

Sharing Indian Experience of Using Multiple Tools for Capacity Building in Biosafety

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INDIAN SCENARIO REGARDING GM CROPS

- Regulatory framework for Genetically Modified Organisms (GMOs) in place since 1989
- Rules notified under Environment Protection Act elaborated by series of guidelines on various aspects viz research, containment requirements , confined field trials, food safety etc.
- Regulations implemented through six statutory committees consisting of multidisciplinary experts and concerned ministries/ departments.
- Extensive investments in research in agricultural biotechnology
- Approval of Bt Cotton, the first GM crop for commercial cultivation in 2002
- More than 10 million hectares under Bt Cotton cultivation in 2011-2012 accounting for approximately 90% of total area under cotton crop.
- Several GM crops viz brinjal, okra, maize, rice, potato, mustard etc are in the pipeline for regulatory approval
- India ratified the Cartagena Protocol on Biosafety in 2003



NEED FOR CAPACITY BUILDING

- Large pool of scientific expertise but knowledge on biosafety and regulatory issues need s to be strengthened.
- Large no. of organizations involved in research and development, more than 600 Institutional Biosafety Committees (IBSCs) in place.
- Multiple languages used, India has 16 official languages.
- Compliance to obligations under the Cartagena Protocol on Biosafety
- Need for sustainable capacity building initiatives.
- Wide range of stakeholders involved.



STAKEHOLDERS TO BE TARGETTED

- Decision/Polymakers (Senior Government Officials)
- Regulators (e.g: Application reviewers/assessors, Advisors)
- Enforcement Officials (e.g: Field trial inspectors, Food and Agriculture department officials, Customs and Plant Quarantine officers)
- Scientists/Technical Experts/Personnel's (inclusive of both public and private sector)
- Legal Experts
- Economists
- Data/Information Managers (including IT specialists)
- Researchers and Technicians
- Graduate and Undergraduate Students
- Interest Groups (e.g: Consumer groups, farmer associations, professional associations, NGOs)
- Mass Media And Outreach/Extension Workers (e.g; Journalists and agriculture extensionists)
- General Public And Politicians



