi Diagnostics	

Project objective and Outcomes	Description of indicator[14]	Baseline level[15]	Mid-term target[16]	End-of-project target	Level at 30 June 2015	Progress rating [17]
Outcome 4: **Outcome 4.1** 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 environment risk evaluation and management in place	20 scientists will be trained	8 scientists/ regulators went for training in OGTR, Australia. 50 scientists were trained on management of field trails in two workshops held at New Delhi and Hyderabad	
Outcome 4.2 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 transboundary movement procedure	Training programs initiated through NBPGR and NACEN. 45 Plant Quarantine & 120 Customs officials will be trained through 7 training workshops by end of 2016	S

Outcome 5:[19] 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	*Draft Risk communication strategy prepared and circulated for comments and suggestions. *IIMC has organized 5 awareness (150 people) workshops for Media persons. *Two workshops for Media and Agriculture scientists organized for Communicating Science by MoEFCC, IFIC, IIMC & BCIL. *Two training workshops for Scientists & regulators on Management & Monitoring of CFTs organized *Outreach materials such as brochures on CFTs and information sources, regulatory requirements, FAQs, Cartagena Protocol etc. prepared by BCIL is under review. *Quarterly Biosafety Newsletter is being circulated to more than 10000 stakeholders regularly	

Overall rating of project progress towards meeting project objective(s) (*To be provided by UNEP GEF Task Manager. Please add columns to reflect all prior year ratings*)

FY2014 rating	FY2015 rating	Comments/narrative justifying the current FY rating and explaining reasons for change (positive or negative) since previous reporting periods
S	S	Several activities have been initiated in parallel to bridge the time gap lost due to delays in approval. The progress of the project is very satisfactory in all the four thrust areas and also in full compliance with reporting requirements in ANUBIS also as per UNEP requirements.

Action plan to address MS, MU, U and HU rating *(To be completed by UNEP GEF Task Manager in consultation with Project Manager)*

Action(s) to be taken	By whom?	By when?

This section should be completed if project progress towards meeting **objectives** was rated MS, MU, U or HU during the previous Project Implementation Review (PIR) or by the Mid-term Review/Evaluation (*To be completed by Project Manager*).

Problem(s) identified in previous PIR	Action(s) taken	By whom	When

[19] Add rows if your project has more than 5 Outcomes.

3.2 Project implementation progress

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
Output 1.1.1: Baseline information to evaluate potential changes in the environment due to introduction of LMOs is compiled and updated					
Activity 1: Preparation of a base paper covering review of crops and traits under development, need for biology documents, information on non-target and beneficiary organisms in different agro ecological zones and status of available guidelines	30/04/2014	80%	100%		S
Output 1.1.2: Existing documentation is reviewed for compliance between the information needed under the prevailing regulatory system and the CPB.					
Activity2: Review of existing documents and identification of gaps with respect to country obligations under Articles 8, 10 and 18 (2) of CPB.	31/4/2015	Yet to be initiated	20%	Activity assigned to NBPGR and will completed by March 2015	
Output 1.1.3:A survey is conducted to identify the public institutions, facilities and laboratories to be up-graded to be national referral laboratory					
Activity 3: Preparation of a base paper on status of facilities, infrastructure, human resource, level	31/5/2014	100%	100%		

[20] Outputs and activities as described in the project logframe or in any updated project revision.
[21] As per latest workplan (latest project revision)
[22] Variance refers to the difference between the expected and actual progress at the time of reporting.
[23] To be provided by the UNEP Task Manager

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
of expertise in selected institutions					
Activity 4: Identification of requirements for operationalizing a state of the art referral lab for the detection of LMOs	30/6/2014	100%	100%		
Output 1.1.4: An assessment is carried out on the long term funding needed from GoI					S
Activity 5: Assessment of long term funding requirements to sustain the national referral laboratory and its associated network of laboratories	31/7/2014	80%	90%		
Output 1.1.5: National consultation with all stakeholders and partners is carried to discuss results from needs assessment studies					
Activity 6: Consultative meetings on final project design based on results of stocktaking assessment	01/6/2014	70%	100%		S
Output: 2A.1.1: Existing RA and RM procedure and guidelines are reviewed to confirm whether India is compliant with CPB obligations					
Activity 7: Preparation of a base paper on the status of conformity of existing procedures and guidelines with Article 15, 16 and Annex III of CPB	30/4/2014	80%	90%	Base paper to be finalized after consultative meeting	
Output: 2A.1.2: Crop-specific biology and ecology document is developed to assist dossier preparation					
Activity 8: Preparation and review of biology documents for eight crops such as mustard,	30/10/2015	60%	80%	7 biology documents ready for printing	

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
pigeonpea, chickpea, tomato, papaya, potato, rubber and sorghum.					
Output: 2A.1.3: Baseline data on presence of wild relatives is gathered for better risk management of LMOs.					
Activity 9: Collection of baseline data on the presence of wild relatives of eight crops such as mustard, pigeonpea, chickpea, tomato, papaya, potato, rubber and sorghum.	31/07/2015	60%	90%	Information covered under biology documents	
Output: 2A.1.4: Guidelines and procedures are developed for specific types of risk associated with specific traits.					
Activity 10: Preparation of a risk analysis framework and its validation using an example	30/10/15	Yet to be Initiated	60%	RAF under preparation	S
Activity 11: Review of international practices in ERA through a study tour and development of ERA guidelines	31/10/2015	20%	100%		
Activity 12: Development of procedures for assessing risks associated with stacking of genes expressing multiple traits	31/10/15	Yet to be Initiated	30%		
Output: 2A.1.5: LMOs are monitored by regulatory agencies after environmental release					
Activity 13: Review of international practices for post release monitoring, development of guidance document and identification of roles and responsibilities of various agencies for post release monitoring	31/10/15	Yet to be Initiated	30%		
Output: 2A.1.6: Indicators to measure gene flow and impact on non-targets are developed to assist					

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
in RA and RM					
Activity 14: Workshop for identification and development of indicators for impact on non target organisms	31/7/15	Yet to be Initiated	30%	Questionnaires ready	S
Activity 15: Listing of non target organisms with reference to specific traits/crops in different agro-ecological zones	31/7/15	Yet to be Initiated	30%		
Output: 2B.1.1 Questionnaire is developed for conducting a socio-economic survey					
Activity 16: Design model questionnaires for socio economic assessment and their validation of the questionnaire through sample survey	31/10/15	Yet to be Initiated	80%		
Output: 2B.1.2 Guidelines and methodologies are developed for socio-economic assessment of GM crops apart from Bt cotton					
Activity 17: Drafting guidelines, tools and methodologies for SE assessment through a network of experts from various institutes and consultation with experts and relevant stakeholders for finalizing the guidance document with respect to both ex-ante and ex-post studies	31/10/2015	Yet to be initiated	20%		S
Output: 2B.1.3 Guidelines are developed for risk benefit analysis					
Activity 18: Drafting guidelines and methodologies for cost benefit analysis through a network of experts from various institutes and consultation with experts and relevant stakeholders for finalizing the document	31/10/2015	Yet to be initiated	20%		S

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
Output: 2C.1.1 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					
Activity 19: Document the steps involved in the identity preservation system for export commodities such as basmati rice	31/7/15	30%	90%		HS
Activity 20: Preparation of a feasibility study of implementing such an IP system for handling LMOs in India.	31/01/16	30%	40%		
Output: 2C.1.2 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					
Activity 21: Review strategies for sampling, detection, quantification and certification of LMOs from selected importing/exporting countries.	31/10/15	Yet to be Initiated	20%		S
Activity 22: Preparation of report on suitable options for India and designation of institutions responsible for certification and testing	30/4/15	Yet to be initiated	20%		
Output: 3.1.1 A feasibility study is carried out on public private partnership (PPP) for LMO detection					
Activity 23: Carry out a feasibility study on LMO detection for developing a network of laboratories.	31/10/14	80%	100%		
Output: 3.1.2 Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMO in agriculture					

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
Activity 24: Establishing a referral laboratory with a network of LMO detection laboratories	31/1/16	Yet to be initiated	80%		S
Activity 25: Improving infrastructure and facilities for LMO detection in the identified laboratories	31/1/16	Yet to be initiated	60%		
Activity 26: Accreditation of laboratories as per the international norms	30/4/16	Yet to be initiated	30%		
Output: 3.1.3 Methodology and procedures are developed for LMO detection					
Activity 27: Development of sampling procedures and methodologies for LMO detection	31/1/16	Yet to be initiated	30%		S
Activity 28: Development of SOPs and protocols for participating laboratories and relevant agencies such as customs and plant quarantine	31/1/16	Yet to be initiated	30%		
Output: 3.1.4: Staff, irrespective of gender, is trained for LMO detection and maintenance of laboratory					
Activity 29: Training of laboratory technicians in LMO detection	31/1/16	Yet to be initiated	30%		S
Activity 30: Training of laboratory staff for maintenance of laboratory equipment	31/1/16	Yet to be initiated	30%		
Output: 4.1.1 Training modules/manuals are prepared for conducting/ evaluating risk assessment and management					
Activity 31: Prepare training modules/manuals for conducting environmental risk assessment and risk management	31/1/16	Yet to be initiated	70%		S
Activity 32: Training of experts in RA & RM involved in technical and scientific advisory	31/1/16	Yet to be initiated	20%		

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
committees and biotech R&D developers					
Activity 33: Training in preparation of guidance documents for dossier development	31/1/16	Yet to be initiated	20%		
Output: 4.1.2 Training modules / manuals are prepared for monitoring field trials of GM crops and compliance evaluation					
Activity 34: Preparation of training modules for monitoring field trials and compliance evaluation	31/7/15	Yet to be Initiated	100%		HS
Activity 35: Training of members of monitoring teams responsible for compliance evaluation, technical persons conducting field trials and extension functionaries	31/10/15	Yet to be Initiated	100%		
Output: 4.2.1: Training modules/manuals are prepared for training of custom and plant quarantine officials for enhanced enforcement at the ports of entry					
Activity 36: Preparation of training modules and working knowledge documents for enhanced enforcement at points of entry	31/10/15	Yet to be Initiated	10%		S
Activity 37: Training of customs officials on verification of documentation requirements for transboundary movement and use of BCH	31/1/16	Yet to be Initiated	10%		S
Activity 38: Training of quarantine officers for on-site verification of LMOs and use of BCH	31/1/16	Yet to be Initiated	10%		
Activity 39: Development of an online technical backstopping mechanism or system for enforcement officers at points of entry	31/1/16	Yet to be Initiated	10%		

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
Activity 40: Hands on workshops for enforcement officers at regional and sub-regional levels (also as part of regional cooperation under component VI.3)	31/1/16	Yet to be Initiated	10%		
SOutput: 5.1.1: Innovative outreach programs are developed for risk communication both through print and electronic media					
Activity 41: Development of a risk communication strategy for various stakeholders	31/1/16	Yet to be Initiated	50%		S
Activity 42: Development of a training module and training workshops in risk communication for key policy makers and experts	31/1/16	Yet to be Initiated	20%		
Activity 43: Development and dissemination of outreach programmes to implement the risk communication strategy through print and electronic media	31/1/16	Yet to be Initiated	20%		
Output: 5.1.2: Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies					
Activity 44: Preparation of audio visual educational material on awareness of biotechnology and biosafety issues for teachers and students	31/1/16	Yet to be Initiated	50%		
Activity 45: Organize awareness workshops on biosafety for the media	31/1/16	Yet to be Initiated	60%		
Activity 46: Organization of a quiz programme for school children	31/1/16	Yet to be Initiated	50%		
Output 5.1.3: Primers/ brochures/ booklets /FAQs					

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc.					
Activity 47: Development of primers/brochures/booklets/FAQs, glossary of terms and other outreach material in regional languages	31/12/15	Yet to be Initiated	60%		
Output 5.1.4: A mechanism is established to communicate regulatory decisions on LMOs to the public.					
Activity 48: Upgrading the National Biosafety websites	30/4/16	80%	85%		S
Activity 49: Timely deposition of regulatory decisions on LMOs in the BCH	30/4/16	90%	90%		
Output 5.1.5: Biosafety newsletters are published regularly and distributed					
Activity 50: Appointment of the newsletter editorial board	31/12/12	100%	100%		HS
Activity 51: Publication and distribution of biosafety newsletter on a quarterly basis	30/4/16	100%	100%		
Output 5.1.6: National, regional and international workshops are organized for targeted audience					
Activity 52: Organization of national workshops for key stakeholders for implementation of public awareness strategy	31/10/15	Yet to be Initiated	30%		S
Activity 53: Organizing an international workshop on sharing experience in risk communication and awareness raising	31/10/15	Yet to be Initiated	Yet to be Initiated		
Output 6.1.1: Project Management					

Outputs [20]	Expected completion date [21]	Implement-ation status as of 30 June 2014 (%)	Implement-ation status as of 30 June 2015 (%)	Comments if variance[22]. Describe any problems in delivering outputs	Progress rating[23]
Activity 54: Establishment of a Project Coordinating and Monitoring Unit	31/10/13	100%	100%		S
Output 7.1.1: Project Monitoring And Evaluation					
Activity 55: Project Monitoring and Evaluation at Mid-term and project termination	31/12/16	20%	50%		S
Output 8.1.1: Regional Networking And Cooperation					
Activity 56: Participation in the Annual Meetings of National Project Coordinators under the implementation projects and other regional activities to facilitate sharing of information	31/1/16	100%	100%		S

Overall project implementation progress [24] *(To be completed by UNEP GEF Task Manager. Please add columns to reflect prior years' ratings):*

FY14 rating	FY15 rating	Comments/narrative justifying the rating for this FY and any changes (positive or negative) in the rating since the previous reporting period
S	HS	The project executing has seen a good delivery of results which can be replicated across the region. In addition as per the guidance of UNEP to execute components in parallel has led to increase in delivery of results

Action plan to address MS, MU, U and HU rating. *(To be completed by UNEP Task Manager in consultation with Project Manager[25])*

Action(s) to be taken	By whom?	By when?

[24] Use GEF Secretariat required six-point scale system: Highly Satisfactory (HS), Satisfactory (S), Marginally Satisfactory (MS), Marginally Unsatisfactory (MU), Unsatisfactory (U), and Highly Unsatisfactory (HU)
[25] UNEP Fund Management Officer should also be consulted as appropriate.

Action(s) to be taken	By whom?	By when?

This section should be completed if project **progress** was rated MS, MU, U or HU during the previous Project Implementation Review (PIR) or by the Mid-term Review/Evaluation (*To be completed by Project Manager*).

