

# CAPACITY BUILDING PROJECT ON BIOSAFETY

PHASE-II

PROJECT BRIEF



Executed By



MINISTRY OF ENVIRONMENT & FORESTS  
Government of India

# The Context

India has been actively engaged in setting up a strong biosafety regulatory systems in response to the fast-growing biotechnology sector in the country. India is also a Party to the Cartagena Protocol on Biosafety (CPB)<sup>1</sup>, an international agreement which aims to ensure the safe handling, transport and use of Living Modified Organisms (LMOs)<sup>2</sup> resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

In view of continuous developments in biotechnology as also emerging challenges in its regulation, several capacity building activities have been regularly undertaken in the country by the Ministry of Environment & Forests (MoEF), housing the apex regulatory body at the national level. MoEF is also the nodal Ministry for implementation of CPB. In addition to national initiatives, MoEF had also accessed funding

from the Global Environment Facility (GEF) through the World Bank in 2004 for a biosafety capacity building project, under which a series of activities were undertaken for a period of four years upto 2007.

Building on the foundations of the above project, the “Phase II Capacity Building Project on Biosafety” has been initiated by MoEF in 2012 for a period of four years with an objective to strengthen the biosafety management capacity in the country. The Phase II project has been conceptualized to supplement the ongoing biosafety capacity building initiatives in India, integrate international experience and promote regional cooperation. The Project including the project design and thrust areas has been prepared through a consultative process by seeking inputs from various stakeholder viz. government, scientists, public-sector institutions, NGOs and potential project partners.

1. The Cartagena Protocol on Biosafety was adopted on 29 January 2000 and entered into force on 11 September 2003. The Protocol has been ratified by 167 countries. The Conference of Parties serving as Meeting of Parties (COP-MOP) is the Governing Body of the Protocol and meets every alternate year to review the implementation of the Protocol. The text of the Protocol and other details can be accessed at <https://bch.cbd.int/protocol/>
2. A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.



# Project Highlights

## Executing Agency

Ministry of Environment and Forests, Government of India

## Duration of the Project

2012-2016

## Fund Allocation

US \$ 2.7 million

## Objective

The objective of Phase II Capacity Building Project on Biosafety is to strengthen the biosafety management system in India to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities in agriculture.

## Thrust Areas

**Risk Assessment and Risk Management (RARM)**

**Handling, Transport, Packaging & Identification (HTPI) of LMOs**

**Socio Economic Considerations (SEC)**

**Public Awareness (PA)**

## Complementarity with the Strategic Plan for the CPB (2011-2020)

The thrust areas and activities outlined in the project are in line with the focal areas identified in the Strategic Plan for CPB for the period 2011-2020, adopted in the year 2010 having five strategic objectives i.e. 1. Facilitating the establishment and further development of effective biosafety systems for the implementation of the Protocol; 2. Capacity building; 3. Compliance and review; 4. Information sharing; 5. Outreach and cooperation.

## Target Stakeholders

Decision/policy makers, scientists/researchers and technicians from public and private sectors, legal/socio-economic experts, enforcement officials including customs, plant quarantine, state agriculture departments, members of regulatory agencies, interest groups such as farmers, teachers, students, mass media, extension workers, developers, lawyers, NGOs etc.



# Project Design

## Technical Components

Stocktaking Assessment	Collection of updated baseline information in specific areas viz. RARM, LMO detection and HTPI to fine tune the project design and guide the planning of specific project activities.
Strengthening Regulatory and Legal Framework	Proposed activities involve preparation of guidelines, protocols and documentation to strengthen the legal and regulatory framework consistent with CPB. Consists of three sub-components centering on RARM, SECs and HTPI.
Institutional Strengthening	Strengthening of laboratories for detection of LMOs to facilitate enforcement and compliance during transboundary movement of LMOs.
Human Resource Development	Development of training modules/manuals and imparting training to strengthen strategic areas such as risk evaluation and enforcement at the ports of entry.
Public Awareness	Improving access to biosafety information systems through various communication tools such as biosafety websites, outreach materials like educational programmes, primers, brochures, FAQs, newsletters etc. in regional languages both through print and electronic media targeting various stakeholders.
Regional Networking and Cooperation	Sharing of information and experience at the regional level through networking with regulatory agencies and experts.