Biotech Consortium India Limited

INCORPORATED

: 1990

PROMOTER

**: Department of Biotechnology,
Government of India & All India
Financial Institutions**

Project
Management

Consultancy

Technology Transfer

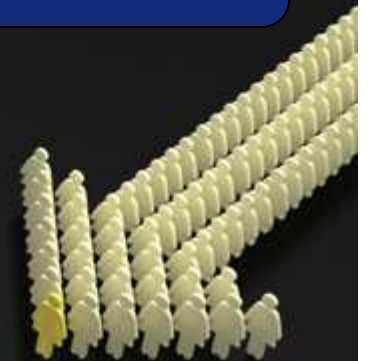
Certification
Services

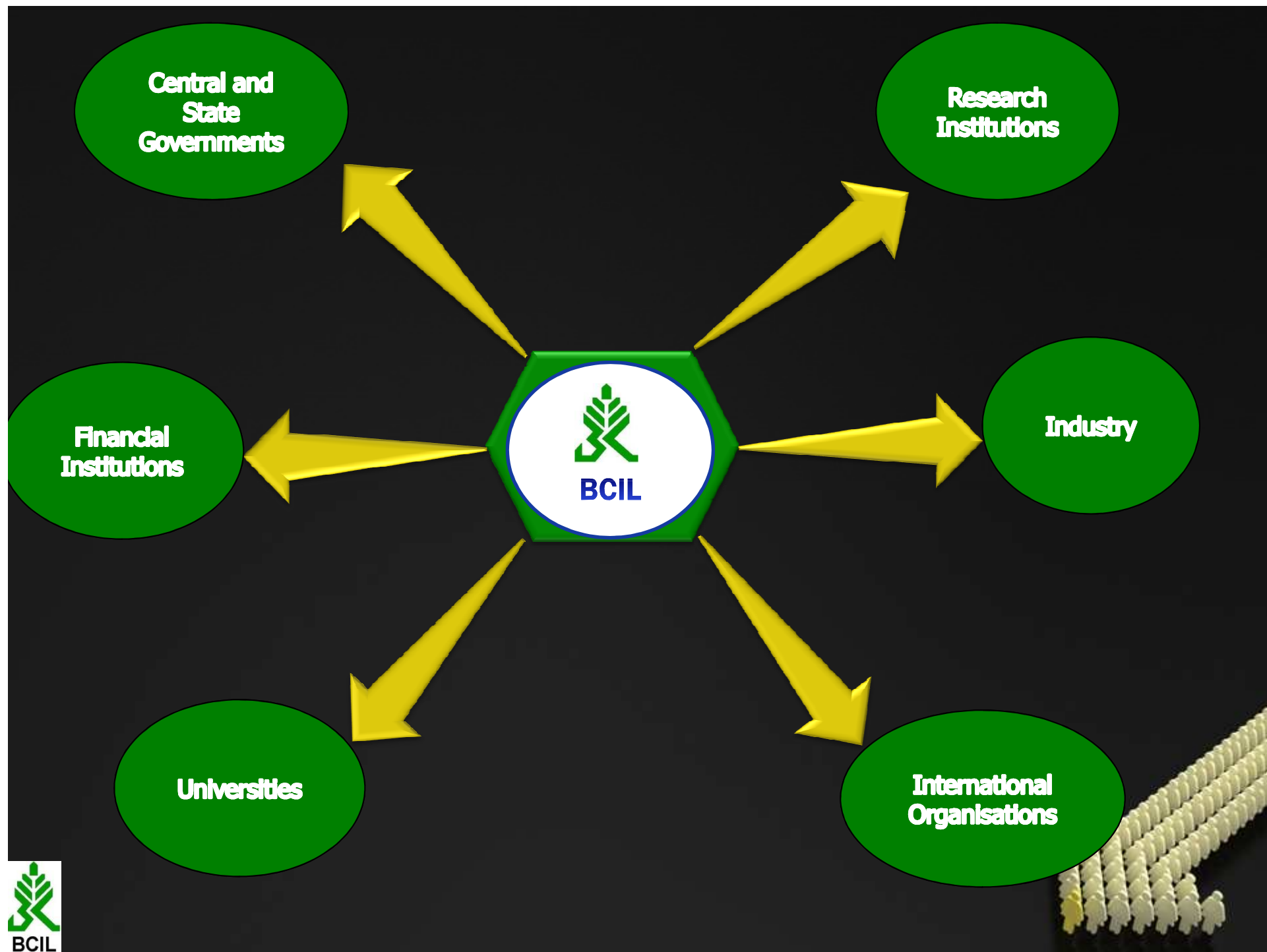
Biosafety

Information
Services

IP Management

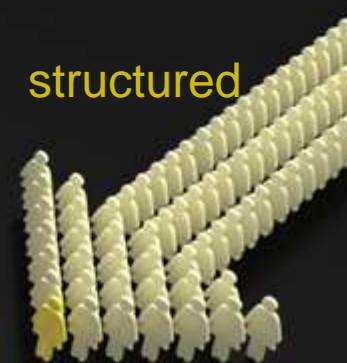
Human Resource
Development





ACTIVITIES INVOLVING BIOSAFETY

- Started working in the area of biosafety in 1998 ; involved in organizing two UNEP/GEF supported Asia Pacific Regional workshops on Biosafety at New Delhi and a series of 5 events on national regulatory framework in India
- Since then working closely with concerned ministries viz Ministry of Environment and Forests, Department of Biotechnology, Ministry of Agriculture, Indian Council of Medical research etc., state governments, universities, research institutions, industry and other concerned agencies.
- Used multiple tool viz. national/international, regional/state level events, technical trainings, websites, newsletters, publication etc. coverage for ensuring wider coverage and outreach
- Conducted a Training needs assessment survey to ensure structured approach and planning



MULTIPLE TOOLS USED FOR CAPACITY BUILDING



INTERNATIONAL/NATIONAL EVENTS ON

- **Foods derived from GE plants: Issues for consumers, regulators and scientists**
- **Implications of the Cartagena Protocol on Biosafety**
- **Current Approaches to the Environmental Risk Assessment of Genetically Engineered Crops**
- **Strengthen regulatory compliance for the DBT nominees and IBSC members.**
- **Management and monitoring of field trials of GM crops**
- **Issues related to CPB**
- **Post release Monitoring at state and district level**
- **Safety assessment of GM foods**
- **Biosafety issues related to transgenic crops with special focus on Bt Cotton**
- **Liability and redress issues**
- **Setting up of Biotechnology Regulatory Authority**
- **Role of State and District level agencies**
- **Technical trainings for experts on food safety**



IGMORIS

INDIAN GMO RESEARCH INFORMATION SYSTEM

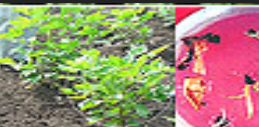
Indian GMO Research Information System (IGMORIS) is a web based database on research on GMOs supported by Department of Biotechnology

Purpose: To make available objective and realistic scientific information relating to GMOs and products thereof under research and commercial.

It is of use to all stakeholders including scientists, regulators, industry and the public in general. It is also expected to promote national and international collaborations in biotech research.

- The collection of information for this database is being done by extensive networking and frequent periodic interaction with various public and private institutions and funding agencies all over the country.
- The information is placed in a user friendly form on the website with a facility to search the database for specific enquiries.