Problem(s) identified in previous PIR	Action(s) taken	By whom	When

3.3. Risk

*There are two tables to assess and address risk: the first "risk factor table" to describe and rate risk factors; the second "top risk mitigation plan" should indicate what measures/action will be taken with respect to risks rated **Substantial** or **High** and who is responsible to for it.*

RISK FACTOR TABLE
***Project Managers** will use this table to summarize risks identified in the **Project Document** and reflect also **any new risks** identified in the course of project implementation. The Notes column should be used to provide additional details concerning manifestation of the risk in your specific project, **as relevant**. The "Notes" column has one section for the Project Manager (**PM**) and one for the UNEP Task Manager (**TM**). If the generic risk factors and indicators in the table are not relevant to the project rows should be added. The **UNEP Task Manager** should provide ratings in the right hand column reflecting his/her own assessment of project risks.*

				Project Manager Rating						**Notes**	**Task Manager Rating**					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
Management structure	Stable with roles and responsibilities clearly defined and understood	Individuals understand their own role but are unsure of responsibilities of others	Unclear responsibilities or overlapping functions which lead to management problems	√						PM : TM:	X					
Governance structure	Steering Committee and/or other	Body(ies) meets periodically	Members lack commitment Committee/bo	√						PM :	X					

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
	project bodies meet periodically and provide effective direction/inputs	but guidance/input provided to project is inadequate. TOR unclear	dy does not fulfil its TOR							TM:						
Internal com-munications	Fluid and cordial	Communication process deficient although relationships between team members are good	Lack of adequate communication between team members leading to deterioration of relationships and resentment	√						PM: TM:	X					
Work flow	Project progressing	Some changes in	Major delays or changes in	√						PM:	X					

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
	according to work plan	project work plan but without major effect on overall timetable	work plan or method of implementation							TM:						
Co-financing	Co-financing is secured and payments are received on time	Is secured but payments are slow and bureaucratic	A substantial part of pledged co-financing may not materialize	√						PM: TM: The project has leveraged substantial cofinance	X					
Budget	Activities are progressing within planned budget	Minor budget reallocation needed	Reallocation between budget lines exceeding 30% of original budget	√						PM: TM:	X					
Financial manageme	Funds are correctly	Financial reporting slow	Serious financial	√						PM:	X					

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
nt	managed and transparently accounted for	or deficient	reporting problems or indication of mismanagement of funds							TM:						
Reporting	Substantive reports are presented in a timely manner and are complete and accurate with a good analysis of project progress and implementation issues	Reports are complete and accurate but often delayed or lack critical analysis of progress and implementation issues	Serious concerns about quality and timeliness of project reporting	√						PM: TM:	X					
Stakeholder involvement	Stakeholder analysis done and positive	Consultation and participation	Symptoms of conflict with critical	√						PM:	X					

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
	feedback from critical stakeholders and partners	process seems strong but misses some groups or relevant partners	stakeholders or evidence of apathy and lack of interest from partners or other stakeholders							TM: Project through the planned interventions has seen several stakeholders join and assist in execution from government agencies, para statals, private sector, universities/research institutions in country and international						
External com-munications	Evidence that stakeholders, practitioners and/or the general public understand project and are regularly updated on progress	Communicati ons efforts are taking place but not yet evidence that message is successfully transmitted	Project existence is not known beyond implementatio n partners or misunderstan dings concerning objectives and activities evident	√						PM: TM:	X					

Risk Factor	Indicator of Low Risk	Indicator of Medium Risk	Indicator of High Risk	Project Manager Rating						Notes	Task Manager Rating					
				Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
Short term/long term balance	Project is addressing short term needs and achieving results with a long term perspective, particularly sustainability and replicability	Project is interested in the short term with little understanding of or interest in the long term	Longer term issues are deliberately ignored or neglected	√						PM: TM:	X					
Science and technological issues	Project based on sound science and well established technologies	Project testing approaches, methods or technologies but based on sound analysis of options and risks	Many scientific and /or technological uncertainties	√						PM: TM: Project is developing useful scientific tools and guidelines which will impact positively on biosafety practice not only in India but across the region	X					

Risk Factor	Indicator of Low Risk	Indicator of Medium Risk	Indicator of High Risk	Project Manager Rating						Notes	Task Manager Rating					
				Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
INTERNAL RISK																
Project management																
Political influences	Project decisions and choices are not particularly politically driven	Signs that some project decisions are politically motivated	Project is subject to a variety of political influences that may jeopardize project objectives	√						PM: TM:	X					
Other, please specify. Add rows as necessary										PM: TM:						

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
EXTERNAL RISK																
Project context																
Political stability	Political context is stable and safe	Political context is unstable but predictable and not a threat to project implementation	Very disruptive and volatile	√						PM: TM:	X					
Environmental conditions	Project area is not affected by severe weather events or major environmental stress factors	Project area is subject to more or less predictable disasters or changes	Project area has very harsh environmental conditions	√						PM: TM:	X					
Social, cultural and economic	There are no evident social,	Social or economic issues or	Project is highly sensitive to	√						PM:	X					

				Project Manager Rating						Notes	Task Manager Rating					
Risk Factor	**Indicator of Low Risk**	**Indicator of Medium Risk**	**Indicator of High Risk**	Low	Medium	Substantial	High	Not Applicable	To be determined		Low	Medium	Substantial	High	Not Applicable	To be determined
EXTERNAL RISK																
Project context																
factors	cultural and/or economic issues that may affect project performance and results	changes pose challenges to project implementation but mitigation strategies have been developed	economic fluctuations, to social issues or cultural barriers							TM:						
Capacity issues	Sound technical and managerial capacity of institutions and other project partners	Weaknesses exist but have been identified and actions is taken to build the necessary capacity	Capacity is very low at all levels and partners require constant support and technical assistance	√						PM: TM:						
Others, please specify																

If there is a significant (over 50% of risk factors) discrepancy between Project Manager and Task Manager rating, an explanation by the Task Manager should be provided below

TOP RISK MITIGATION PLAN
Rank – importance of risk Risk Statement – potential problem (condition and consequence) Action to take – action planned/taken to handle the risk Who – person(s) responsible for the action Date – date by which action needs to be or was completed

Rank	**Risk Statement[26]**		**Action to Take**	**Who**	**Date**
	Condition	**Consequence**			

Project overall risk rating (Low, Medium, Substantial or High) (*Please include PIR risk ratings for all prior periods, add columns as necessary*):

FY14 rating	**FY15 rating**	**Comments/narrative justifying the current FY rating and any changes (positive or negative) in the rating since the previous reporting period**
Low	Low	The project delivery is on course with a mechanism in place to identify and manage any potential project delivery risk. The focus on expertise for diverse source has also helped in a balanced delivery of results

[26] Only for Substantial to High risk.

If a risk mitigation plan had been presented for a previous period or as a result of the Mid-Term Review/Evaluation please report on progress or results of its implementation

4. RATING MONITORING AND EVALUATION

*Based on the answers provided to the questions in 4.1, 4.2 and 4.3 below, the **UNEP Task Manager** will provide ratings for the following aspects of project monitoring and evaluation:*

*(i) Overall **quality** of the Monitoring & Evaluation plan*
*(ii) Performance in the **implementation** of the M&E plan*

4.1. Does the project M&E plan contain the following:

- Baseline information for each outcome-level indicator — Yes √□ No □
- SMART indicators to track project outcomes — Yes √□ No □
- A clear distribution of responsibilities for monitoring project progress. — Yes √□ No □

4.2. Has the project budgeted for the following M&E activities:

- Mid-term review/evaluation — Yes √□ No □
- Terminal evaluation — Yes√ □ No □
- Any costs associated with collecting and analysing indicators' related information — Yes√ □ No □

Please rate the **quality** of the project M&E plan (use HS, S, MS, MU, U, HU):

4.3 Has the project:

- Utilized the indicators identified in the M&E plan to track progress in meeting the project objectives; — Yes√ □ No □
- Fulfilled the specified reporting requirements (financial, including on co-financing and auditing, and substantive reports) — Yes√ □ No □
- Completed any scheduled MTR or MTE before or at project implementation mid-point; — Yes □ No√ □ MTR planned
- Applied adaptive management in response to M&E activities — Yes □ No√ □
- Implemented any existing risk mitigation plan (see previous section) — Yes □ No √□

Please rate the performance in **implementing** the M&E plan (use HS, S, MS, MU, U, HU): S

4.4. Please describe activities for monitoring and evaluation carried out during the reporting period[27]

A Project Management and Monitoring Committee (PMMC) has been constituted to oversee the progress of the project on a regular interval and this PMMC has meet 3 times and National Steering Committee has met once during the period from July 2014 to June 2015. Minutes of the PMMC and NSC meetings are uploaded in ANUBIS.

A. Fifth PMMC meeting was held on September 14, 2014
B. Sixth PMMC meeting was held on March 16, 2015
C. Seventh PMMC meeting was held on June 23, 2015
D. Third meeting of the National Steering Committee was held on March 16, 2015
E. The team from Phase-II biosafety project had also participated in the Cartagena Protocol COP-MOP 7 and made a poster presentation titled" Publications as tools for strengthening biosafety capacities in India" held from September 29, 2014 to October 3, 2014 at Pyeongchang, Korea.

4.5. Provide information on the quality of baseline information and any effects (positive or negative) on the selection of indicators and the design of other project monitoring activities

The baseline information in most of the project activities is as expected and accordingly so far no effect has been observed on selected indicators and design of activities.

4.6. Provide comments on the usefulness and relevance of selected indicators and experiences in the application of the same.

So far, the selected indicators have been useful and relevant.

4.7. Describe any challenges in obtaining data relevant to the selected indicators; has the project experienced problems to cover costs associated with the tracking of indicators?

Identification of international agencies/ experts for activities related to HTPI component particularly strengthening enforcement capacities was a major challenge. As of now due to rigorous and continuous follow up with several international and national agencies was able to streamline the activities. NBPGR, NACEN and University of Murdoch have been identified as potential partners for undertaking this activity.

[27] Do not include routine project reporting. Examples of M&E activities include stakeholder surveys, field surveys, steering committee meetings to assess project progress, peer review of documentation to ensure quality, etc.

4.8. Describe any changes in the indicators or in the project intervention logic, including an explanation of whether key assumptions[28] are still valid

No changes in the indicators or project intervention logic; key assumptions are still valid.

4.9. Describe how potential social or environmental negative effects are monitored

So far no major negative effects have been observed, PMMC is responsible for overall monitoring

4.10. Please provide any other experiences or lessons relevant to the design and implementation of project monitoring and evaluation plans.

As the project design was prepared in a consultative manner with involvement of stakeholders, the implementation is also taking place in line with project design. So it is important to engage stakeholder right from the beginning of project formulation.

5. PROJECT IMPLEMENTATION EXPERIENCES AND LESSONS

5.1. Please summarize any experiences and/or lessons related to project design. Please select relevant areas from the list below:

- Conditions necessary to achieve global environmental benefits such as (i) institutional, social and financial sustainability; (ii) country ownership; and (iii) stakeholder involvement, including gender issues.
- Institutional arrangements, including project governance;
- Engagement of the private sector;
- Capacity building;
- Scientific and technological issues;
  The broad involvement of area specific expertise in LMO Detection, development of biology documents and Socio economics among others has lead to high quality focus in highlighting and developing science based technological tools

- Interpretation and application of GEF guidelines;
- Factors that improve likelihood of outcome sustainability;
- Factors that encourage replication, including outreach and communications strategies;

[28] Assumptions refer to elements of the "theory of change" or "intervention logic" (*i.e, the problem is a result of A, therefore, if we change B, this will lead to C*) and not to pre-conditions for project implementation. It is a common mistake to include statements such as "political will" as an assumption. This is rather a necessary condition to implement the project.

A strong focus on risk communication coupled with the development of communication strategies will provide a useful platform for replication

- Financial management and co-financing.

5.2. Please highlight a few major achievements resulting so far from the project implementation, including but not limited to:

- Concrete results, both on-the-ground and normative
  Several concrete results on ERA, Biology Documents, LMO Detection, Communication tools have been developed supported by audio visuals and this will go a long way in entrenching the biosafety system to support biotechnology development and decision making in India

- Gender and indigenous peoples issues
- Private Sector
- Sustainability
- Innovation
- Upscaling

BEST PRACTICES IN MANAGING A CAPACITY BUILDING PROJECT ON BIOSAFETY:

A CASE OF THE INDIA BIOSAFETY CAPACITY BUILDING PROJECT — PHASE II

UN environment
United Nations Environment Programme

gef

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FORWARD

DISCLAIMER

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ACKNOWLEDGMENTS

ABBREVIATIONS

AS	Additional Secretary
BCIL	Biotech Consortium India Limited
CBD	Convention on Biological Diversity
CCA	Common Country Assessment
CPB	Cartagena Protocol on Biosafety
CSIR	Council for Scientific and Industrial Research
DBT	Department of Biotechnology
DST	Department of Science and Technology
EPA	Environment Protection Act
FSSAI	Food Safety and Standards Authority of India
GEAC	Genetic Engineering Appraisal Committee
GEF	Global Environment Facility
GOI	Government of India
ICAR	Indian Council of Agricultural Research
LMOs	Living Modified Organisms
MoA	Ministry of Agriculture
MOEF&CCCC	The Ministry of Environment, Forests and Climate Change
NBA	National Biodiversity Authority
NBAP	National Biodiversity Action Plan
NBPGR	National Bureau of Plant Genetic Resources
NEA	National Executing Agency
PCU	Project Coordination Unit
PL3 and PL4	Protection Level 3 and Protection Level 4
R&D	Research and Development
ToR	Terms of Reference
UNDAF	United Nations Development Assistance Framework
UNEP	United Nations Environment Programme
WB	World Bank

EXECUTIVE SUMMARY

Extensive efforts have been made towards capacity building within the country to address biosafety issues. The Ministry of Environment, Forest and Climate Change (MoEF&CC), Department of Biotechnology (DBT) and Ministry of Agriculture (MoA) have organized several workshops for creating awareness on biosafety and regulatory requirements related to use of LMOs across the country.

With the support of World Bank/GEF, a demonstration project to enhance national capacity for implementing the National Biosafety Framework (NBF) related to the transboundary movement of LMOs was completed in June 2007 as part of the 12 National GEF Supported Biosafety Projects implemented by UNEP (8 countries), UNDP (2 countries) and World Bank (2 Countries). The learning gained from this project highlighted the urgent need to intensify capacity building initiatives on priority areas through a focused program anchored on a mixed approach of Federal and specific state level interventions. The focus should be continuous sharing of best practices in biosafety regulation, which keeps evolving, to ensure effective implementation of the CPB.

It is in this context that MoEF&CC developed the GEF Phase II project on capacity building on biosafety. This project aimed at assisting India to fully implement her obligations as Party to the CPB related to the transboundary movement of LMOs with a specific focus on AgriBiotechnology. 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.

The purpose of the assessment is to examine the performance of the Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India – Phase II project since the beginning of its implementation and develop a Best Practices Report.

The Assessment includes:

- Reviewing the progress to date on project implementation, measured against planned outputs in the project document in accordance with the rational budget allocation
- Evaluating the processes involved in achieving the outputs
- Understanding the underlying causes/issues contributing to lack of or under achievement of targets
- Identifying and recommending Best Practices to facilitate the implementation of the Indian Biosafety System

Immediate and development objectives of the project

The overarching goal of this project was 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

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 as pertains to the management of Agricultural Biotechnology and to ensure that adequate protection of human health and biodiversity from potential risks arising from all LMO-related activities. The project seeks to build 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.

Overview of the project components

A LOOK INTO THE IMPLEMENTATION APPROACH, ITS CHALLENGES, ADVANTAGES AND RESULTS

Component	Implementation Approach	Results	Advantages	Disadvantages
Project Management	Design Location of Project Collaboration/ Partnership Development Plan of the Country Communicating Information Managing Project changes Monitoring and Reporting on Project Performance UNEP Supervision and Backstopping	Procurement plan for goods and services in place Up to date progress reports Up to date audited reports for expenditure Yearly inventory of non expendable equipment Up to date project implementation reports Up to date minutes of steering committee meetings	The leadership right from the high office of the Additional Secretary as Project Director and the National Focal Point for the Cartagena Protocol on Biosafety as National Project Coordinator; The two are also Chair and Member/Secretary of the Genetic Engineering Approval Committee (this ensured linkages and uptake by the mandated Agency for handling Biosafety issues) The ownership and Commitment by the Government in the Co-financing; The collaboration and creation of a mix between national and international experts Public-Private partnership built through the use of BCIL as a facilitating agency of the Ministry guided by its institutional memory from the earlier World Bank-GEF Project BCIL (the Faclilitating Agency) has been actively engaged ministries/departments in biosafety activities through implementation of various national projects The technical backstopping by UNEP including peer reviews and guidance The availability of ANUBIS as a project management tool to ensure systematic reporting and management of data	The delay in starting the project due to delay in release of the funds due to the institutional set up of the project and procurement of the facilitating agency. This issue was raised by the Government of India as the start of signing of legal agreements.