# RISK ASSESSMENT AND RISK MANAGEMENT

## Thrust Area I

The CPB features a set of procedures for LMOs that are to be intentionally introduced into the environment and for LMOs that are intended to be used directly as food or feed or for processing. For taking decisions on the above, the Protocol empowers governments to make decisions in accordance with the scientifically sound risk assessments. These assessments aim to identify and evaluate the potential adverse effects that a LMO may have on the conservation and sustainable use of biodiversity in the receiving environments. They are to be undertaken in a scientific manner using recognized risk assessment techniques. Each country is also required to manage and control any risks that may be identified by risk assessments. Key elements of effective risk management include monitoring systems, research programmes, technical training etc.

Article 15, 16 and Annex-III of the Protocol provide for guidance in this matter. Several decisions have been taken in various meetings of COP-MOP emphasizing on the need for capacity building in RARM. Guidance documents and training tools have also been developed through the technical groups, which are presently under discussion and testing.

Since India is a major developer of LMOs with extensive research and development underway in the country, strengthening risk assessment and risk management is a thrust area identified under the project.



## Activities

### Stocktaking

- Prepare base paper on crops & traits under development, need for biology documents and information on non-target and beneficiary organisms in different agro-ecological zones

### Resource documents

- Prepare base paper on the status of conformity of existing procedures and guidelines with Article 15, 16 and Annex III of CPB.
- Prepare and review of biology documents for eight crops such as chickpea, pigeon pea, sorghum, papaya, mustard, tomato, rubber and potato.
- Collect baseline data on the presence of wild relatives of eight crops mentioned above.

### Guidance documents

- Develop risk analysis framework and its validation using an example.
- Review of international practices in ERA through a study tour and development of ERA guidelines.
- Develop procedures for assessing risks associated with stacking of genes expressing multiple traits.
- Identify roles and responsibilities of various agencies for post release monitoring and development of guidance document for post release monitoring.
- Convene workshop for identification and development of indicators for study of impact on non-target organisms.
- Develop list of non-target organisms with reference to specific traits/crops in different agro-ecological zones.

### Training

- Develop training modules/manuals for conducting environmental RA & RM.
- Training of experts in RA & RM involved in technical and scientific advisory committees and biotech R&D developers.
- Training in dossier development for product developers.
- Develop training modules for monitoring field trials and compliance evaluation.
- Training of members of monitoring teams responsible for compliance evaluation, technical persons conducting field trials and extension functionaries.