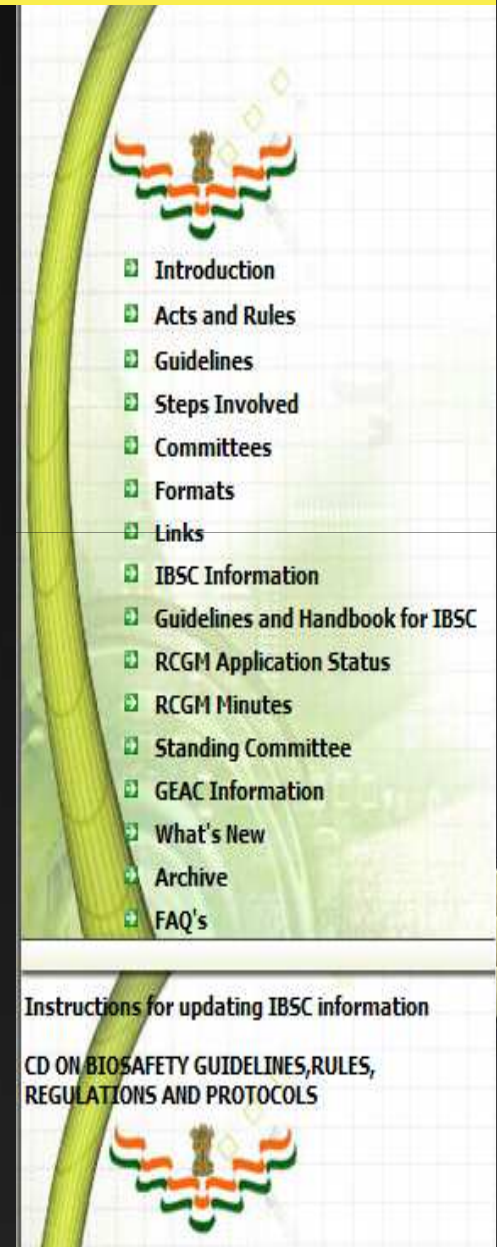
For more details please visit: (<http://igmoris.nic.in/>)



DBT BIOSAFETY REGULATORY WEBSITE

- The objective to facilitate and disseminate the statutory requirements to be adhered by the researchers in the R&D work using modern biotechnology tools.
- As part of an ongoing process, DBT continues to bring out the latest information and modifications/amendments in the guidelines etc. from time to time.
- All the relevant Acts, Rules, Guidelines, proformas are available.
- The detailed stepwise procedures to be adopted for development of GMOs as on date can be viewed or downloaded from this website.
- In addition to information exchange, the website also provides tracking of regulatory clearance applications to RCGM and e-monitoring of IBSCs on personalized web features

For more details please visit: <http://dbtbiosafety.nic.in>



NEWSLETTERS

Biosafety Newsletter

SABP Newsletter

July - September 2012, Vol. V Issue 1

BIOSAFETY

A Quarterly Newsletter

Newsletter

From the Desk of Editor

I am pleased to inform that the Phase II capacity building project on biosafety has been initiated with the organization of the Inception Workshop on June 18-19, 2012. The initial set of activities of the project that primarily focus on increasing awareness related to the key components of the project. This project is not a standalone project and has been conceptualized in a manner so as to supplement the ongoing capacity building initiatives in the country. I invite all stakeholders to actively participate in the project and share ideas for achieving the underline objectives of the project i.e. to strengthen the biosafety management in the country.

The forthcoming COP11-MOP6, one of the largest international conferences to be held in India, will bring together more than 15,000 people from more than 193 countries for participation in a series of meetings, fairs, exhibitions and side events. It is a unique opportunity to associate with such an event. The fair and exhibitions to be held in conjunction with COP11-MOP6 present a great opportunity for national and local governments, academic institutions, private enterprises, NGOs, many other organizations and citizens from around the world to learn about issues on biodiversity and biosafety. I invite all to suitably take benefit of this great event.

Hem Pande
Joint Secretary
Ministry of Environment and Forests

In this Issue

- Consultative Meeting For Preparation of MOP6
- Inception Workshop - Phase-II Capacity Building Project on Biosafety
- Release of Second National Report
- ANUBIS Training
- Interactive Fair for Biodiversity at COP-MOP6
- CEPA Fair on National Experiences with Implementation of CPB
- Side events in parallel to COP-MOP6
- Biosafety Clearing House Training workshop
- Science express-Biodiversity special train
- New Releases
- Upcoming Events

COP11-MOP6 and Interactive Fair for Biodiversity

Event	Year	Oct 13, 2012	Oct 14, 2012	Oct 15, 2012
COP11	2012	Oct 13, 2012	Oct 14, 2012	Oct 15, 2012
Interactive Fair for Biodiversity	2012	Oct 13, 2012	Oct 14, 2012	Oct 15, 2012

Official Website of COP11-MOP6

MoEF has set up a website at <http://icbdcop11india.in> to provide information regarding the COP11-MOP6.