Component	Implementation Approach	Results	Advantages	Disadvantages
Risk Assessment and Risk Management	Preparation of Biology Documents Training Programs E-Module	Crop- Specific Biology to assist dossier preparation Baseline data on presence of wild relatives Guidelines and procedures for specific types of risks associated with specific traits A Base paper titled "Genetically Engineered Plants in the Product Development Pipeline in India: Results from a Survey" prepared and published. See http://www.tandfonline.com/doi/pdf/10.1080/21645698.2016.1156826#.VynHC4RcSko	Thorough interactions with the concerned institutions Working through an institution with crop specific mandate and expertise, rather than through an individual consultant, enabled the ownership of the work. Over 200 scientists were involved in the development of the Eight Biology document. Capacity building of the persons and institutions involved. Working with different experts as well as the OECD builds the capacity of the scientists and each scientist was able to learn something new from the other. Consensus among scientists and institutions as they all responded or gave their input to the Biology Documents Supportive approach of international and national consultants to verify and validate quality More than thirty plus crops are under various stages of product development	Brain drain – many of the trained personnel move to other areas or jobs. Delays in approvals on use of GMOs has slowed down research and development activities in India.

Component	Implementation Approach	Results	Advantages	Disadvantages
Institutional Capacity Development for Handling, Packaging and Identification	From Unknown to Known-Feasibility Study Collaboration in Research Building on Existing Institutions and capacities Use of Modern Technology	Feasibility Study on measures to be taken for putting in place an Identity Preservation System for Handling LMOs Network of Laboratories for detection of LMOs across five regions in India For Laboratories have been notified as National Reference Laboratories under the project Infrastructure and equipment for detection and verification of LMOs in Key laboratory across five regions in India Staff of various labs across five regions in India trained on LMO detection and maintenance of laboratory	Feasibility Studies on Identity Preservation will give the needed data to support systems for handling of LMOs The setting up of Network of Laboratories for Detection with notification to give legal status will support continuous institutional capacity building on LMO Handling. The choice of Laboratories with mandates for testing will ensure its uptake beyond the project supported by the notification The dedicated infrastructure and training on LMO detection is a key to supporting testing of LMOs in India Standard Operating Procedures for Handling of HTPI to assist the work of the GEAC (See http://www.geacindia.gov.in/applications.aspx) includes formats for handling applications for confined field trials, import and export, import of LMOs as food, feed and for processing, for approval of transgenic plants and LMO pharmaceuticals, veterinary drugs, environmental approval of clinical trials and hazardous microorganisms Online system for handling applications (see http://www.geacindia.gov.in/applications.aspx) Procedures for handling confined field trials (Tools for Trainers) E-modules and E-Tools (yet to be finalized) SOPs for LMO Detection has been developed as a follow up to the training in Sweden Standard Operating Procedures for Confined Field Trials of Genetically Engineered Plants (2008) developed earlier	1. The Labs, especially in the NBPGR have two full time senior scientists with support from permanent technical staff. The staff situation will need more dedicated staff as some of the assistants in the lab are part time students on very short contracts. 2. Lack of funding to hire/ contract Lab assistants. The NBPGR has hired the lab assistants on contract. Once their contracts run out they will have to exit because NBPGR had not set aside funds to sustain their salaries.

Component	Implementation Approach	Results	Advantages	Disadvantages
Socio-Economic Considerations	Collaboration with a world renown think tank on socioeconomic issues Using an interdisciplinary team	• Questionnaire for conducting a socio-economic survey • Developing and validating questionnaires, conducting baseline surveys, organizing workshops and meetings for development of guidelines and methodologies • Guidance document made by the RIS team within first four months from the commencement of the project. Capturing the existing studies on socio-economic assessment of certain crops based on extensive literature review and analysis of available ex-ante and ex-post studies undertaken by various institutions and researchers across the crops and regions in India. • Data collected for different crops and different traits having a common questionnaire (namely brinjal and maize; Bt Cotton and Aerobic Paddy; pigeon pea and black gram) thus ensuring that essential information that is relevant for understanding SE impacts is collected for the identified crops and traits. On the basis of the questionnaires, a common set of variables and parameters was prepared prepared. • Resource document on Socio-Economic Considerations of LMOs. • Booklet on Resource document on Socio-Economic Considerations of LMOs	The broad based stakeholder consultative meetings with experts in interdisciplinary teams helped harness the vast experience and knowledge base to assist in developing the needed resource document. Approach was designed guided by the resources available The scoping approach in a consultative manner help in setting the parameters to consider in identifying socio economic issues The task has provided the needed tools to support decision making which takes into consideration risk assessment and socio economics using science based assessment approaches	The informal meetings with the experts in the interdisciplinary team were not easy to arrange or get all of them together in one meeting. This is because the country is vast and many are traversing the country working on other projects or issues. It was not easy to identify how much data was required- who to be interviewed, what information to choose. The institutions involved therefore sat and agreed on the major issues to focus on, the crops, traits and the field area that would be used to identify the socioeconomic issues. Deciding on what the socioeconomic considerations was also a difficult task. This required extensive literature survey including survey from other countries and interaction with experts globally. It is not easy to quantify some of the agreed upon parameters such as gender, culture, indigenous communities. This therefore made the debate more difficult. The scientists are yet to appreciate that risk assessment and socioeconomic issues go hand in hand in decision-making

Source - Ministry of Environment & Forests, Government of India

Component	Implementation Approach	Results	Advantages	Disadvantages
Information Dissemination for Enhancing Public Awareness	Development of a risk communication strategy Use of print and electronic media for information dissemination Translation of public awareness material into local language Preparation of audio visual material on awareness of biotechnology and biosafety issues for teachers and students Use of culture in creating and disseminating the awareness material	Innovative outreach programs for risk communication both through print and electronic media Educational programs on biosafety issues for TV and radio developed in collaboration with local and national lead agencies Primers/brochures/booklets/FAQs/Glossary of Terms in different local languages widely distributed to policy makers, researchers, students, farmers, civil society Regular publication and distribution of Biosafety newsletters Translated documents in 8 Key languages to support outreach National, regional and international workshops	Stakeholders with expertise and mandates were involved in the development of outreach materials including CABI, the Indian Institute of Mass Media and International Experts in Risk Communication The targeted approach in the development and delivery of outputs ensured uptake with potential "ripple offs" The approach was anchored on the fact that Public Awareness is a continuous process. Target audiences were identified and specific resource documents prepared for them. Follow up plans have been developed to prepare other documents for farmers, students, parliamentarians/politicians	The dissemination of the public awareness material has been slow due to size and varied stakeholder holder views. Some of the material developed was either too detailed or too complicated for persons such as the peasant farmers who would not be interested in such reading

FINDINGS:
KEY OPPORTUNITIES AND ISSUES

OPPORTUNITIES:

(a) Government Support

Support to science and undertaking of research in publicly funded institutions has been the dominant feature of science and technology growth in India in the post- independence period. Government support has given a significant boost to the biotechnology sector. In recent times, the Government has formulated policies and has reviewed the existing policies that support the biotechnology segment. Many of these policies, like the EPA Act, the Biosafety Rules, the National Biotechnology Development Strategy (2007) and its updated version (2015 – 2020), National Environment Policy (2006), Stem Cell Research guidelines, Pharma Policy, Seed Policy, Special Economic Zone (SEZ) Act and Foreign Trade Policy, aim at creating an atmosphere of trust and transparency, simplifying procedures, along with offering attractive incentives where possible

(b) Role of Private Sector

Both the public and private organizations have important roles to play in harnessing the benefits of modern biotechnology and emerging field of genomics in India. Collaboration between the two sectors has played a critical role in the development of the biotechnology sector.

(c) The Already Existence of Expertise, Human Resource and Biotechnology Infrastructure

India has world class facilities for DNA sequencing, protein engineering, bioprocessing, PL3 and PL4 level containment for work on dangerous pathogens, prescribed glass/animal houses for transgenic animal/plant research, repositories of micro-organisms important in agriculture, GM testing labs and recently micro arrays, automated DNA sequencing as well as robotic plasmid isolation equipment. India also boasts in adequate expertise in the fields like biochemistry,, molecular biology, organic chemistry, taxonomy, pharmacology and traditional systems of medicine.

ISSUES:

(a) The question of Brain Drain and Building Critical Mass

How to create and maintain a critical mass of researchers who will consistently and systematically contribute to and sorb such a knowledge base seems to be a fundamental challenge faced by the GOI.

(b) Overcoming The Political Landscape

India has approximately eighty GMOs in the development pipeline, notable among them Brinjal, Mustard, Rice, Maize (corn) and Chickpea. The bureaucratic hurdles faced in decision making on GM crops and the hostile climate has made it difficult for GM research and development to be carried on.

(c) Devolving Biotechnology to the States

The responsibility for agriculture in India is largely devolved to State level (as per Rules 1989) and all States have Departments of Agriculture that include extension services. Six National Committees are involved in the Indian Biosafety System of which two are devolved to the State level to handle Monitoring of LMOs. With several advances in biotechnology, it is natural that State governments wish to take part in the ongoing biotechnology revolution and its envisaged benefits. The project seems to have centered its activities within the Central Government with very few activities having the involvement of the State Governments. This could be attributed to the fact that within the decentralized system of government, field trials and environmental releases are a function of the State Government which is a normal follow up to the establishment of the Biosafety Regulatory Framework. The approach also could be due to resource constraints at this stage but the interventions and results achieved should be highlighted and translated for State Level uptake to entrench biosafety system at both the Union and State Levels especially as it relates to monitoring and environmental releases due to differentiated mandates.

Source - BCIL - Celebrating 25 Years of Excellence

(d) The Role of Gender in Biotechnology

The project integrated gender issues in all of its activities. This may be seen through the trainings, for instance the training of staff on GMO detection and lab maintenance, irrespective of gender. However, what was glaring is the fact that there were more females than males in the Labs, during the workshop meeting as well as the major policy makers.

A. Best Practices

A. Best Practices in Project Implementation

(i) Project design

Good design of any project avoids unnecessary complexity, and is based on firm commitments of parties, with clear exit strategies. The project was designed in a manner that ensured there is proper documentation of the project development process which helps in the assessment of the of the progress of the project in particular with respect to involvement of stakeholders and the degree to which ownership of activities and outputs is perceived. The project was also carefully designed thus securing integration and spatial linkage of measurements and related activities among national projects and plans.

(ii) Importance of Finding the Right Approach to Capacity Building as an Integral Approach

Capacity Building in biotechnology is not restricted to training of individuals or groups, but is rather a process that requires the integration of all stakeholders (policy makers, academic institutions, finance institutions, the general public, etc.) that can have an influence on the performance of specific biotechnology activities (such as training of skilled personnel in the Biotechnology Sector).

(iii) Local Ownership

With regards to local ownership, two different success factors were identified:

> **publicly funded institutions has been the dominant feature of science and technology growth in India**

Source - BCIL - Celebrating 25 Years of Excellence

(a) High-level institutional backup and
(b) The inclusion of cultural aspects into Capacity building.

(iv) Regional approach and Capacity building

Regional and sub-regional cooperation is highly instrumental for further enhancing capacity building and sharing experiences. There are several countries that are already engaged in developing long-term linkages on a regular basis (e.g. Bangladesh, Bhutan and Sri Lanka just to name a few. The enhancement of regional and sub- regional cooperation would benefit the region as a whole and, more particularly low-income countries.

B. Best Practices with regard to Presence of Strategic Elements

(i) Definition of Goals, Vision and Mission

The Project is in line with the Country's vision, mission and goals and/or defines their own set of goals. Clearly defined goals and desired outputs are an important precondition to define concrete activities and handle expectations, and form the core of every capacity building strategy.

(ii) Geographical Focus

It is recommendable that a capacity building program should define its geographical focus, maybe in combination with the time dimension (for example, Phase I (short-term): 1-3 States within India, Phase II (medium-term): one region of India, Phase III (long- term) with a wider coverage across regions. The decision should be based e.g. on existing partnerships as well as the level of quality of capacities available and the thus resulting demand for building up new capacities.

(iii) Strategic Partnerships

The establishment of strategic partnerships is fundamental for the sustainability of Biotechnology at a national, regional and international level. Collaboration enhances the capacity of people and organization to achieve goals through synergy effects, brought about by the efficient and effective

C. Best Practices with regard to Methods and Instruments

(I) Building upon Existing Strategies, Tools and Structures

A large number of institutions including donors, universities, training centers, etc. carry out Biotechnology activities. Most of them have many years of experience in the field of Biotechnology, whether related to medical, agriculture or industrial Biotechnology. A notable example is the testimony of the number of crops in development.

(ii) Establishment of Local Technology Centers

Local Research and Training Centers are the most effective platform for establishing a pool of experts. Biotechnology Training Centers cannot only build capacity for individuals, they can also contribute to the deployment of technologies by conducting technology research, analyzing the local framework conditions, supporting reform processes, facilitating dialogue between local and international stakeholders and participating in policy making processes. A notable example in this context is the BCIL, whose services are aimed at facilitating accelerated commercialization of biotechnology by establishing linkages among the various stakeholders including industry, R&D institutions, Government, financial institutions and international agencies and providing access to technologies; creating awareness about business opportunities, IPR protection, regulatory and biosafety requirements; preparing feasibility and detailed project reports; arranging financial support and manpower training and placement.

(iii) Training the Trainers

The project has shown that building local capacity for training is crucial to ensure the sustainability of Biotechnology and Biosafety. Training

Training a set of individuals for a specific project will only ensure that the project activity is executed successfully, given that the trained capacities work in the project for its entire lifetime. In order to achieve a constant supply of trained capacities in India for biotechnology it is necessary to build up qualified local training and teaching staff. The project successfully trained several nationals from the universities and from research institutions on LMO Detection as well as Risk Assessment methodologies.

(iv) Including Biotechnology into Basic Education Curricula

In order to create a new generation of Biotechnology practitioners, the concept of biotechnology should be also enrooted in basic education. The project has introduced some interesting initiatives targeted at young people, which the Government can adopt and replicate in the school curricular.

(v) Networks

Networking does not only enhance the proliferation of knowledge and expertise but it also furthers the establishment of partnerships, working relationships, etc., which are key to the sustainability of biotechnology.

(vi) Synergies–Potentials for Partnership

In the present, a large number of biotechnology initiatives have been launched and are operating, or are being planned. The project has supported knowledge transfer projects. The lesson learnt from this, is that should take into account these dynamics and integrate cooperation considerations as an important element of their strategy. The running of the Asia Biosafety conferences pulled synergies due to the invitation of participants from the region. Different dimensions are brought in during the workshops

CONCLUSION AND WAY FORWARD

CONCLUSION

While the importance of capacity building is widely acknowledged, more attention needs to be drawn to the identification and implementation of effective capacity building approaches. The ultimate goal of capacity building is to sustain a process of individual and organizational change and to enable organizations, groups and individuals to achieve their development objectives. Any capacity building activity needs to be carefully designed so that it contributes to this goal.