# SOCIO-ECONOMIC CONSIDERATIONS

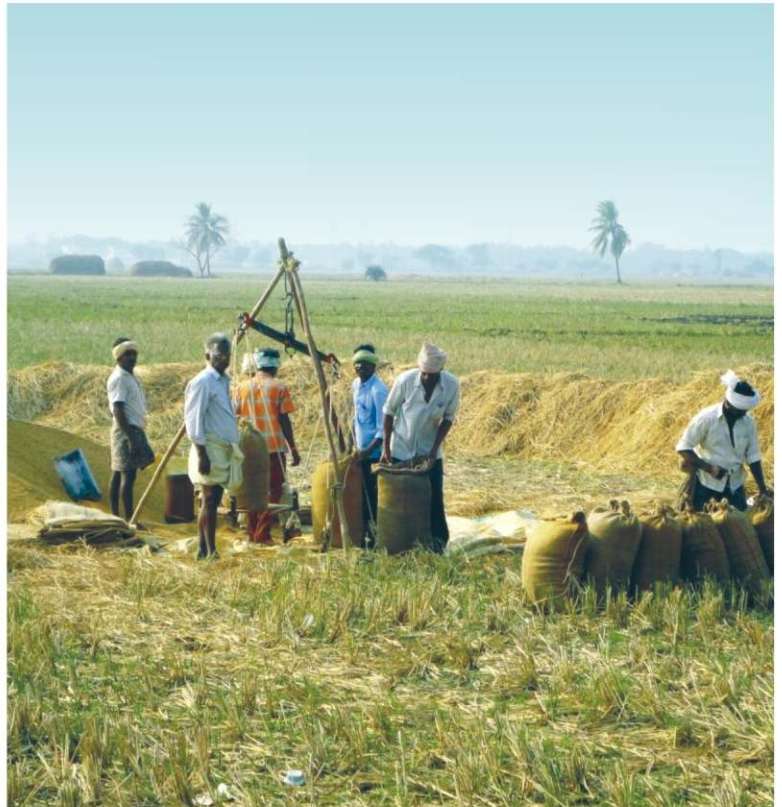
## Thrust Area II

Article 26 of the CPB provides an enabling provision to Parties to take into account SECs arising from the impact of LMOs on the conservation and sustainable use of biodiversity. As per COP-MOP decisions, Parties are encouraged to conduct research on socio-economic impact of LMOs through involvement of local institutes of higher education with a view to build domestic capacity in socio-economic impact analysis. Accordingly, relevant activities have been included as a separate component in the project design to work on development of guidelines and methodologies for socio-economic assessment and cost benefit analysis including designing of questionnaires and their validation through sample surveys. These activities are expected to help in understanding relevance of socio-economic considerations in domestic scenario as well as develop India's position for future meetings of the COP-MOP.

## Activities

### Resource Documents

- Design model questionnaires for socio-economic assessment and validate them through sample survey.
- Develop guidelines, tools and methodologies for socio-economic assessment respect to both ex-ante and ex-post studies.
- Develop guidelines and methodologies for cost benefit analysis.

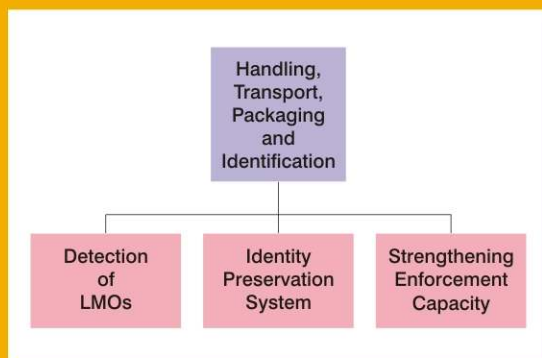


# HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

## Thrust Area III

The CPB requires safe handling, transport, packaging and identification of LMOs that are subject to transboundary movement. Parties are required to have specific measures in place to ensure the above that may include specifying documentation requirements, strengthening enforcement systems and facilities for sampling, detection and identification of LMOs.

The proposed activities under HTPI in the project can be categorised into three subcomponents as indicated under:



## Activities

### DETECTION OF LMOs

#### Stocktaking Assessment

- Prepare a base paper on status of facilities, infrastructure, human resource, level of expertise in selected institutions.
- Identify requirements for operationalizing a state of the art referral laboratory for the detection of LMOs.
- Conduct long term funding assessment to sustain the national referral laboratory and its associated network of laboratories.

#### Institutional Strengthening

- Carry out a feasibility study on LMO detection through a network of LMO detection laboratories.
- Identify potential project partners.
- Establish referral laboratories with a network of institutions for LMO detection.
- Improve infrastructure and facilities for LMO detection in the identified laboratories.
- Accredite laboratories as per international norms.

#### Resource Documents

- Develop sampling procedure and methodologies for LMO detection.
- Develop SOPs and protocols for participating laboratories and relevant agencies such as customs and plant quarantine.

#### Training

- Training of laboratory technicians in LMO detection.
- Training of laboratory staff for maintenance of equipments.

### FEASIBILITY OF IDENTITY PRESERVATION (IP)

#### Resource Documents

- Conduct a study of existing IP systems for export crops like Basmati Rice and Soybean.
- Conduct a feasibility study for implementing an IP system for handling LMOs in India.