India to host the eleventh Conference of the Parties (COP11) to the Convention on Biological Diversity (CBD) and the sixth Conference of the Parties serving as Meeting of the Parties (COP-MOP6) to the Cartagena Protocol on Biosafety

1-19 October 2012, Hyderabad

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NEWSLETTER

for private circulation only - not for sale

www.oera-gmo.org

SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with national governmental agencies to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds and environmental protection.

SABP is working with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

BANGLADESH PROBLEM FORMULATION WORKSHOP ON THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED PLANTS

The South Asia Biosafety Program (SABP) and the Partnership Program for Biosafety Risk Assessment and Regulation in collaboration with Bangladesh Agricultural Research Council (BARC) and Department of Environment (DoE) organized a Problem Formulation Workshop on the Environmental Risk Assessment of Genetically Engineered Plants at the BRAC-CDM, Rajshahi, Rajshahi, Bangladesh on July 13 and 14, 2012. Twenty-five participants from the National Agricultural Research System (NARS), policymakers, members of the Biosafety Core Committees (BCC) and Institutional Biosafety Committees (IBC) attended. Dr. Raymond Layton of Pioneer Hi-Bred, USA and Dr. Andrew Roberts, Deputy Director, Center for Environmental Risk Assessment (CERA) conducted the workshop.

A brief and informal inaugural ceremony included a welcome and a workshop outline by Dr. Roberts followed by a brief speech by Dr. M. Khalequzzaman A. Chowdhury, Member Director (Crops), Bangladesh Agricultural Research Council (BARC) who expressed his hope that the workshop would be helpful to stakeholders in light of the fact that Bangladesh has been performing confined field trials of Bt brinjal and late blight resistant (LBR) potato.

Dr. Layton gave an introduction to problem formulation that covered its background, the need for protection goals and the connection to a testable hypothesis. He pointed out that problem formulation is the foundation of the ecological risk assessment. Dr. Layton also described the risk assessment process and, in particular, problem formulation, risk analysis and risk characterization.

Dr. Roberts's presentation, Exemplifying Problem Formulation using *Brassica napus* (Canola) in Canada, 1995 and 2010, reviewed the concepts of problem formulation through a case study on canola in Canada. He concluded with remarks about the role of experience and familiarity in problem formulation and subsequent risk assessment.

Prof. M. Imdadul Hoque, Country Coordinator, South Asia Biosafety Program, gave an overview of the Regulations for Genetically Engineered Biotech of Bangladesh. Prof. Hoque described the chronological developments of different biosafety regimes in Bangladesh including the Biosafety Guidelines of Bangladesh, its elements and the functions of the different committees. He also gave the status of transgenic crops in Bangladesh and, more specifically, the status of confined field trials of Bt-brinjal and LBR potato being conducted by the Bangladesh Agricultural Research Institute (BARI).

Mr. Mohammed Solaiman Haider, Deputy Director, Department of Environment (DoE), spoke about the decision making process for the clearance of development projects/industries through environmental impact assessment (EIA) wherein he described the importance and benefits of EIA and its development history in Bangladesh. He also highlighted the assessment parameters for clearing an application for an environmental clearance certificate and briefly described the salient features of Environment Policy of 1992.

One of the main objectives of the workshop was to give the participants a hands-on opportunity to assess the ERA of GE plants through group exercises. Led by Dr. Layton, using MON 15985 insect resistant cotton as a case study, the participants were divided into three separate groups. The groups first discussed amongst themselves the identification of protection goals, relevant for the ERA of GE plants in Bangladesh. The discussions concluded with a PowerPoint presentation given by each group to describe the outcome. The three groups then discussed amongst themselves various aspects of the ERA of GE cotton summarizing the discussions with a PowerPoint presentation. In the final group exercise, conducted in a similar fashion, groups

(continued on page 2 - see Bangladesh)

SOUTH ASIA BIOSAFETY PROGRAM (SABP)