Source - BCIL -

WAY FORWARD

(a) Institutionalizing capacity building programs at regional and national level

To increase the effectiveness of capacity building activities the focus should be on building the structures both at the Federal and State Level thus offering capacity building on a regular and long-term basis. India has capacity building providers of different type who are already available but they are usually under funded and not well equipped (e.g., universities, government training centers, etc.). In the case of Biosafety, it is key that the Biosafety Coordination Authority be established, resourced and capacitated at both Federal and State Level to take up the task of filling in the missing gaps, tying the knots and ensuring a seamless approach to regulatory practices on modern biotechnology in India.

(b) Building on Existing Institutions

For any new activity, from the planning stage onwards, local institutions and experts should be involved as much as possible in organizing and carrying out the capacity building action. While receiving technical and financial support, any involvement will already be a learning-by- doing experience for the institutions, and will be the first step towards building in-house capacity and a reputation.

(c) Target the right people to build a critical mass

Capacity building activities often put strong emphasize on training key players in government, such as senior officials that actually take decisions. This can lead to a situation where a fairly limited group of people, who usually already received a comparably good education, is involved in all sorts of capacity building activities. In the context of the project, capacity building activities were targeted towards a wide range of stakeholders including agriculture officers, students of media/ journalism, Customs, plant quarantine officers, Indian Information Service Officers, Food Inspectors and Seed Inspectors. Another good approach was the use of mandated institutions to handle LMO Testing and also the use of Crop specific mandated institutions to develop the Biology documents. This approach is a best practice to assist in uptake beyond a project as instruments developed are relevant to the institutions and end users.

CHAPTER ONE
INTRODUCTION

1.1 Background to the Project

India is known for its rich heritage of biological resources, having already documented over 91,000 species of animals and 45,000 species of plants. 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 Centre's of Origins and Diversity of Crop Plants having more than 300 wild ancestors and close relatives of cultivated plants still growing and evolving under natural conditions.

The intent towards ensuring progress in Environment protection is clear as it 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 endeavor 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".***

India enacted the Environment (Protection) Act (EPA) in 1986, which is an umbrella legislation to enable Central Government to promulgate notifications and rules thereunder by regulating various activities for conservation of the 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.

The GOI further acceded to the Convention on Biological Diversity (CBD) on 18 February 1994 and ratified the CPB on 17 January 2003. The Ministry of Environment, Forest and Climate Change (MoEF&CC) is the nodal Ministry for implementing the obligations under the CPB in India.

As a party to the CPB, GOI is committed to fully implementing the obligations under CPB related to transboundary movements of LMOs. The GOI aims to ensure that biotechnology R&D is guided by a process of prudent decision-making

Source - Flikr

Source - Ministry of Environment & Forests, Government of India

that safeguards both biodiversity and human health while adhering to the highest ethical standards.

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 formed under the Ministry of Science & Technology to support research endeavors in biotechnology. Apart from DBT, biotechnology research in the country is also supported by several other bodies including; 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.

> **"the State shall endeavor to protect and improve the environment and to safeguard the forests and wildlife in the country"**
>
> **Constitution of India. Article 48-A and Article 51-A (g) of the Directive Principles of State Policy in the Constitution of India**

Over two decades, the country has built a strong infrastructure for biotechnology research in public and private sectors, universities and research institutions. Extensive investment in R&D is resulting in development of innovative products and processes. India commercialized the first transgenic crop i.e. Bt Cotton in 2002 and in a span of six years, the area under Bt cotton cultivation has increased to approximately 70 million hectares, an equivalent of 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. through public and private institutions are under various stages of development and field-testing. With this progress, 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.

Extensive efforts have been made towards capacity building within the country to address biosafety issues. The MoEF&CC, DBT and Ministry of Agriculture (MoA) have organized several workshops for creating awareness on biosafety and regulatory requirements related to use of LMOs across the country.

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 learning gained from this project highlighted the urgent need to intensify capacity building initiatives on priority areas through a focused program and continuous sharing of best practices in biosafety regulation, which keeps evolving, to ensure effective implementation of the CPB.

India being a vast and diverse country needs additional cooperation in terms of technical and financial resources for building capacity of its personnel and infrastructure to enable institutions to implement the various provisions of the CPB. This entails harmonizing the domestic biosafety regulation with international best practices.

It is in this context that the GEF Phase II project on capacity building on biosafety was developed by UNEP-GEF,

MoEF&CC. This project 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.

1.2 Purpose of the Assessment

The purpose of the Assessment is to examine the performance of the Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India – Phase II project since the beginning of its implementation and develop a Best Practices Report. The Assessment includes:

- Reviewing the progress to date on project implementation, measured against planned outputs in the project document in accordance with the rational budget allocation
- Evaluating the processes involved in achieving the outputs
- Understanding the underlying causes/issues contributing to lack of or under achievement of targets
- Identifying and recommending the Best Practices for the Future

In summary, the Assessment is intended to identify strengths and weaknesses of the project design after assessing (chapter 3) its adequacy, efficiency, and effectiveness and what has been implemented based on a thorough assessment of the project outputs and outcomes to date and thereafter coming up with recommendations (chapter 4) for any necessary overhaul in the design, orientation and work plan for the remaining project period.

In chapter 5, early learning and best practices from the project are taken into account. The success stories are proposed for immediate acceleration on other on-going projects and part of the future implementation matrix and failures analyzed with remedial action suggested accordingly.

1.3 Methodology of the Assessment

The collection and compilation of the Best Practices assignment was conducted in a participatory manner in order to provide a basis for potential improvement in the implementation and other decisions.

According to the given ToR, this assessment used the following steps:

i. Desk review of project document, outputs, monitoring reports (such as Project Inception Report, Minutes of Steering Committee meetings including other relevant meetings, Project Implementation Report (PIR/APR), quarterly progress reports, and other internal documents including consultant and financial reports)
ii. Review of specific products produced so far, including datasets, management and action plans, publications and other material and reports
iii. Interviews with the Project Manager
iv. Participation at the Project Closure Workshop (March 13 2017) in New Delhi, India where a report of the project was launched and was presented. There, various stakeholders could be interviewed and the results of the demonstration projects review were commented
v. Interviews with other relevant stakeholders involved, including the Task Manager from the Implementing Agency UNEP

1.4 Structure of the Assessment on Best Practices

The structure of the assessment follows the UNEP-GEF Sample Outline for minimum UNEP-GEF requirements. The report will look at the development context and the project design, as presented in the UNEP-GEF Project Document (chapter 2), then assesse the approach to the implementation, the opportunities, issues and the challenges (Chapter 3 and 4) on the basis of produced reports and stakeholder interviews, provide what is considered as the Best Practices for the future projects or programs not just for India but globally (chapter 5) and concludes with recommendations and way forward for the future

CHAPTER TWO

THE PROJECT AND ITS DEVELOPMENT CONTEXT

2.1 Project Start and its Duration

The UNEP-GEF project "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India – Phase II " (PMS: 00388) was operationalized in May 2012 for a period of 48 was extended to end in June 2017.

2.2 Immediate and development objectives of the project

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.

The project objective was 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 with specific emphasis on Agriculture Biotechnology. The project seeks to build 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.

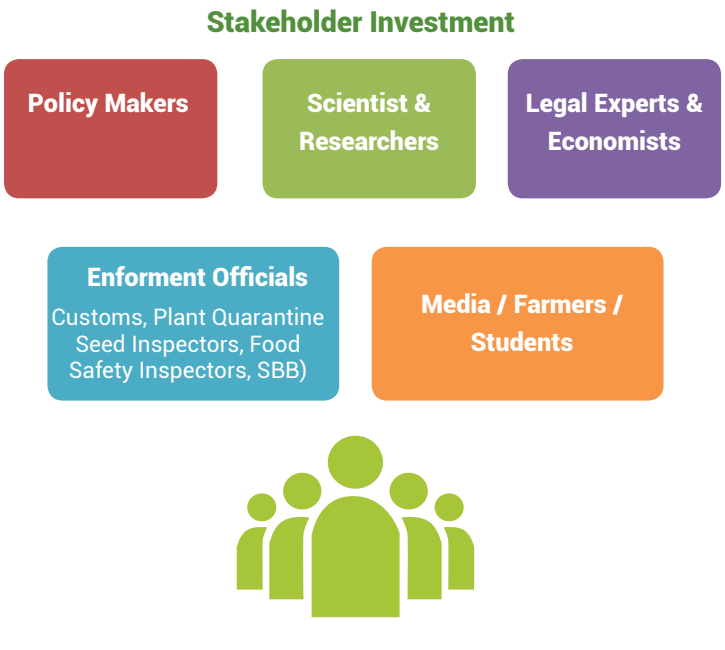
This project is also consistent with and supportive of the national priorities of India, and its global commitments. The Twelfth Five Year Plan, in its pursuit for achieving 8 percent growth, focuses on faster, more inclusive growth and sustainable growth. The plan also recognizes the need for sustainable utilization of Biotechnology to support agriculture and agro based industry especially when anchored on sound Biosafety practices. Sections 7.33 and 8.22 under Goal 13 – Environment, Forestry and Wildlife sector highlights the need for a Biotechnology Regulatory Authority of India to harmonise recognized as essential to streamline regulation of modern biotechnology products of Biotechnology.

The project also aimed at facilitating the National Biodiversity Action Plan version 3 (NBAP) of 2008; supporting the National Biotechnology Development Strategy (2007), the NEP (2006), the National Seeds Policy (2005), the National Farmers Policy (2007), the Food Safety and Standards Act (2006), the Biological Diversity Act (2002) and the Plant Quarantine Order, (2003). The project is therefore 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.

2.3 Main stakeholders and their roles

As per project design, the key stakeholders relevant to the capacity building for the implementation of the CPB in India include

- Decision makers/policy makers [MoEF&CC, DBT, MoA, Ministry of Health and Family Welfare (MoHFW), Ministry of Finance(MoF), Ministry of External Affairs (MEA]; Relevant agencies/Authorities [FSSAI, PPV&FRA, ICMR, ICAR, CSIR, NBA] Members of Statutory Committees [GEAC, RCGM, MEC and SBCCs]
- Scientists/technical experts, researchers and technicians from public and private sector including academic institutions
- Legal experts and economists
- Enforcement officials including customs, plant quarantine, state agricultural departments, members of SBCCs, DLCs and IBSCs;
- Interest groups, teachers, students, mass media and extension workers



CHAPTER THREE
OVERVIEW OF THE PROJECT COMPONENTS – A LOOK INTO THE IMPLEMENTATION APPROACH, ITS CHALLENGES, ADVANTAGES AND RESULTS

3.1 COMPONENT VI: PROJECT MANAGEMENT

3.1.1 Implementation approach

3.1.1.1 Design of the Project

The project was the second phase of the Biosafety Capacity Building Initiative by the Government of India. The World Bank through the GEF in collaboration with the GOI had funded the first phase. The second phase saw the GOI collaborating with UNEP-GEF. The project began in 2012. The Phase II Project was based on the outcome of the phase I project. The approach taken to implement the second phase involved a combination of (theoretical) policy improvement with (practical) local demonstration activities.

The implementation approach involved:

- Problem Analysis- identifying the main problems, establishing the cause and effect relationships which result therein and flow from these problems
- Analysis of Objectives
- Stakeholder Analysis-giving further consideration to who these problems actually impact the most, the would be roles and interests of different stakeholders in tackling the problems and reaching solutions
- Analysis of Strategies-involving the comparison of different scenarios to address different situations.
- Having analyzed all the above, the Project divided the issues into four components and designed the project activities around these four components namely;
  - i. Risk Assessment and Mitigation
  - i. Handling, Transportation, Packaging and Identification (HTPI)
  - ii. Socio Economic Considerations
  - iii. Public Awareness

Institutional Arrangement

The Project set up a decision making team to manage the project. The model developed in the institutional arrangement included the National Steering Committee, the National Project Director, the National Project Coordinator and the Project Coordination Unit.

(a) The National Steering Committee (NSC)

was constituted by the MoEF&CC to advise and guide the implementation of the project. It was expected to meet at least once a year. The functions of the NSC included:

- To provide overall policy advice on the execution implementation of the project;
- To 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;
- To make recommendations to UNEP when revision of Results Framework, work plan or M&E plan are needed;
- To mobilise necessary expertise, as needed for proper execution of the National Project outputs;
- To catalyse inter-ministerial and broader stakeholder support towards achieving the objectives of the project.

(b) National Project Director (NPD)

The NPD was appointed by the National Executing Agency (NEA) to provide overall supervision of the project. The Additional Secretary in charge of the Biosafety Unit within MoEF&CC was appointed as the NPD of the project. The tasks of the NPD were as follows-

- To act as Convener of the NSC;
- To 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;
- To approve the of selection of consultant and subcontracting agencies;
- To ensure effective communication with the relevant

authorities, institutions and government departments in close collaboration with the NSC;
- To foster, establish and maintain links with other related national and international programs and National Projects
- To oversee overall resource allocation and where relevant submit proposals for budget revisions to the NSC and UNEP;
- To ensure submission of regular progress, financial reports, and terminal report at project completion;
- To oversee the preparation of annual Project Implementation Review (PIR)) and GEF Tracking Tools by NPC.
- To participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan.
- To ensure the project is in conformity with objectives of the CPB;
- Any other task as decided by the NEA.

(c) The National Project Coordinator (NPC)

The National Project Coordinator (NPC) is appointed by the NEA for day to day coordination of implementation of project activities. The NPC is to report to the NPD and NSC on all project activities. The functions of the NPC are as follows-
- To coordinate, the planning, management and execution of the project activities as set out in the project document and as guided by NSC;
- To assist the NPD in discharging its functions;
- To prepare 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;
- To manage the project budget in line with the approved work plans;
- To coordinate selection of subcontractors and consultants and supervise PCU;
- To carry out technical review of the TOR as well as reports prepared by sub-contractors and consultants.
- To supervise the timely preparation and submission of quarterly and annual progress reports, work plans, budgets, and financial reports by all the executing/ implementing partners to UNEP and the NSC;
- To coordinate with line ministries, state governments, institutions and project partners involved in the project execution;
- To review project budget revisions and all other administrative arrangements required under GOI and UNEP procedures;
- To work with UNEP to prepare the annual Project Implementation Review (PIR) and the GEF Tracking Tool Works with UNEP to prepare the annual Project Implementation Review (PIR);
- To prepare the terminal report and other project closure procedures at project completion;
- To 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.
- To provide administrative inputs to the project and monitoring arrangements as per GOI/ UNEP procedures;
- To attend workshops and consultations as appropriate;
- To support resource mobilization efforts and development of partnerships;
- To support in replication of project lessons through sharing of information with UNEP and other countries at regional and sub regional levels.

(d) Project Management and Monitoring Committee (PMMC)

The PMMC is chaired by the NPD. The members of the committee include the NPC, experts from DBT and other relevant organisations such as ICAR, NBPGR etc. The PMMC was expected to meet at least once in two months and provide technical support to the NPD and NPC as indicated below, thus-
- 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.