### STRENGTHENING ENFORCEMENT CAPACITY

#### Stocktaking Assessment

- Prepare a base paper documenting the gaps between existing system and country obligations under Articles 8, 10 and 18(2) of CPB.

#### Resource Documents

- Review strategies for sampling, detection, quantification and certification of LMOs from selected importing/exporting countries.
- Prepare a report on suitable options for India and identify institutions responsible for certification and testing.
- Prepare training modules and working knowledge documents for enhanced enforcement at points of entry.

#### Training

- Training of customs officials on verification of documentation requirements for trans boundary movement and use of Biosafety Clearing House (BCH).
- Training of plant quarantine officers for on-site verification of LMOs and use of BCH.
- Develop an online technical backstopping mechanism or system for enforcement officers at points of entry.
- Develop hands on workshops for enforcement officers at regional and sub-regional levels.

# PUBLIC AWARENESS

## Thrust Area IV

Public awareness, education and participation have been identified as key elements for the effective implementation of the CPB. It is important for the public to know and understand the issues and processes related to LMOs and to have access to relevant information in order to make informed choices and to be able to participate effectively in the decision-making processes.

The Protocol therefore calls for cooperation on promoting public awareness on the safe transfer, handling and use of LMOs. It specifically highlights the need for education, which will increasingly have to address safety concerns of LMOs as biotechnology becomes more and more a part of our lives. Several activities related to public awareness have been regularly carried out through the national resources as well as Phase-I capacity building project. It is proposed to continue with such initiatives as part of Phase-II capacity building project with newer communication and outreach tools and techniques.



## Activities

### Resource Documents

- Develop risk communication strategy for various stakeholders.
- Develop training modules and training workshops in risk communication for key policy makers and experts.
- Develop and disseminate outreach programmes to implement the risk communication strategy through print and electronic media.
- Prepare audiovisual educational material on awareness of biotechnology and biosafety issues for teachers and students.
- Develop primers/brochures/booklets/FAQs, glossary of terms and other outreach material in regional languages.

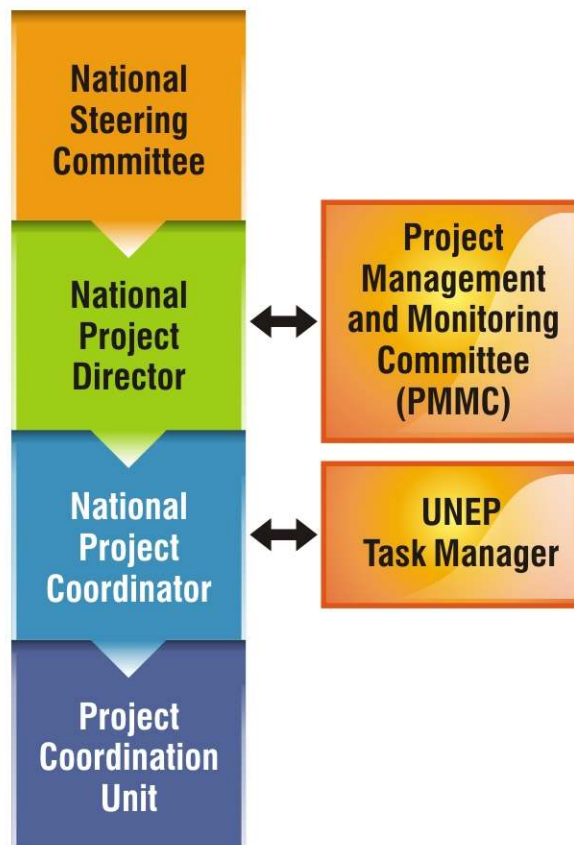
### Awareness Programs

- Organize awareness workshops on biosafety for media.
- Organize a quiz programme for school children.
- Organize national workshop for key stakeholders for implementation of public awareness strategy.
- Organize an international workshop for sharing experience.
- Upgrading the national biosafety websites.