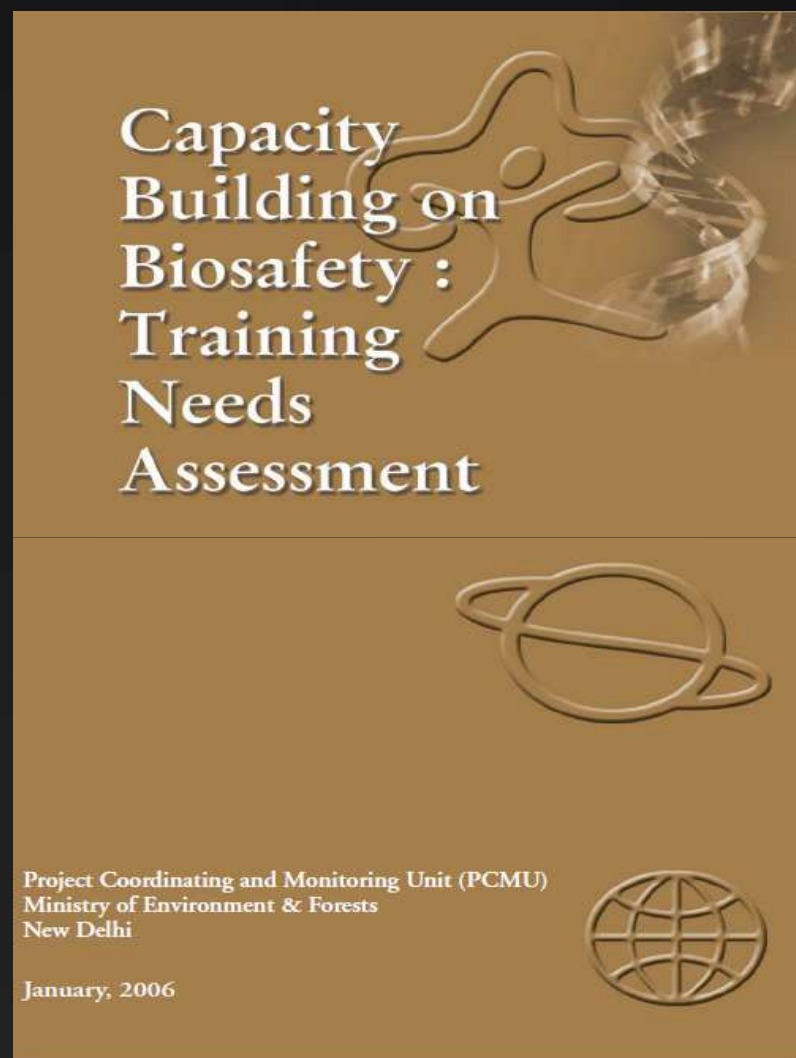
The South Asia Biosafety Program (SABP) is an international developmental program implemented by Centre for Environmental Risk Assessment (CERA-ILSI) in India and Bangladesh to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.

BCIL is the In-country partner of SABP in India



STUDIES/SURVEYS



Training Needs Assessment Survey in the context of CPB



TRAINING NEEDS

MAJOR TARGET GROUPS

(KEY COMPETENCES – KNOWLEDGE AND SKILLS REQUIRED)

Decision makers

Government regulators

Scientists, technical advisors

& experts

Enforcement officials

Customs officials

Lawyers

Economists

Information managers

Researchers & technicians

Graduate & undergraduate

students

Interest groups (Consumer

groups, farmers, NGOs)

Associations

International organizations

Workers

General public, politicians

General biosafety/ biotech knowledge

✓

✓

✓

✓

✓

✓

✓

✓

✓

✓

✓

✓

Molecular biology skills
Biosafety research/ field trial techniques (e.g. buffer zone, isolation distance, etc.)

✓

✓

✓

✓

Risk assessment & management
Audit of risk assessment reports and risk management plans

✓

✓

✓

✓

✓

✓

✓

✓

✓

✓

Safety requirements and procedures for international and unintentional LMO releases

✓

✓

✓

✓

✓

Tools for monitoring the handling, transport, packaging and use of LMOs

✓

✓

✓

✓

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✓

Compliance requirements under the CPB

✓

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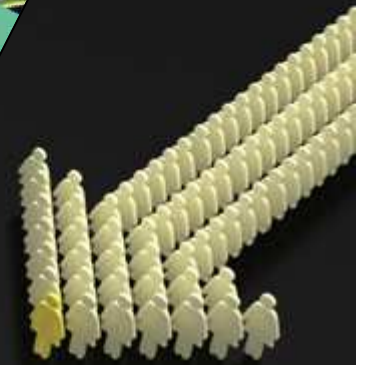
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TRAINING NEEDS	MAJOR TARGET GROUPS													
(KEY COMPETENCES – KNOWLEDGE AND SKILLS REQUIRED)	Decision makers	Government regulators	Scientists/technical advisors & experts	Enforcement officials	Customs officials	Lawyers	Economists	Information managers	Researchers & technicians	Graduate & undergraduate students	Interest groups (Consumer groups, farmers, NGOs)	International organizations	Workers	General public, politicians
Harmonization of biosafety related sectoral laws/policies including international agreements	✓		✓	✓		✓					✓		✓	✓
Regulatory training (legal, policy, enforcement, inspection, etc.)	✓	✓	✓	✓	✓	✓								
Preparation and presentation of LMO export or release applications/dossiers			✓			✓			✓					
Review of applications and the accompanying dossiers			✓	✓		✓								
Administrative practices (including handling of requests for LMO imports or releases)		✓						✓						
Decision-making practices, including assessment and integration of socio-economic considerations	✓	✓	✓	✓							✓		✓	✓