(e) Project Coordination Unit (PCU)

From the onset of the project, the PCU was designed to be contracted and located in a facilitating agency having experience in biotechnology and biosafety issues. The criteria of selection also included experience in similar assignments earlier. It was also designed that the Funds to execute the project will also be channeled through the facilitating agency selected for the purpose. The PCU was designed to carry out the following tasks:
- To provide administrative and technical support to NPC in implementation of the project activities;
- To assist the NPC in ensuring that all the activities are

carried out on time and within budget to achieve the stated outputs;

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

In providing interlinkages of the organizational structure to the national and international biosafety forum, the NPD serves as the Chair of the Genetic Engineering Appraisal Committee (an Additional Secretary) whereas the NPC is the National Focal Point to CPB and Secretary to the GEAC. Whilst the NPD provides higher level and Political linkages/oversight the NPC ensures linkages to the COP/MOP processes and related CPB obligations whilst at the Local level shares results and networks to mainstream results into the Technical approval processes and update of results of the governmental processes. The design also highlights a facilitative agency in the absence of a coordination agency with experience and institutional knowledge and linkages on biotechnology and biosafety, the reason for the choice of BCIL.

3.1.1.2 Project Location Rationale

The location of the project unit was the Biotech Consortium India Limited (BCIL). This should be considered a very pragmatic and efficient decision. BCIL is a knowledgeable, well-established cooperation platform on Biotechnology and project management in the wider region. It is a public limited company. The PCU team chosen provides the right competence and experience needed for successful implementation. This decision to have BCIL manage the project was based on various factors including the bureaucracies that government departments face while procuring or accessing finance for their project activities. Though the agreement between the GOI and UNEP-GEF had been reached, there was a delay in the releasing of funds and the commencement of the project was therefore delayed. The challenges faced led the government to decide whether to have the funds transferred through UNDP or identify project partners through whom the funds would be transferred. Having weighed its options, the Government decided to have BCIL, a public limited company, promoted by the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India and All India Financial Institutions, to manage the project.

3.1.1.3 Collaboration/ Partnerships

The successful implementation of the project needed the collaboration and partnering of various players and experts. The Ministry, Research Organizations, the Private Sector, Farmers, UNEP –GEF, are the key players and meeting their strategic interests is key to this project. The design of the project also ensured that the different components were handled through partnerships with individual or mandated institutions that were experts in their own right. The Project built a multi-stakeholder platform, comprising champions from business, government, donors and civil society in in India as well as internationally, designed to engage business, facilitate dialogue
and innovation, and directly support public private partnership action on key biotechnology development challenges.

Through partnerships the project was able to reap the benefits of others' efforts. There was accelerated learning and distribution of skills and knowledge. The Partnerships also added depth and breadth to the project's impact. Although there were different organizations with whom the project partnered, and each had its structures and approaches, these organizations were able to show that they could work together towards common purposes and achieve shared results.

Annex 1 contains the list of the stakeholders or partners and the roles that they played in the implementation of the project.

3.1.1.4 Aligning of the Project with the Long Term Development Plan of the Country

In designing the project, the project planners reviewed the existing policies and long-term development plans and aligned the project objective with that of the Country Development Plan. According to Dr Ranjini Warrier (Advisor, MoEF&CCC), the project was not simply designed in a generic way. She emphasized on the need for a clear vision, a long-term plan rather than a quick fix solution for such a project.

EXPERT VIEWS

Dr Ranjini - Former Advisor/NPC MoEF&CCC

A biosafety capacity building project must be aligned with the Country's research and development strategy and addresses a tangible need of the Country. If not, there is high risk of investing in projects that have little or no impact. It is imperative to ensure that there is a tight link between the current Economic development Plan or Economic Blue Print and the Project."

The point made is that there should be a vision within the Country about what the project will provide to the Country.

3.1.1.5 Communicating Information

The project team kept information flowing on the project status and has used various dissemination approaches such as announcements in newsletters, contests to name the project, road shows describing the purpose and benefits of the project. Additionally, a monthly project newsletter is used to publicize accomplishments.

Several celebrations and workshop have been held to celebrate completion of significant milestones with branded pens, bags or coffee cups distributed to enhance awareness and connection to the project.

Annex 3 is a list of the workshops organized in the life of the project

3.1.1.6 Managing Project Changes

Change management is the process of identifying and documenting potential changes, determining whether the changes are beneficial and necessary, analyzing the scope and impact of the changes, estimating the effort and cost of the changes, deciding whether to make the changes, and finally managing the changes after they're added to the project. Change is by nature disruptive. The introduction of new systems or processes has the potential to upset the normal operation of the organization or of the project. If we are unable to effectively manage the level of disruption, the backlash will prevent a fully successful realization of the desired project outcomes. Likewise, if the project team is effective in managing and minimizing the disruption the effected organizations will be more likely to accept and readily adopt the changes being implemented. There were instances of change in the project and the project team was able to adapt or handle the change. For instance, the delay in starting the project meant that the activities had to be completed in a much shorter time than anticipated. The Project, with the approval of UNEP was able to readjust the work plan so as to ensure successful completion of the project without having to omit some activities. Another instance of change that was managed effectively was when the project underwent a change of guard in that the Focal Point Dr Ranjini was retiring, a new NPC was appointed, the project manager who had run the project from inception was also leaving for greener pastures. This change could have left the project almost orphaned with bare minimal institutional memory. However, BCIL was able to quickly adapt by reconstructing and gathering information that had been stored in different forms and seeing the project to its logical conclusion.

3.1.1.7 Monitoring and Reporting on project performance

The Project uses a tracker with start dates, finish dates, durations, work, and cost, which it uses to calculate performance. The design of the project includes the baseline information and actual values, and the Project uses these to estimate values at completion and balance to go. By understanding the difference between these values, the project is able to track and interpret its progress easily.

By tracking actual costs the project is able to compare them to the original estimate i.e. the baseline. The project is therefore able to measure cost performance by finding out if the actual costs are more or less than baseline costs.

The project is expected to provide quarterly and annual reports to the UNEP-GEF. These are progress reports on the activities and financial status of the project. The Project Document also clearly specifies the various stages of the project (from pre- start- up through inception and implementation) and the processes that would be taken to ensure that the agreed project program would be followed. In addition, the key monitoring and reporting steps (including: Steering Committee meetings, project management and monitoring committee meetings, project logical framework use, audits, the tracking tool and review and responsibilities for different monitoring actions, etc.) were defined. Responsibilities for M&E actions are defined in the Project Document.

Source - Ministry of Environment, Forest and Climate Change

3.1.1.8 UNEP Supervision and Backstopping

UNEP has been effective in providing supervision and backstopping and providing technical support on all the project activities. UNEP was able to-

(a) Coordinate the development of the project document and enabling the project to commence;

(b) Provide review guidance to the project team on preparation of the project reports

(c) Broaden the use of the ANUBIS thus providing a reporting tool and training on use

(d) Peer review and technical guidance on project outputs and also provided linkages to best practices and institutions in Biosafety Regulatory practice and capacity building

3.1.2 Challenges

- The delay in starting the project due to delay in release of the funds was due to the institutional set up of the project and procurement of the facilitating agency

3.1.3 Advantages

- The leadership right from the high office of the Additional Secretary and Chair of GEAC;
- The ownership and Commitment by the Government in the Co-financing ;
- The collaboration and creation of a mix between national and international experts

3.1.4 Deliverables/ Results Attained

Outputs at the time of the Assessment
Procurement plan for goods and services in place
Up to date progress reports
Up to date audited reports for expenditure
Yearly inventory of non expendable equipment
Up to date project implementation reports
Up to date minutes of steering committee meetings

3.2.1 what was the status before the Project

By the end of the Phase I project, the law and policies on GMO use were in place. However, there were gaps in the regulatory regime that needed to be identified and addressed. India also had experience with Environmental Release of Bt Cotton. Bt cotton expressing cry1Ac gene from *Bacillus thuringiensis* is the only GM crop that had been approved for commercial cultivation at the start of the project. The approval was first accorded in 2002 to M/s Maharashtra Hybrid Seeds Company Ltd. To date, 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 was introduced in 2008. Several public and private institutions are in the process of developing GM crops expressing different traits. (See https://www.tandfonline.com/doi/full/10.1080/21645698.2016.1156826)

Bt Brinjal was approved for commercialization in India in 2009. This approval was granted to Mayhco Company, which had applied for the approval of two Brinjal Hybrids. However, there was public outcry as the public had doubts that GMOs were safe for consumption and several debates in which representatives from Mayhco, scientific community and several NGOs made presentations on the subject. The then Minister for Environment, Jairam Ramesh, issued a moratorium on the commercial release, until further tests were conducted to ensure that the genetically modified Brinjal was safe for consumers and the environment. This would have been the first GM food crop in India.

Source - India Farmers: Flikr

3.2.2 Approach

3.2.2.1 Preparation of the Biology Documents; working through multidisciplinary teams

The Project's approach in developing capacity for risk assessment and risk management in India was carefully

considered. The project went through a selection process that resulted in choosing an institutions with mandates on the specific crops. The institution was also capable of giving field level data for different crops. The preparatory work was initiated with a Day's workshop facilitated by the OECD representative on how they prepare Biology documents. This was followed up with with informal meetings with experts in the fields, field level data collection, development and testing of questionnaire and workshops to identify which crop to study. The preparatory work took approximately 6-9months.

After selection of the institution(s) to carry out the activities of this component, the work here began by development of biology documents of eight key crops namely tomato, papaya, potato, sorghum, chickpea, pigeon pea, Indian mustard and rubber. (see http://www.geacindia.gov.in/resource-documents.aspx). A biology document is a document that describes the characteristics of the species in question- e.g. plant species, including its habitat, fertility, dispersal and endogenous toxins as well as information about the species major interactions with other life forms in its production range such as predators, grazers, parasites, pathogens, competitors or humans if appropriate. This information is important, as it will help identify potential risks associated with a GMO under review, relative to its counterpart of the same species already existing in the environment. It is important to note that the review of any application for a GMO will not be initiated unless and until a finalized Biology Document is available.

The project also ensured that baseline data on the presence of wild relatives of two crops such as okra and pigeon pea was collected and a risk analysis framework was thus developed. The project took the approach of using a multi-disciplinary team, involving subject matter experts and institutions to develop the documents. The teams also used peer reviewed literature and consensus documents developed by the Organization for Economic Cooperation and Development (OECD).

3.2.2.2 Training programs

The aim of this was to provide a hands-on approach in the safety assessment of a GMO and also to present environmental considerations for the safety assessment of GM plants. The project launched several training programs in several universities across India on how to conduct a Confined Field Trial of a GMO.

3.2.2.3 E- Module

The project prepared an e-module course that will be used by universities across India to train on GMO risk assessment. An e-module is an electronic learning platform that has no more than one or two learning concepts and incorporates a blend of teaching and assessment tools that may include video clips, direct instruction, gaming elements and social media.

3.3 Advantages of the Approach taken to implement the Activities of this Component

- Thorough interactions with the mandated institutions
- Working through an institution, rather than through an individual, enabled the ownership of the work. Over 5000 scientists were involved in the development of the Biology document.
- Capacity building of the persons and institutions involved. Working with different experts as well as the OECD builds the capacity of the scientists and each scientist was able to learn something new from the other.
- Consensus among scientists and institutions as they all responded or gave their input to the Biology Documents

3.4 Constraints to Capacity Building of Risk Assessment

- Brain drain – many of the trained personnel move to other areas or jobs.
- The ban on use of GMOs has impacted negatively on research and development in India. Several institutions have had to stop collaborations or simply conducting research on transgenics. The four products that were in the pipeline have also been put on hold till the moratorium is lifted

EXPERT VIEWS

Dr S.R. RAO - Department of Technology

The area is small. The number of people familiar with the technology is small such that the same people are always being involved in any given capacity building exercise, hence repeated capacity building. The effectiveness of a capacity building exercise is to develop a critical mass that should make a difference. Currently, we cannot say that India has a critical mass in terms of institutions, infrastructure or policy makers.

The ban on imports has also impacted adversely on regulatory science in that since there is no cultivation, no product, no approval and generally no business related to use of GMOs, you cannot entice anyone to take up regulatory science. Recent studies show that scientists are not taking up any research on transgenic crops.

3.5 Deliverables/Results Attained

Deliverables/ Outputs attained at the time of the Assessment
Crop- Specific Biology and ecology document has been developed to assist dossier preparation
Existing RA and RM procedure and guidelines have been reviewed to confirm that India is compliant with CPB obligations
Baseline data on presence of wild relatives has been gathered for better risk management of LMOs
Guidelines and procedures for specific types of risks associated with specific traits and stacked events
LMOs are monitored by regulatory agencies after environmental release

3.3 COMPONENT 2C: INSTITUTIONAL CAPACITY DEVELOPMENT FOR HANDLING, TRANSPORTATION, PACKAGING AND IDENTIFICATION

3.3.1 what was the status before the Project

Handling, Transport, Packaging and Identification has been the subject of lengthy discussion at the International forum. The CPB places an obligation on the Parties to the protocol to take measures to require that documentation accompanying GMOs destined for contained use and GMOs for intentional introduction to the environment to clearly identify them as GMO and to specify the requirements for their safe handling, storage, transport and use. In 1990, GOI developed DNA Biosafety Guidelines that contain the procedures for importing GMOs for contained use including the type of containment, packaging, labeling, contact point and documentation to accompany shipments.

3.3.2 Approach

3.3.2.1 from unknown to Known- Feasibility Study

The approach used by the project was one of going from the unknown to the known. The project. The project began by undertaking a feasibility study for putting in place an Identity Preservation System for Handling GMOs in India. This was because the Government through the project decided to undertake a feasibility study in the context of Article 18(2) to provide a background on a development of an Identity Preservation Policy. Identity preservation is the practice of tracking the details of agricultural shipments so that the specific characteristic of each shipment is known. IP is the designation given to such bulk commodities marketed in a manner that isolates and preserves the identity of a shipment, presumably because of unique characteristics that have value otherwise lost through co-mingling during normal storage, handling and shipping procedures. The concept of IP has been accorded greater importance with the introduction of GMOs into agriculture. Both technical and managerial skills and techniques are needed in tracking and documenting the paths that agricultural products move in the production process. A fully integrated IP system might track and document a commodity's seed characteristics, initial planting, growing conditions, harvesting, shipping, storage, processing, packaging and finally selling to the consumer.

The feasibility study was therefore conducted on the Basmati Rice and the Soya Bean. The Basmati Rice was chosen because it is indigenous to India. India is known to produce 70 percent of the world's basmati rice. Thus Identity preservation of the basmati rice would be for economic gains.

The second crop that was used in the feasibility study was Soya Bean. Soya bean production in India may be said to be relatively low, producing approximately 3 percent of the world soya bean. India does not grow GM Soya Bean. The conventional Soya bean is grown, and many farmers mix the yellow and green soybean.

The feasibility study concluded that an IP system is important and has to be considered for implementation.

The study also brought out the issue of Labeling of GMOs. In the year 2015, the GOI enacted a law on Labeling of GMOs. This law has faced challenges in implementation because other operators in the value chain do not isolate GMO from non-GMO hence it is difficult to prove if a product is GMO or not. The study concluded that Labeling is not a Biosafety issue but a matter of consumer choice and this is not an issue in India.

3.3.2.2 Collaboration in Research

The Project worked through collaboration and partnerships with research institutions with a view to develop collaborative research projects. By bringing together top scholars and research bodies from within India as well as different countries, the project facilitated high quality collaborative research on Biotechnology. In particular, the project worked with the International Life Science Institution-Research Foundation (ILSI-RF) and organized various trainings programs on "Detection Methods for GM Foods and Plants" and created a pool of resource persons in the country in this area. The programs were organized jointly with Department of Biotechnology, GOI, Center for DNA fingerprinting and Diagnostics, Hyderabad Industrial Toxicology Research Center, Lucknow, American Association of Cereal Chemists, and ILSI International Food Biotechnology Committee.