### Website and Newsletter

- Timely deposition of regulatory decisions on LMOs in the BCH.
- Publication and distribution of biosafety newsletter on a quarterly basis.
- Convene regional workshop on sharing experience in risk communication for awareness raising.

## Institutional Co-ordination and Support for Project Supervision



## ANUBIS: A New UNEP Biosafety Information System

Project management and financial reporting for the Phase II Capacity Building Project on Biosafety is undertaken using ANUBIS, a project management tool provided by UNEP. It is a web based central database developed by UNEP with access to national project coordinators and other concerned persons for all UNEP supported capacity building projects. The use of ANUBIS helps in timely reporting, management of information and release of funds. The project implementation staff have been trained in use of ANUBIS with UNEP support.



## Stakeholder Involvement

Stakeholders	Type of Involvement
Decision /Policy Makers	<ul style="list-style-type: none"> <li>❖ Members of National Steering Committee.</li> <li>❖ Consultative meetings on key issues at national, sub-regional and regional level.</li> <li>❖ Resource persons in programmes on awareness raising.</li> </ul>
Scientists, Researchers and Technicians from Public and Private Sector including Academic Institutions	<ul style="list-style-type: none"> <li>❖ Consultations and workshops for training of trainers and awareness.</li> <li>❖ Developing training modules and working knowledge documents.</li> <li>❖ Developing outreach materials for different target groups.</li> </ul>
Legal and Socio-economic Experts	<ul style="list-style-type: none"> <li>❖ Consultations on documents related to socio-economic assessment.</li> </ul>
Enforcement Officials: Customs, Plant Quarantine, State Agricultural Departments, members of State Biotechnology Coordination Committees (SBCCs), District Level Committees (DLCs) and Institutional Biosafety Committees (IBSCs) etc.	<ul style="list-style-type: none"> <li>❖ Participate in training workshops for enforcement at border controls.</li> <li>❖ Participate in training workshops for strengthening monitoring mechanisms including pre and post release monitoring.</li> </ul>
Interest Groups : Farmers, Teachers, Students, Mass Media, Extension Workers, Inspectors, Developers, Lawyers, NGOs etc.	<ul style="list-style-type: none"> <li>❖ Participate in awareness raising meetings.</li> <li>❖ Receive outreach material designed for different target groups.</li> </ul>

## Expected Project Outcomes

Project Components	Expected Outcomes
Strengthening Regulatory and Legal Framework	<ul style="list-style-type: none"> <li>❖ A legal and regulatory framework that is consistent with the CPB is strengthened to facilitate informed and scientific decision making. <ul style="list-style-type: none"> <li>• Technical tools for effective risk evaluation, management and monitoring of LMO(s) is in place.</li> <li>• Parameters and methodologies for socio economic assessments is developed.</li> <li>• An operational administrative systems for safe handling, transport, packaging and identification of LMOs is in place.</li> </ul> </li> </ul>
Strengthening Institutional Capacity	<ul style="list-style-type: none"> <li>❖ Institutional capacity is enhanced for LMO detection in a network of laboratories in terms of infrastructure, procedures and trained manpower.</li> </ul>
Human Resource Development	<ul style="list-style-type: none"> <li>❖ Trained manpower is available for strategic areas such risk evaluation, monitoring and management and enforcement of procedures for detection of LMOs during transboundary movement.</li> </ul>
Information Dissemination for Enhancing Public Awareness	<ul style="list-style-type: none"> <li>❖ Methods and modules for public education and awareness in national and regional languages are available for wider dissemination of information on biotechnology and biosafety.</li> <li>❖ Public awareness on biosafety issues is enhanced.</li> </ul>
Regional Networking and Cooperation	<ul style="list-style-type: none"> <li>❖ Regional networking and cooperation in biosafety including implementation of similar projects is promoted.</li> <li>❖ A cost effective method to pool regional resources is developed.</li> </ul>



### Important Contacts

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