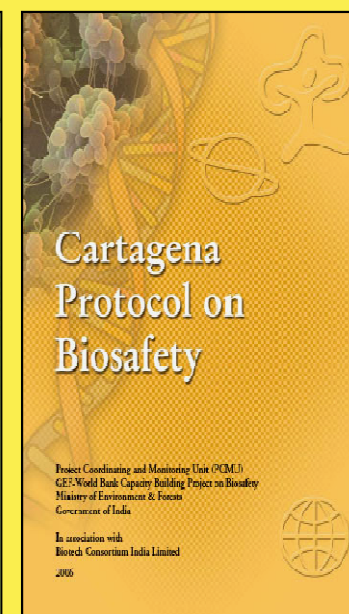
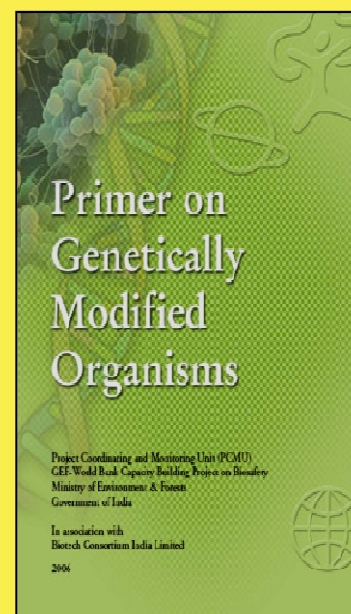
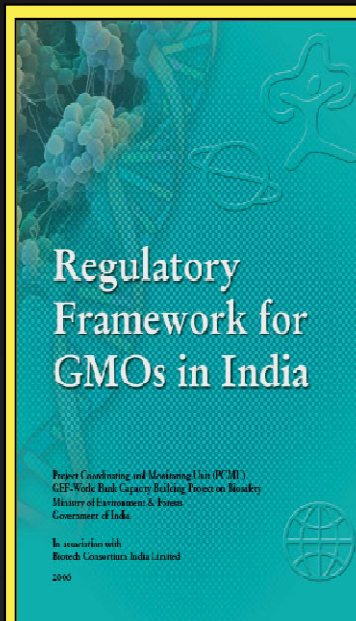
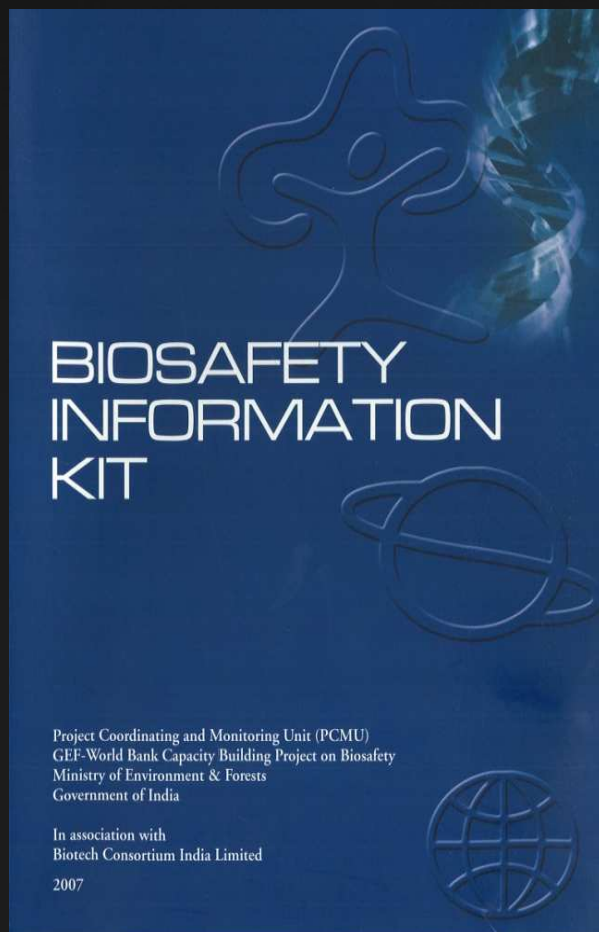
PUBLICATIONS