6 international and 7 national experts conducted these training programs. This collaboration was deemed useful because it also built the capacity of the national experts who were trained as trainers. Of note is the LMO Detection Training contract with Intertek Scan Bi, a Swedish Private Company. The training was offered in India with a follow up trainer of trainer workshop to expose selected participants to advanced techniques and State of the Art facilities. This is a key example of a Public-Private Sector Partnership which should be highlighted as part of Best Practice

3.3.2.3 Building on Existing Institutions and Capacities-Equipping existing Institutions and Technical Skills

The Project has been able to establish a Network of four GMO detection laboratories with the support of UNEP-GEF. Prior to the project, the capacity to identify any authorized/ unauthorized GMO in the food/feed and in the fields, before the project, was available but limited. The methods of GMO detection relied heavily on the conventional PCR (Polymerase Chain Reaction) based methods that may not provide a clear picture when a gene-knockout or single gene mutations are introduced.

This particular approach involved a stock taking exercise to understand the existing capacity in the Country. Based on the stock taking Report, it was decided that the National Bureau of Plant Genetic Resources (NBPGR) would take the lead in equipping its labs with the necessary GMO detection equipment and equip its technical staff with the necessary skills in GMO detection.

The NBPGR is the institution responsible for the germplasm Bank in

Dr Vibha Ahuja of Biotech Consortium India Limited at a project workshop. Source Flickr

India. India is known to have the second largest gene bank after the USA, with 4.3 Lakh digital materials. The main role of a plant gene bank is to preserve genetic diversity, in the form of seeds or cuttings in the case of plants reproduced vegetatively, and subsequently make this material, together with associated information, available for future use in research and plant breeding. Thus this institution being key in exploration, conservation, quarantine, exchange of germ plasm, knowledge management and technology management of the genetic pool of India, needs to have not only the equipment but also personnel with technical skill in GMO detection, share the Protocols within the network and also offer training as the Apex Laboratory. The four laboratories have been notified as the National Network of GMO Detection Laboratories.

It was also agreed that nodes would be established in Mohali, Kochi and Hyderabad. These satellite labs take samples and would test on regular basis and if there were any cases of unauthorized GMOs they would report to the NBPGR for action. NBPGR was also expected to continue conducting GMO research and development on protocols and SOPs on GMO Detection.

The project also built the capacity in GMO detection by establishing and equipping a State of the Art Lab for GMO detection in Kochi, through the Export Inspection Council (EIC). The EIC is also the institution mandated by the Government to issue Non-GMO certificates for various products. The Council is expected to draw random samples to verify compliance of the Non-GMO status before issuing the Non-GMO certificate. This would require the Council to have the capacity to test the GMO. It is therefore through this project that the capacity was built through equipping the lab with the appropriate equipment as well as training the lab technicians on GMO sampling and detection.

The project led to capacity development through training of plant and quarantine officers, enforcement officers and customs officers. NBPGR is developing SOPs for LMO Testing.

3.3.2.5 Use of Modern Technology

The project was able to purchase four real time PCRs and other equipments to support GMO Testing in the four Nodal laboratories. A Real Time PCR is a specialized machine that allows a PCR reaction to be visualized in 'real time as the reaction progressed. It allows one to measure minute amounts of DNA sequences in a sample. A conventional PCR tells us what whereas a Real time PCR tells us how much. The Real Time PCR is able to:

(a) Carry out gene expression analysis
(b) Determine the percentage of GMO in food

Through the use of this technology, the country is in a position to carry out a thorough analysis of a GMO and provide qualitative and quantitative results of a GMO.

3.3.3 Constraints to the Approach

1. 1.The Standard Operating Protocols (SOPs) for HTPI are in development to supplement the earlier SOPs developed under Phase I. SOPs are a set of detailed instructions that define and standardize procedures for handling, Transport, Packaging and Identification of GMOs. An important aspect when building up capacity for the detection, identification and quantification of living modified organisms (LMOs) is to apply minimal standard criteria to ensure the adequate handling and processing of samples, as well as the quality and confidence in the results obtained. It is essential to ensure that the selected methods produce reliable and consistent results, while, at the same time, meeting minimum performance criteria, is essential.

   Understanding the relevance of minimal performance criteria, and monitoring some of the method's parameters on a routine basis, allows the lab-facility to establish a quality assurance and quality control system (QA/QC) and Standard Operating Procedures (SOP) that can be used later on for corroborating laboratory proficiency. This has already been initiated by NBPGR and is an ongoing activity for the Detection laboratories.

2. Use of certified reference materials is fundamental for protocol harmonization between laboratories and method validation. This is of particular interest when it becomes necessary to allow for result comparison and harmonized interpretation.

3. The Labs, especially in the NBPGR are understaffed. The manpower is insufficient. The Laboratory is run by a single scientist that is full time staff of the NBPGR. The assistants in the lab are part time students on very short contracts.

4. Lack of funding to hire/ contract Lab assistants. The NBPGR has hired the lab assistants on contract. Once their contracts run out they will have to exit because NBPGR had not set aside funds to sustain their salaries.
5. Staff that have been trained are unable to utilize to the fullest and in a continuous manner, the skills gained. The staff are not continuously working on GMOs hence the competencies are not tested or honed.

Image: Courtesy - Ministry of Environment & Forests, Government of India

EXPERT VIEWS

Dr S.K Saxena is the Director for the Export Inspection Council. The Export Inspection Council (EIC) is a regulatory body under the Ministry of Commerce. Under this project, the EIC managed to procure GMO testing equipment for its labs in five regions, namely Kochi, Mumbai, Kolkata, Chennai and Delhi. According to Dr Saxena the challenge that faces the people trained on GMO testing and use of the acquired equipment is that they gain the competence but are unable to continuously work on GMOs. He compares this to learning how to drive. If one does not continuously drive after acquiring the skill, they are bound to forget.

Deliverables/Results Attained

Deliverables/ Outputs attained at the time of the Assessment
Feasibility Study on measures to be taken for putting in place an Identity Preservation System for Handling LMOs
Network of Laboratories for detection of LMOs across five regions in India
Notification, Infrastructure and equipment for detection and verification of LMOs in 4 National Referral Laboratories
Staff of various labs across five regions in India trained on LMO detection and maintenance of laboratory

3.4 COMPONENT 2B: CAPACITY DEVELOPMENT IN SOCIO-ECONOMIC CONSIDERATIONS

3.4.1 what was the status before the Project

The initial guidance document for Socio Economic Considerations had been made by the RIS team within first four months from the commencement of the project. It captured the existing studies on socio-economic assessment of certain crops based on extensive literature review and analysis of available ex-ante and ex-post studies undertaken by various institutions and researchers across the crops and regions in India. It also encompassed analysis of available studies on cost-benefit analysis.

3.4.2 APPROACH

3.4.2.1 Collaboration with a world renown think tank on Socioeconomic Issues

The Project collaborated with the Research and Information Systems for Developing Countries (RIS). RIS is a think tank that specializes in policy research on international economic issues. RIS is known to foster effective policy dialogue and capacity building on economic issues. The institution was thus selected to partner with the government on this project based on its experience in socio-economic research and also because it could provide field level data for different crops.

3.4.2.2 Using an Interdisciplinary Team

The use of different experts including agricultural economists, socio-economists, botanists just to name a few brought in different expertise and views

3.4.3 Challenges to the Approach

These approaches faced several challenges, among them included-

(a) The informal meetings with the experts in the interdisciplinary team were not easy to arrange or get all of them together in one meeting. This is because the country is vast and many are traversing the country working on other projects or issues.

(b) It was not easy to identify how much data was required- who to be interviewed, what information to choose. The institutions involved therefore sat and agreed on the major issues to focus on, the crops, traits and the field area that would be used to identify the socioeconomic issues.

(c) Deciding on what the socioeconomic considerations was also a difficult task. This required extensive literature survey including survey from other countries and interaction with experts globally.

(d) It is not easy to quantify some of the agreed upon parameters such as gender, culture, indigenous communities. This therefore made the debate more difficult.

(e) The scientists are yet to appreciate that risk assessment and socioeconomic issues go hand in hand in decision-making.

3.5 Deliverables/ Results Attained

Deliverables/ Outputs attained at the time of the Assessment
Questionnaire for conducting a socio-economic survey
Proceedings of the socioeconomic workshop
Resource Document on Socio economics of LMOs
Booklet on Resource document on SECs

3.5 COMPONENT V: CAPACITY BUILDING ON INFORMATION DISSEMINATION FOR ENHANCING PUBLIC AWARENESS

3.5.1 what was the status before the project

The Biosafety Capacity Building Project Phase I had established basic infrastructure for awareness creation. 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.

3.5.2 Approach

3.5.2.1 Development of a risk communication strategy

GMOs in India have been received with mixed reactions. There are several activist groups that are anti GMO those that are pro GMO. Aside from the activist groups, the public perception of GMOs also has to be set right so that the right information is communicated to the public.

In developing a risk communication strategy, the project collaborated with Centre for Agriculture and Biosciences International (ABBI) and CABI (India) in the development of the public awareness material and dissemination of the information for public awareness. CABI started by reviewing literature of work that had already been done in the area of public awareness and also identified the different target audience, which included Industry, Academics, Farmers, Students and Scientists. For the farming community, the strategy was to work with the district level farmers associations set up by the government. ABBI developed a Risk Communication Strategy to be finalized by GoI.

3.5.2.2 Use of print and electronic media for information dissemination

The project involved the media to get the relevant information across. The Project recognizes the role that the media plays in increasing public awareness, collecting the views, information and attitudes toward certain issue. The project first created awareness to the media through various training and workshops on Biosafety. The trained media personnel were then engaged whenever the project had an event so as to cover the event by reporting and providing media coverage. This was lead by the Indian Institute of Mass Communication. (See the Biosafety Resource Catalogue - http://www.geacindia.gov.in/resource-documents.aspx)

PMU please confirm, I do not see their outputs in anubis.

3.5.2.3 Translation of Public Awareness Material into Local Languages

India is a vast country with a large population. There are over 1600 languages spoken in India with 22 official languages as per the Constitution. India is divided into Twenty Nine

States and Seven Union Territories for administrative purposes. The project developed and translated the public awareness material in the eight regional languages namely Bangla, Gujrati, Hindi, Kannada, Marathi, Punjabi, Tamil and Telegu. This involved working with the scientists and agencies to provide the content and CABI to do the translation work.

3.5.2.4 Preparation of audio-visual educational material on awareness of biotechnology and biosafety issues for teachers and students

CABI prepared several audio and visual educational materials. The strategy they used in disseminating was first to have the material translated into the eight regional languages and distributed in all the State Universities for feedback.

3.5.2.5 Use of culture in Creating and Disseminating the awareness material

The use of electronic media such as radio programmes and the preparation of a movie was a strategic approach. The film industry is big in India. The public also appreciates and enjoys movies. CABI developed an animated movie that explained Biotechnology and the risks and benefits associated with it, with very simple yet relevant messaging for the entire public using bt Cotton as a case study. The Additional Secretary also on several occasions encouraged the project to involve Bollywood celebrities in creating awareness through movies. The UNEP Task Manager also emphasized and called for the involvement of the movie industry in follow up interventions.

3.5.3 Challenges to the Approach

- The dissemination of the public awareness material has been slow.
- Some of the material developed was either too detailed or too complicated for persons such as the peasant farmers who would not be interested in such reading

3.6 Deliverables/ Results Attained

Deliverables/ Outputs attained at the time of the Assessment
Innovative outreach programs for risk communication both through print and electronic media
Educational programs on biosafety issues for TV and radio developed in collaboration with local and national lead agencies
Primers/brochures/booklets/FAQs/Glossary of Terms in different local languages widely distributed to policy makers, researchers, students, farmers, civil society
Regular publication and distribution of Biosafety newsletters
National, regional and international workshops

REGIONAL
Cooperation & Networking

The Ministry of Environment, Forest and Climate through the UNEP-GEF Biosafety Project Phase II engaged partners and other parties through cooperative Activities notable among them quarterly Biosafety newsletters to share information, Participation in the South Asia Biosafety Conferences, hosting of two Regional conferences on "Strengthening Biosafety Capacities and Sharing of Experiences inthe Region" and a Regional Workshop on Risk Communication. The Project also took part in the National Project Cvoordination Meetings and COP-MOPs where side events were held to showcase the project results and share experiences with other Parties.
http://www.geacindia.gov.in/resource-documents/16-Strengthening_Regional_Cooperation.pdf

CHAPTER FOUR

FINDINGS: KEY OPPORTUNITIES AND ISSUES

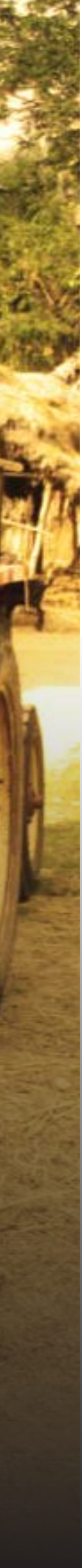
4.1 OPPORTUNITIES

4.1.1. Government Support

The State support to science and undertaking of research in publicly funded institutions has been the dominant feature of science and technology growth in India in the post-independence period.

Government support has given a significant boost to the biotechnology sector. In recent times, the Government has formulated policies and has reviewed the existing policies that support the biotech segment. Many of these policies, like the Stem Cell Research guidelines,

Pharma Policy, Seed Policy, Special Economic Zone (SEZ) Act and Foreign Trade Policy, aim at creating an atmosphere of trust and transparency, simplifying procedures, along with offering attractive incentives where possible.



Source -Flikr

In an effort to keep the scientists abreast of the advanced research and development in the fields of modern biology and related fields, the Government has sponsored Distributed Information Centers (DICs) in 9 universities and R & D laboratories. In addition, the Government has created user centers in different parts of the country with access mechanism to make the information available at universities, laboratories and manufacturing institutions.

From the beginning the DBT laid high emphasis in sponsoring higher educational training in the area of biotechnology for the generation of adequate R & D human resources. From the early 1980s, DBT made available funds for institutionalizing MSc/PhD and post-doctoral studies.

Through the project, several international workshops and conferences in the areas related directly to biotechnology growth have been organized and this has particularly brought the leading biologists and scientists from India and abroad together. Some of these workshops and symposiums not only strengthened the international connectivity to Indian molecular biology and biotechnology, but in varying ways played a catalyzing role in strengthening and inaugurating the formal research groups in these areas in the national laboratories and universities. The spin off from the professional growth of biotechnology and closely related fields of research has been the expansion of biotechnology industry in the country.

4.1.2. Role of Private Sector

Both the public and private organizations have important roles to play in harnessing the benefits of biotechnology and emerging field of genomics in India. Collaboration between the two sectors has played a critical role in the development of the biotechnology sector. It is estimated that the private sector employs 10-20,000 people and generates roughly revenue of US$ 500 million annually. The participation of the private sector in agricultural research and development in India has increased slowly since the 1960s. By the end of the 1980s there were only twelve private sector seed firms in India, focusing mainly on the development of improved hybrids (Dhar 2002).

4.1.3. The Existence of Expertise, Human Resource and Biotechnology Infrastructure

India has world class facilities for DNA sequencing, protein engineering, bioprocessing, crystallography, molecular graphics and modeling, PL3 and PL4 level containment for work on dangerous pathogens, prescribed glass/animal houses for transgenic animal/plant research, repositories of micro-organisms important in agriculture, healthcare and industry, ex-situ and in-situ gene banks for crops and endangered medicinal and aromatic plants, medium and high throughput screening facilities for drugs and pharmaceuticals, biosensors, nuclear magnetic resonance machines, different mass spectrometers for various purposes, GM testing labs and recently micro arrays, automated DNA sequencing as well as robotic plasmid isolation equipment. India also boasts in adequate expertise in the fields like biochemistry, organic chemistry, taxonomy, pharmacology and traditional systems of medicine.

4.2 ISSUES

4.2.1. the question of Brain Drain and Building Critical Mass

How to create and maintain a critical mass of researchers who will consistently and systematically contribute to and absorb such a knowledge base seems to be a fundamental challenge faced by the GOI. The exploration on the growth of biotechnology field in the Indian context lends considerable support to the hypothesis that the institutionalization and growth of specialist communities over a period of time has a direct bearing on the problem to check the process of brain drain.

What is also clear from this study is, it is not just sufficient to create institutions of research and higher training by inducing funds to foster a frontier field of science, and it is essential that an intellectual climate is induced or created by the community concerned. What this entails is a certain viable number of research groups, university chairs and centers of higher learning with research infrastructure, professional societies or informal networks of collegiate pattern, local and national journals and above all sources of intellectual leadership who give a direction and leadership in the emergence of specialist groups and who can act as "gate keepers " to inter-national connectivity in the relevant field of research.

There are three aspects to this notion of professionalization observed in the field of biotechnology in India. The first is the professional basic research base created in the areas directly related to the emergence of biotechnology in biochemistry, molecular biology, cells biology, immunology, genetics and virology. The second aspect is the

underpinning of these basic stocks of knowledge for furthering the techniques and methods in biotechnology which related to genetic/protein engineering, enzyme engineering, hybrodoma, diagnostics and techniques of tissue culture - to name some prominent ones in which the Indian community developed recognizable competence. The third is the question of connection to the practical and production processes, which are generally seen as the potential of commercialization and market development in the field of biotechnology.

Among these features, the growth of recognizable communities at the local-national level, which sustain the field of research in terms of R&D groups, is seen to be central to the process of professionalization. The point that trained intellectual human resources would have vanished without these specialized laboratories, leaders and R & D groups stands out glaringly in the Indian context.

In addition, it is important to develop a solid science based regulatory system to ensure safety and confidence of the people in technologies that are developed

4.2.2. Overcoming The Political Landscape

India has 85 crop species in the development pipeline Brinjal, Mustard, Rice, Maize (corn) and Chickpea. The bureaucratic hurdles faced by GM crops and the hostile political climate has made it difficult for GM research and development to be carried on and the GMO in the pipeline cannot seem to advance to the next stage, which is commercialization. In the year 2010, the Minister for Environment, placed a moratorium on the domestic cultivation of GM eggplant, also known as Brinjal. This move put an indefinite hold on the production of GM Crops in India. This has also slowed down research activities involving GMOs as the scientists see further research as an exercise in futility. The situation is further exacerbated by pending supreme cases on commercial release of GM crops

4.2.3. Devolving Biotechnology and Biosafety Capacity to the States

The responsibility for agriculture in India is largely devolved to state level and all states have Departments of Agriculture that include extension services. With several advances in biotechnology, it is natural that state governments wish to take part in the ongoing biotechnology revolution and benefit from the same. The project seems to have centered its activities within the Central Government with very few activities having the involvement of the State Governments. Devolving biotechnology to the States, especially agri-biotech may influence biotechnology development in villages as well as the uptake of the technology.

4.2.4 Paradigm Shift- Uptake of Biotech as agric biotech, time to consider other uses and players

According to a BCIL (2001) report there are total 176 biotechnology based companies in India. As many as 49 per cent of the companies are agriculture-based companies having interests ranging from tissue culture to bio pesticides. Almost 25 per cent of the companies are active in health related activities and are in medical sciences while 26 per cent have varied interest including environmental biotechnology and Agricultural Biotechnology, more so where the food crops are concerned seem to have hit a snag, with the moratorium.

While issuing the moratorium, the then Minister for Environment, said more studies were needed to ensure genetically modified brinjal were safe for consumers and the environment. The minister said "independent scientific studies" were needed to establish "the safety of the product from the point of view of its long-term impact on human health and environment". Making a paradigm shift from agribiotech to use of biotech in other related fields such as Medical Biotechnology and Bioinformatics may be an option to getting the technology make inroads. Medical biotechnology is already playing a major role in shaping the concept of drug discovery, drug delivery, diagnostic methodology, clinical trials, and to a great extent the major lifestyle of the human society. Like in information technology, India has great potential in bioinformatics as well. This comprises a distributed database and network system namely Biotechnology Information System Network (BTISnet) with 7 Centers of Excellence (COE), 11 Distributed Information Centers (DIC), 51 Distributed Information Sub-Centers (DISC), and 98 Bioinformatics Infrastructure Facilities (BIF) in India to promote research in Biotechnology and Bioinformatics. The more other branches of biotechnology are used and are in the limelight, the easier it will be to demystify agricultural biotechnology.

4.2.5. The Role of Gender in Biotechnology

The project integrated gender issues in all of its activities. This may be seen through the trainings, for instance the training of staff on GMO detection and

lab maintenance, irrespective of gender. However, what was glaring is the fact that there were more females than males in the Labs, during the workshop meeting as well as the major policy makers. The project carried out SME training especially for women. The concern here is that there have been several initiatives focused on empowering the women that tend to leave men behind.

4.2.6. Inadequate Public Participation of the real public

Though the project had an entire component on public awareness, the awareness material seemed to focus on regulators, policymakers, scientists, communication specialists, legal experts, and industry. The project also developed and translated material in various regional languages. The dissemination of the material is still underway. The numerous court cases in India are lodged by the public- the common person, who questions the safety of the GMOs. It is apparent that the common person, including the farmers might have had minimum interaction with the project.

Source - Ministry of Environment & Forests, Government of India

CHAPTER FIVE
BEST PRACTICES

5.1 Best Practices in Project Implementation

One characteristic that distinguishes best practice in project implementation is how well the execution is managed. A prerequisite for a successful project implementation is a dedicated project manager who is involved in both planning and ongoing management. In addition, the Government must also be willing to commit sufficient resources to the project before, during, and after implementation.

Dr Vibha Ahuja the Project Coordinator observes that all the staff within the project must understand the entire cycle from planning to execution and must not only focus on one aspect of the implementation. She emphasized on the importance of the internal organization to be actively involved in implementation because they will own the project once the planning phase is completed.

She emphasized on the need for strong project controls and governance as important elements needed to implement a Biosafety system. The implementation plan should include ongoing reviews of project phases throughout implementation, with full participation of all internal and external resources. A combination of project management skills, technical and financial resources, and methodologies are therefore vital to a successful project implementation.

5.1.1Project design

Good design of any project avoids unnecessary complexity, and is based on firm commitments of parties, with clear exit strategies. The project was designed in a manner that ensured there is proper documentation of the project development process which helps in the assessment of the of the progress of the project in particular with respect to involvement of stakeholders and the degree to which ownership of activities and outputs is perceived. The project was also carefully designed thus securing integration and spatial linkage of measurements and related activities among national projects and plans. The design also got full commitment and proactive participation from those actors who play indispensable roles during and after the project completion. The role and support of the higher legally constituted authorities plays a critical role, in the case of the Project, the National Project Director was also the Chair of the GEAC whilst the Secretary of the GEAC was the National Project Coordinator. This helped in the uptake of the project results directly into the Indian Biosafety System for immediate use. This was clearly manifested when the new GEAC website was launched on the margins of the "Way Forward workshop" in March 2017. See www.geacindia.gov.in for tools developed under the current project to be used in support of Government review processes.

5.1.2 Importance of Finding the Right Approach to Capacity Building as an Integral Approach to Capacity Building

Capacity Building in biosafety is not restricted to training of individuals or groups, but is rather a process that requires the integration of all stakeholders (policy makers, academic institutions, finance institutions, the general public, etc.) that can have an influence on the performance of regulatory practices on specific biotechnology activities (such as training of skilled personnel in the Biotechnology Sector). Capacity development as a "stand-alone" action outside the context of a substantive program or project is aimed only at building capacity for its own sake, rather than to address a substantive need (UNEP-UNDP-GEF, 2007).

The project has ensured that Capacity Building takes place at institutional and organizational levels, thus guarantying that safe use and potential benefits of modern biotechnology are widely understood and that the supporting policies are developed and adopted by authorities and the general public and that there is a sustainable development of human resources for Biotechnology and Biosafety. This has been evident in the facilities, equipment and human resource that have been built in institutions.

5.1.3 Local Ownership

With regards to local ownership, two different success factors were identified:

(f) High-level institutional backup and

(g) The inclusion of cultural aspects into Capacity building.

(a) High-level institutional backup

Integrating Capacity Building in the planning and implementation of national policies, strategies and initiatives has proven to be successful for creating ownership and ensuring sustainability. Country ownership and leadership in CB is of critical importance. Capacity Building is effective as long as it is part of an endogenous process of change, getting its main impulse from within.

Many examples can be quoted from the analyzed CB initiatives. For instance, the Ministry of Environment, Forest and Climate Change has fully owned the program and has matched up the funding. During staff interviews, political motivation and ownership were often mentioned as success factors. The linkages of the project with the GEAC through the National Project Director and the National Project Coordinator, who were Chair and Secretary of the GEAC and was a useful practice as it ensures synergies and update by the legally mandated GEAC project results. The linkages of the project with the GEAC through the National Project Director and the National Project Coordinator, who were Chair and Secretary of the GEAC and was a useful practice as it ensures synergies and update by the legally mandated GEAC project results.

A lesson learned during the preparation of Phase II project was that involving all relevant stakeholders into the process from the beginning (participation) was crucial to secure stakeholder interest and commitment to the subsequent implementation of CB measures.

(b) The inclusion of cultural aspects into Capacity building.

Another important aspect to be considered in a CB Strategy is culture. Cultural considerations need to be integrated as part of the strategy, in order to increase the chances of success of Biotechnology activities. Working together with local actors and individuals can provide important insight into cultural issues and help to identify key factors for success of a particular intervention. For example, the public participation component used the approach of developing a film. The film industry- Bollywood in particular is big in India. A lot of people appreciate movies and films. The involvement of the major actors and the production of the films and documentaries on project component activities in the local language- Hindi, which is widely spoken will enable the project reach a wider audience and build more capacity that way. This again stresses the importance of having local infrastructure in place that develops a target group adapted CB offer, taking into account cultural and language issues.

5.1.4 Regional approach and Capacity building

Regional and sub-regional cooperation is highly instrumental for further enhancing capacity building and sharing experiences. There are several countries that are already engaged in developing long-term linkages on a regular basis (e.g. Bangladesh, Bhutan and Sri Lanka). The enhancement of regional and sub-regional cooperation would benefit the region as a whole and, more particularly, low-income countries. This approach mirrors the GEF strategy on regional harmonization of Biosafety Frameworks and will be supporting the implementation of Article 14 of the Cartagena Protocol on Biosafety. Actually, a wealth of information, expertise and tools to detect and make risk assessments have been generated in different countries under the UNEP-GEF funded projects, which will be very useful when shared with the countries lagging behind.

National experts that acquired an outstanding experience through the Project could be highly effective in disseminating good practices at regional level, in crucial areas such as technical guidelines definition, risk assessment and management, risk monitoring, advanced laboratory techniques, among others. Donors' support could also

be more cost-effective when addressing nascent regional approaches and increased South-South cooperation. The project managed to share project results to scientists from developing countries who had come on training under other programs.. This program for instance, saw over 30 scientists working in the labs in India and experiencing first hand the handling of GMOs, from the decision making process, to the use of GMOs in the labs and in the fields.

5.2 Best Practices with regard to Presence of Strategic Elements

5.2.1 Definition of Goals, Vision and Mission

The Project is in line with the Country's vision, mission and goals and/or defines their own set of goals. Clearly defined goals and desired outputs are an important precondition to define concrete activities and handle expectations, and form the core of every capacity building strategy.

A Capacity Building Strategy or project in the context of safe use of modern Biotechnology should, therefore, allow for a long-term planning (at least 5 years) and consist of a mix of short-term, medium-term and long-term targets to - put out the burning fires in capacity demand and at the same time ensure that, in the long run, there will be a sustainable Capacity Development in the sector, with the necessary local leadership and ownership.

5.2.2 Geographical Focus

It is recommendable that a capacity building program should define its geographical focus, maybe in combination with the time dimension (for example, Phase I (short-term): 1-3 States within India, Phase II (medium-term): one region of India, Phase III (long- term): all regions). The decision should be based e.g. on existing partnerships as well as the level of quality of capacities available and the thus resulting demand for building up new capacities.

5.2.3 Strategic Partnerships

The establishment of strategic partnerships is fundamental for the sustainability of Biotechnology at a national, regional and international level. Collaboration enhances the capacity of people and organization to achieve goals through synergy effects, brought about by the efficient and effective combination of complementary skills and strengths, as well as of the human, material and financial resources between the parties engaged in a partnership.

Partnerships differ in form (alliances, consortia, coalitions, networks, etc.), the goal(s) they are trying to achieve and in which stakeholders they bring together (national/local governments, agencies, donors, NGOs, private sector, network, etc.).

5.2.4 Secure Financing

Financing is often the largest barrier to capacity building; and securing financing will be crucial for the success of a capacity building program in a region as wide as India. Many times its lack represents a barrier to the sustainability of certain activities. The Government of India has shown commitment by putting down finance both in cash and in kind. This has contributed considerably to the success of this project. Securing long-term reliable finance is an extremely important factor to the success of a capacity building project.

5.3 Best Practices with regard to Methods and Instruments

5.3.1 Building upon Existing Strategies, Tools and Structures

A large number of institutions including donors, universities, training centers, etc. carry out Biotechnology activities. Most of them have many years of experience in the field of Biotechnology, whether related to medical, agriculture or industrial Biotechnology. This also means that over the years, structures have been built up and strategies, instruments and tools have been developed to develop and implement Biotechnology activities/initiatives/programs. It is therefore crucial for the success of this Project the project engages in a close cooperation with other organizations and institutions in the field of Biotechnology, in order to avoid efficiency losses and overlaps in activities and maximize resource utilization by focusing on the existing gaps with regards to structure, tools and instruments.

5.3.2 Establishment of Local Technology Centers

Local Research and Training Centers are the most effective platform for establishing a pool of experts. Biotechnology Training Centers cannot only build capacity for individuals, they can also contribute to the deployment of technologies by conducting technology research, analyzing the local framework conditions, supporting reform processes, facilitating dialogue between local and international stakeholders and participating in policy making processes.

The project provided leadership in Biotechnology and Biosafety issues through national and regional technology centers. This is also important from the point of view of attracting financing for the development of biotechnology. A large institution stands more chances of acquiring

significant funds for financing Capacity building initiatives in Biotechnology than individual initiatives.

5.3.3 Training the Trainers

The project has shown that building local capacity for training is crucial to ensure the sustainability of Biotechnology and Biosafety. Training a set of individuals for a specific project will only ensure that the project activity is executed successfully, given that the trained capacities work in the project for its entire lifetime. In order to achieve a constant supply of trained capacities in India for biosafety, it is necessary to build up qualified local training and teaching staff. These individuals, whether embedded in an institution (university, training center, research institute, etc.) or working on an independent basis, can guarantee that the demand for acquiring new skills and knowledge is covered. The project has used various approaches to training the trainers but many common elements can be found, such as working with local partners (institutions, universities, etc.), identifying potential training providers and equipping them with the necessary skills to implement training (training skills, training methods but also knowledge transfer on biotechnology), encourage trainers to train other trainers to achieve multiplication effects, twinning, etc.