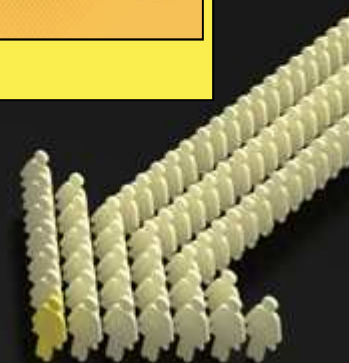
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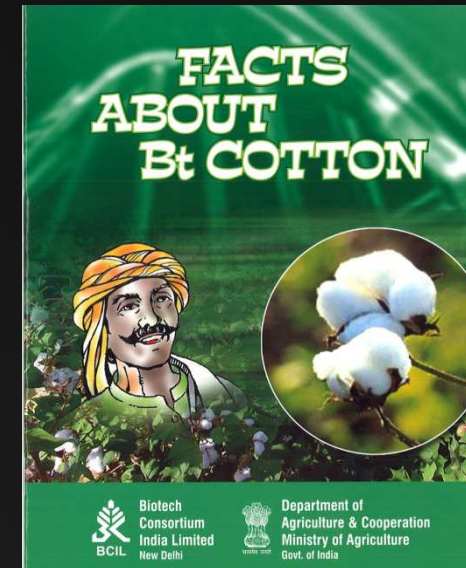
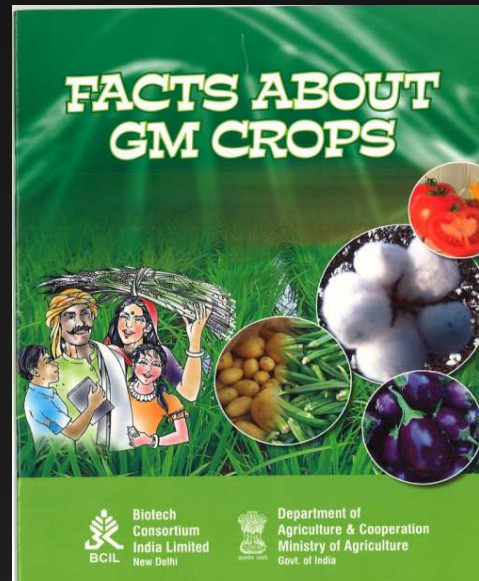
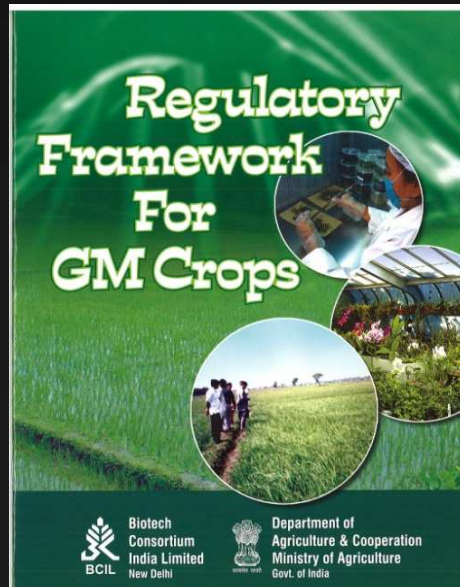
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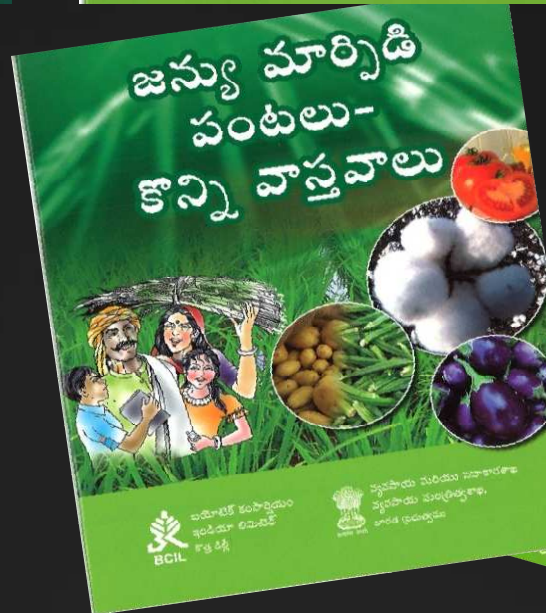
BIOSAFETY INFORMATION KIT