5.3.4 Including Biotechnology and biosafety into Basic Education Curricula

In order to create a new generation of biosafety practitioners, the concept of safe use of biotechnology should be also enrooted in basic education. The project has introduced some interesting initiatives targeted at young people, which the Government can adopt and replicate in the school curricula.

5.3.5 Networks

Networking does not only enhance the proliferation of knowledge and expertise but it also furthers the establishment of partnerships, working relationships, etc., which are key to the sustainability of biotechnology. Only when a trained human resource is actually applying its acquired skills and expertise, the capacity building process can be regarded as successful. The project has established and used new or existing network. This can be viewed as an important element for the success of its activities.

5.3.6 Synergies–Potentials for Partnership

Presently, a large number of biotechnology initiatives have been launched and are operating, or are being planned. The

CHAPTER SIX
CONCLUSION AND WAY FORWARD

6.1 CONCLUSION

While the importance of capacity building is widely acknowledged, more attention needs to be drawn to the identification and implementation of effective capacity building approaches. The ultimate goal of capacity building is to sustain a process of individual and organizational change and to enable organizations, groups and individuals to achieve their development objectives. Any capacity building activity needs to be carefully designed so that it contributes to this goal. In this process, it is essential that the needs of the beneficiaries as well as the already existing capacities in a country are carefully assessed and that the specific capacity building objectives are clarified.

To eventually sustain a process of change, a critical mass of people is needed that shares the same values, pursues the same objectives, and is equipped with the necessary knowledge and skills. To move in this direction, groups outside the national government need to get more attention, including local level officials, researchers, civil society groups and private sector representatives to ensure their continuous contribution towards sustainable development. In addition, the generation of future decision-makers need to be targeted through the systematic integration of sustainable development into national education programs.

This task obviously goes beyond the scope of the human and financial resources of international organizations and implies a fundamental change in the approach to capacity building. Rather than offering a vast variety of capacity building activities, which are often one-off events and not properly coordinated, international organizations could focus their efforts on institutionalizing capacity building programs at regional and national levels and building the structures in the countries through which capacity building programs could be offered on a regular and long- term basis. Instead of offering capacity building programs themselves, international organizations could see their role in identifying institutions at national and regional level that have a potential to become capacity building providers, catalyzing and kick-starting activities, and providing targeted financial and technical assistance, while national institutions and local exerts take the lead in implementing the activities.

6.2 WAY FORWARD

6.2.1 Institutionalizing capacity building programs at regional and national level

To increase the effectiveness of biosafety capacity building activities the focus should be on building the structures in the regions thus offering capacity building on a regular and long-term basis. India has capacity building providers of different type who are already available but they are usually under funded and not well equipped (e.g., universities, government training centers, etc.). Technical and financial assistance provided by international organizations could focus on sustaining, expanding and improving these structures, with the objective that capacity building programs on biotechnology can eventually be provided on a regular basis. Efforts and funding should also be put up to support cutting edge biosafety research which can then feed into the regulatory practice on Biosafety in India.

Once structures are established and functioning, new developments or topics can be easily brought to the relevant target group. If the programs are attractive enough they could even be run as part of a commercial activity, raising funds to reach financial sustainability.

The range of biotechnology and courses offered at the university could be adopted and linked to any other major program initiated in the country to create synergies and strengthen efforts by offering accompanying training courses. With courses being offered on a regular basis, and a larger number of people being trained, these efforts are much more likely to contribute to the critical mass of people needed that embrace the ideas of sustainable development of Biotechnology in India.

6.2.2 Building on Existing Institutions

International organizations will still have a major role to play in catalyzing and kick-starting activities, but any program initiated should at least to some extent contribute to building institutional capacities for long-term delivery of capacity building activities. Rather than planning capacity building workshops themselves, international organizations could identify the institutions in a country that have a potential to become capacity building providers. As much as possible it should be avoided that new structures are created, as long as there are already some in place. For any new activity, from the planning stage onwards, local institutions and experts should be involved as much as possible in organizing and carrying out the capacity building action. While receiving technical and financial support, any involvement will already be a learning-by-doing experience for the institutions, and will be the first step towards building in-house capacity and a reputation.

Shifting the focus of work to building up institutional structures for long-term capacity building programs in countries, the results and indicators reflecting the success or failure of capacity building programs also need to be adjusted. The success of capacity building activities is genuinely difficult to monitor, as it is a soft target difficult to quantify. Reports on capacity building therefore often remain at a level describing that trainings have been held, that participants have been trained, and the workshop report qualifies as a main output. Giving stronger emphasize to the institutionalization of capacity building activities at regional/ local level, will require redefining results, such as:

(h) Training courses on biosafety have been integrated into the national training and education system;

(i) Budget for the mid-term delivery of the course has been secured externally or internally;

(j) A local institution is running a capacity building program with local trainers on a regular basis; etc.

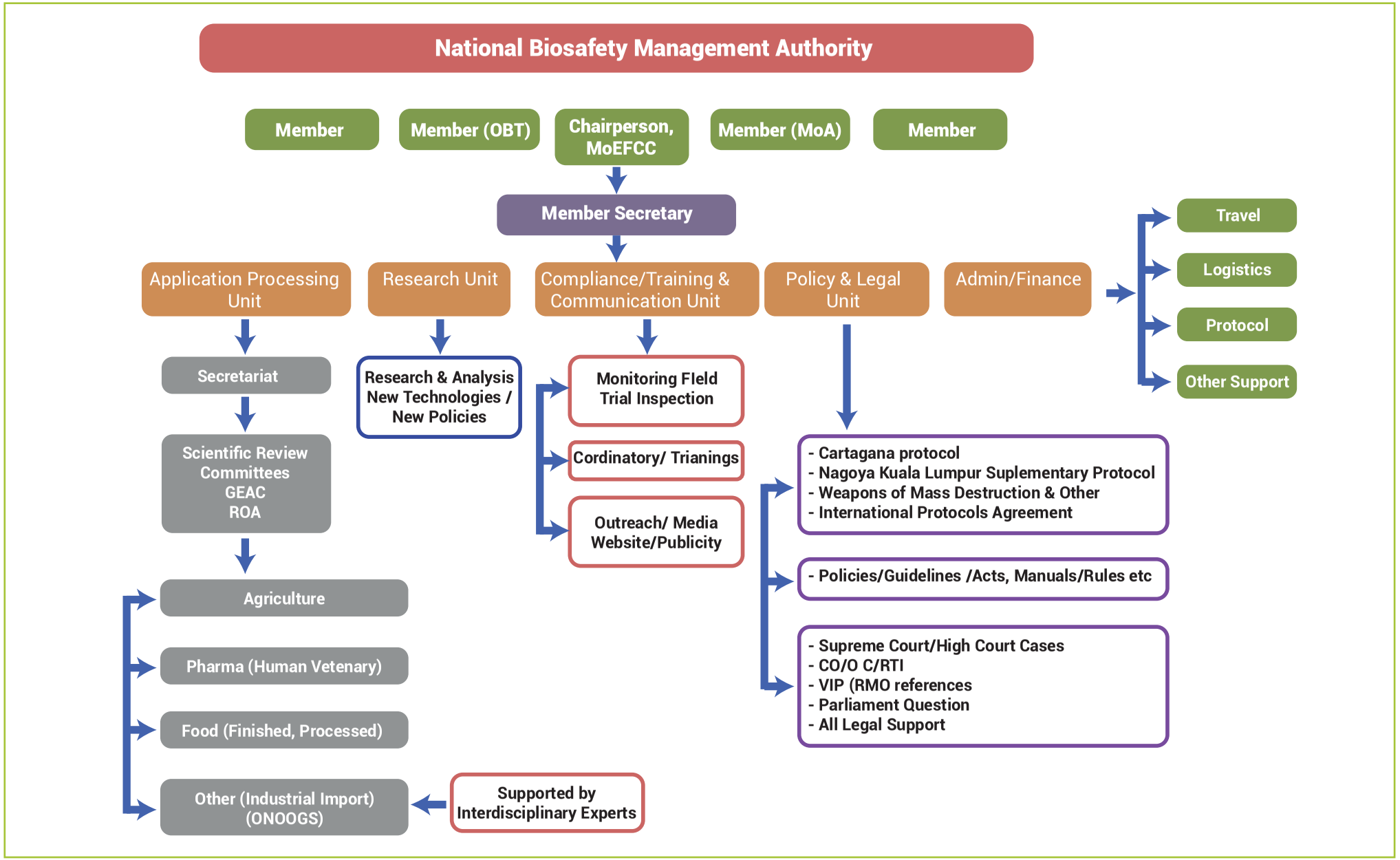
EXPERT VIEWS

Alex Owusu-Biney, UNEP Biosafety Expert

To actualize these processes and guided by the assessment and feedback, the issue of a coordinated regulatory process comes to the fore and brings to light the earlier discussion on a National Biosafety Regulatory Authority to "sew" or bring in the missing gaps at both the Federal and State Levels. To consolidate such an approach, it is recommended guided by best practices in Jurisdictions such as Australia, Vietnam and Philippines where field visits were undertaken and South Africa, that a coordinated Regulatory Authority to be set up similar to the organogram below

Source - Getty Images

Possible Biosafety Regulatory Authority



6.2.3 Target the right people to build a critical mass

Capacity building activities often put strong emphasize on training key players in government, such as senior officials that actually take decisions. This can lead to a situation where a fairly limited group of people, who usually already received a comparably good education, is involved in all sorts of capacity building activities. While senior official are definitely an important target group, more emphasis needs to be put on building the capacities of other groups in society. One major constraint of developing country administrations is often the capacity to implement reforms.

While the necessary legislation to regulate biotechnology may exist, problems arise in the implementation. Implementation, however, is not merely the task of senior officials at national level, but involves different levels of governments, usually putting a lot of responsibility into hands of officials at the local level. There is tremendous need to build capacity at these levels, but the attention for those groups is comparatively low. A dedicated Regulatory Authority could pick up such a mandate and build the capacity to assist India meets its obligations at the national and international levels.

Similarly important is capacity building for other stakeholders groups outside the government to eventually build a critical mass of people that can initiate and sustain a process of change. Any capacity building activity, including training workshops and country projects, should make an effort to build capacity of stakeholders from different groups of society, and provide a platform for these groups to interact with each other.

Researchers, civil society groups, companies, associations, farmers unions are important groups to push and redirect government decisions or initiate processes of change outside the government sphere through new business ideas or social trends. To build a critical mass of people pursuing the ideas of biotechnology development, these groups need as much attention as government officials. For any policy decision that a government is taking the support or opposition of major stakeholder groups will be key to the success of the capacity development. If, however, these groups lack knowledge about the issues at stake as well as the capacity to sufficiently analyze the situation, decisions may be made without their input.

Considering all the different groups mentioned, the number of individuals and institutions that need to be targeted by capacity building activities becomes fairly large. Just dealing with senior officials - assuming that there would be 100 developing countries and 50 key officials in each country – 5000 thousand people need to be targeted. Assuming each country has 5 provinces and another 50 key people at provincial level should be involved, this will be an additional 25,000 people. Including the local level and other stakeholder groups, numbers will rise quickly. This obviously goes beyond the scope of the human and financial resources of international organizations. To actually build a critical mass of people that can sustain a process of change towards the development of biotechnology is a fundamental change in the approach to capacity building is needed.

From the lessons learnt and best practices assessment, most stakeholders were calling for a follow up Phase III project. For such an intervention, the following areas could be considered:

The Indian Biosafety Regulatory System – Decision Support Tools in the management of new trends in Modern Biotechnology (USD 4 – 5 million grant, MoEF&CC as Exec Agency)

Envisaged areas of intervention

- Strengthening of institutional capacity and mainstreaming Biosafety at the Federal and State Levels through the Indian Biosafety Regulatory System
- Development and implementation of regulatory instruments to support handling of new and emerging biotechnology products beyond Agri biotechnology
- Review and update Risk Assessment and Risk Management instruments to enable handling of stacked events and new products post adoption of the Cartagena Protocol on Biosafety including testing of the Road map on Risk Assessment/Internalization and updates of developed Biology documents
- Development of a Liability and Redress Regime to support the Indian Biosafety Framework
- Tools on sampling, thresholds and testing of LMOs including handling of Low Level and Adventitious Presence of LMOs
- Tools and instruments for monitoring and enforcement including dedicated training for customs and front line staff in handling of transshipments of LMOs
- Regional Networking and harmonization of Biosafety Regulatory Frameworks in the South Asia Region

ANNEX 1

Stakeholders	Type of involvement
Decision Makers/ Policy Makers Concerned Ministries viz MoEF&CCC, DBT, MOA, Ministry of Health and Family Welfare (MoHFW), Ministry of Finance (MoF), Ministry of External Affairs (MEA) etc. Relevant agencies and authorities viz. FSSAI, PPV&FRA, ICMR, ICAR, CSIR, NBA, etc. Members of statutory committees viz. GEAC, RCGM, MEC and SBCCs.	involved in project implementation as members of National Steering Committee to provide for the required inter-ministerial cooperation. Invited to take part in consultations and meetings on key issues at national, sub-regional and regional level. The relevant agencies were also involved as resource persons in programs on awareness raising.
Scientists/technical experts, researchers and technicians from public and private sectors including academic institutions	invited to take part in consultations and workshops for training of trainers and awareness raising. involved in developing training modules and working knowledge documents involved with developing outreach materials for different target groups.
Legal experts and economists	invited for consultations on documents related to socio-economic assessment. Legal experts and economists were involved in developing training modules and working knowledge documents involved in developing outreach materials for different target groups.
Enforcement officials including Customs, Plant Quarantine, state agricultural departments, members of SBCCs, DLCs and IBSCs etc.	invited to participate for training workshops. assist in post-release monitoring and enforcement at border controls.
Interest groups, teachers, students, mass media and extension workers	invited to take part in awareness raising meetings received outreach material designed for the different target groups.

ANNEX 2

LIST OF PERSONS INTERVIEWED

1. Dr. Amita Prasad, Additional Secretary, MoEF&CC&CC and National Project Director (NPD), Phase II Capacity Building Project on Biosafety
2. Dr. Alex Owusu-Biney, Portfolio Manager, United Nations Environment Program (UNEP)
3. Dr. Morven McLean, Executive Director, ILSI-Research Foundation
4. Dr Sachin Chaturvedi, Director-General, Research and Information System for Developing Countries (RIS)
5. Shri Ajay Narayan Jha, Secretary, MoEF&CC&CC
6. Dr Vibha Ahuja, Chief General Manager, BCIL, the Project Coordination Unit (PCU) for the Phase II Capacity Building Project on Biosafety
7. Dr. S.K. Saxena, Director, Export Inspection Council
8. Dr. (Mrs.) Gurinder Jit Randhawa, Principal Scientist, ICAR-NBPGR
9. Dr P.K. Ghosh, Former Advisor, Department of Biotechnology
10. Dr. Ravi Khetarpal, Regional Advisor (Strategic Science Partnerships), CABI South Asia
11. Dr. Murali Krishna Scientist - D Ministry of Environment, Forest & Climate Change
12. Dr. Gita Bamezai, Professor, Department of Communication Research, Indian Institute of Mass Communication
13. Dr. Celia Chalam, Principal Scientist, National Bureau of Plant Genetic Resources

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