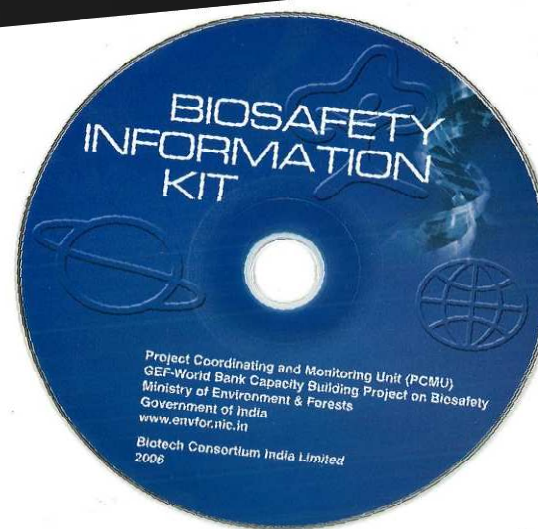
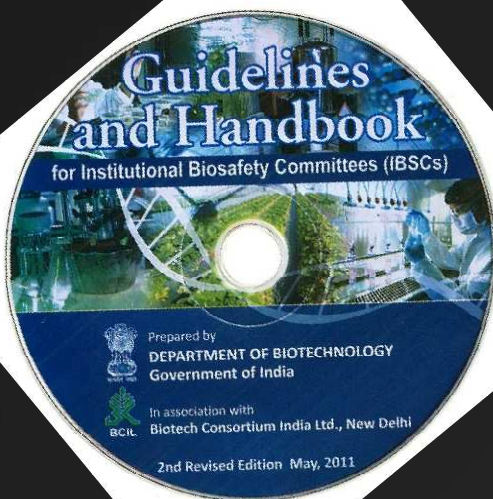
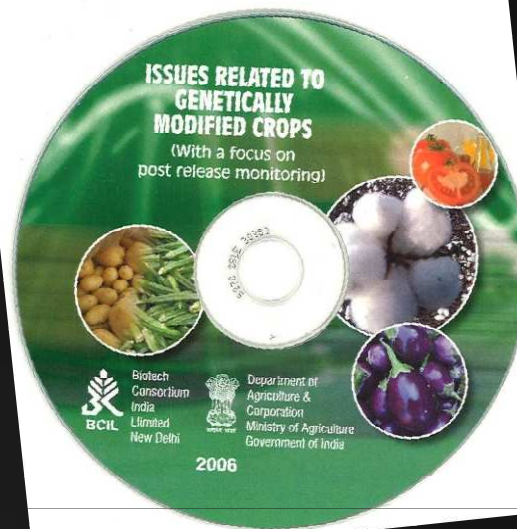
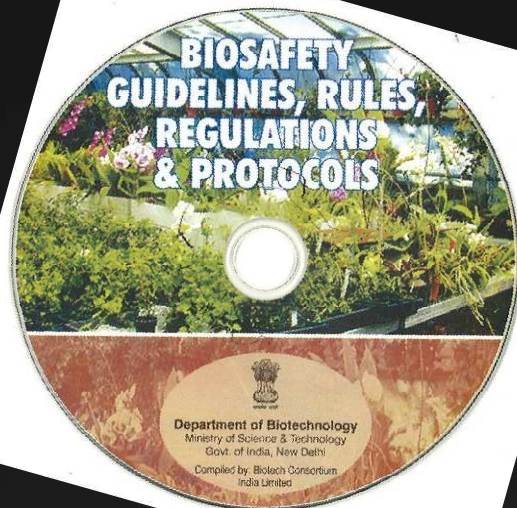
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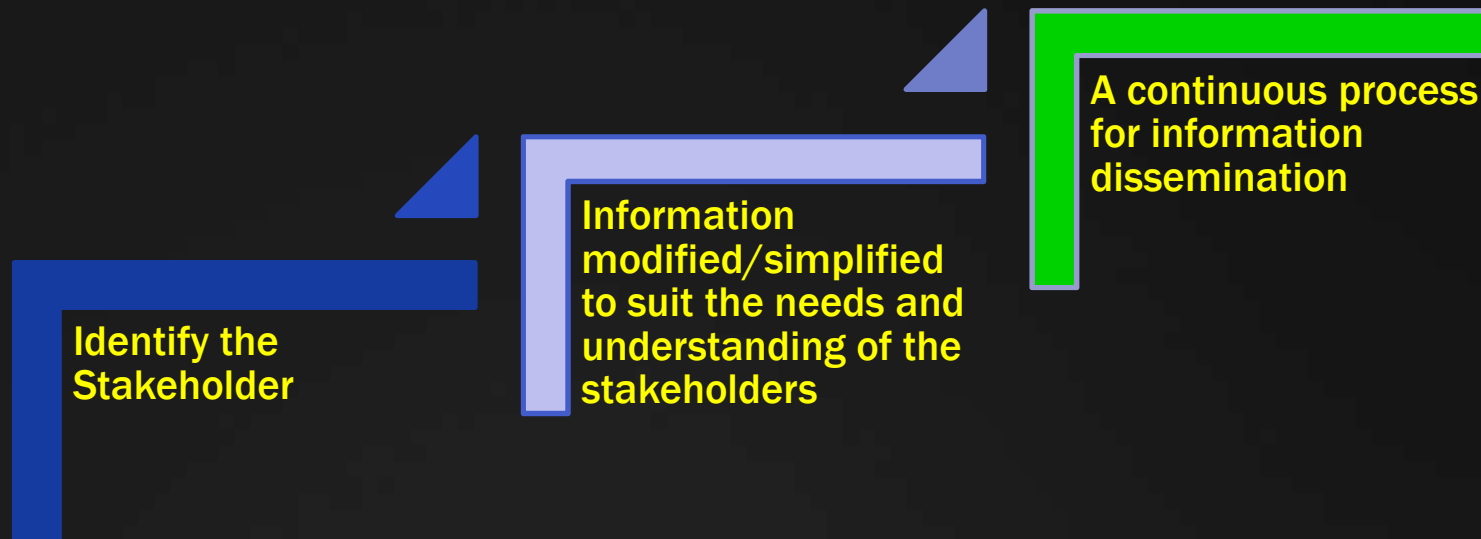
**Use of
Regional Languages**



CDs



APPROACH FOR ENSURING SUSTAINABILITY OF CAPACITIES



THANK YOU

