PROJECT BRIEF

1. IDENTIFIERS:

PROJECT NUMBER	GE-PO-79856
PROJECT NAME	Capacity Building for Implementation of the Cartagena Protocol
DURATION	3 years
IMPLEMENTING AGENCY	Ministry of Environment And Forests
REQUESTING COUNTRY	India
ELIGIBILITY	Ratified the Cartagena Protocol 17 JANUARY, 2003
GEF FOCAL AREA	Biodiversity
GEF PROGRAMMING FRAMEWORK	ENABLING ACTIVITY

2. SUMMARY

The capacity building project will enhance the India's national capacity in order to implement the Cartagena Protocol on Biosafety. India already has in place biosafety regulatory framework in the form of the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganism/Genetically Engineered Organisms or cells, 1989 notified under the Environment Protection Act, 1986. This project will address the capacity building needs of the country for implementing the national biosafety framework related to the transboundary movement of LMOs in the context of the Cartagena Protocol and coordination of the implementation of the Biosafety Clearing House (BCH).

Specifically, the project will develop national capacities in biosafety required to: (i) increase institutional capacity in line ministries, related agencies and in state government to implement the provisions of the Cartagena Protocol; (ii) enhance technical capacity for risk assessment, management and monitoring; (iii) establish the biosafety database system and Biosafety Clearinghouse Mechanism (BCH); (iv) support centers of excellence and a network for research, risk assessment, and monitoring; and (v) establish the Project Coordination and Monitoring Unit (PCMU). The development of national capacities in these areas will enhance the national capabilities for implementation of the biosafety issues. .

3. COSTS AND FINANCING (MILLION US$):

Project	Total (US$) (in million)
GEF	**1.00**
Sub-total	**1.00**
GOI counterpart funding	**2.07**
Sub-total	**2.07**
Total Project Cost	**3.07**

4.Operational Focal Point Endorsement: The Ministry of Environment and Forests, Government of India have approved the project

5.1 Implementing Agency Contact : The World Bank

5.2 Operational Focal Point Endorsement: Dept. of economic affairs, govt. of India

5.3 executing AGENCY: ministry of environment and forests

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6. List of Acronyms

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CFTRI	Central Food Technology Research Institute
CTN	National Technical Committee
CP	Cartagena Protocol
DCGI	Drug Controller of India
DBT	Department of Biotechnology
DLC	District Level Committee
EPA	Environmental Protection Act
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
GEAC	Genetic Engineering Approval Committee
GMOs	Genetically Modified Organisms
GOI	Government of India
IBSC	Institutional Biosafety Committee
ICAR	India Council for Agricultural Research
ICCP	Intergovernmental Committee Cartagena Protocol
LMO	Living Modified Organism
MoEF	Ministry of Environment and Forests
MoA	Ministry of Agriculture
MoFPI	Ministry of Food Processing Industries
MoH&FW	Ministry of Health and Family Welfare
MoC&I	Ministry of Commerce and Industries
NBF	National Biosafety Framework
NGO	Non Governmental Organisation
NBPGR	National Bureau of Plant Genetic Resources
NRCPB	National Research Center on Plant Biotechnology

PCMU	Project Coordinating and Monitoring Unit
PSC	Project Steering Committee
RDAC	Recombinant DNA Advisory Committee
RCGM	Review Committee on Genetic Manipulation
SBB	State Biodiversity Boards
SBCC	State Biotechnology Coordination Committee
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
WWF	World Wildlife Fund
WTO	World Trade Organization
NATP	National Agriculture Technology Project
ARIS	Agriculture Research Information System
NRC on DNAF	National Research Centre on DNA Fingerprinting

7. Background and Project Context

7.1 National Environmental Policy

Environmental protection and the conservation of natural resources emerge as key national priorities in India in the wake of various summits on environment. India has been able to develop a stable organizational structure for environmental protection in the country. Laws, policies and programs have also been developed to meet the goals of improved environmental management. Several policy instruments have been enunciated and various action programs have been developed and implemented by the Ministry of Environment and Forests (MOEF) in order to address the problems of environment and development and to consider several cross-sectoral issues having direct bearing on conservation as well as sustainable uses of national resources including forestry and wildlife.

National environment policy strives to achieve a balance between development and conservation. The National Conservation Strategy And Policy Statement On Environment and Development (1992) provides for the integration of environmental considerations in the policies and programs of different sectors. It emphasizes sustainable life styles and the proper management and conservation of resources. The legal framework for the environment includes the Indian Forest Act, 1927, the Forest Conservation Act, 1982, the Water Prevention & Control of Pollution Act, 1981 and the Environment Protection Act, 1986. Other enactments include the Public Liability Insurance Act, 1991, the National Environment Tribunal Act, 1995 and the National Environment Appellate Authority Act, 1997. The implementation of law is undertaken by various agencies of the Central and State Governments.

Biosafety means minimizing the potential risk to human health and environment from the handling and transfer of Living Modified Organisms (LMOs) produced through modern biotechnology. Recognizing the potential risks of LMOs, the Convention on Biological Diversity (CBD) addressed this issue of biosafety in Articles 8(g), 19.3 and 19.4. An Open-ended Ad-hoc Working Group under the aegis of CBD negotiated the protocol. The protocol was adopted during an extraordinary meeting of the Conference of Parties to the CBD in January 2000. India ratified the Protocol on 13 January 2003. .

7.1.2 National Focal Point on Bio-Safety

The Ministry of Environment and Forests is the focal point for Convention on Biological Diversity and all biodiversity related matters including biosafety.

7.2 Biosafety Framework in India

Government Commitment

Since 1989, the Government of India has shown its commitment to biosafety issues when the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically engineered organisms or cells were attached to the Environment Protection Act (1986). The 1989 Rules cover the entire spectrum of activities relating to research, development and use of genetically modified organisms (GMOs) and their products. Four principal facets of the biosafety regulatory framework namely, institutional, legal, environmental and public information, are detailed below.

7.2.1 Legal context

India is a party to the CBD. In accordance with Article 8(g) of the Convention, India is committed to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. India signed and ratified the Cartagena Protocol on 24 January, 2001. As mentioned above, however, an operative biosafety framework has been in place since 1989 for research development and release of GMOs.

India's richness in biological resources and indigenous knowledge related to those resources is well recognized. One of the major challenges before India lies in adopting an instrument which helps realize the objectives of equitable benefit sharing enshrined in the CBD. India has developed biodiversity legislation which aims at regulating access to biological resources and making such access subject to terms and conditions which secure equitable sharing of benefits for the resources accessed. This legislation was prepared after extensive consultations with all the stakeholders including local government, NGOs, the private sector, academic institutions, state governments and Central Government Ministries and departments. The CBD Bill was introduced in the Lok Sabha on 15th May, 2000. The Parliament of India has approved the Bill.

The main intent of this legislation is to protect India's rich biodiversity and associated knowledge against their use without sharing the benefits arising out of such use. It also seeks to control biopiracy. The Environmental Protection Act of 1986 (EPA) provides for setting up of a National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) at the local level. All foreign nationals/organizations require prior approval of NBA for obtaining biological resources and/or associated knowledge for their commercial use. While granting approvals, the NBA will impose terms and conditions to secure equitable sharing of benefits. Before applying for any form of International Patent Rights (IPRs) in or outside India for an invention based on research or information on a Indian biological resource, prior approval of NBA will be required. There is an enabling provision for setting up a framework for protecting traditional knowledge. The monetary benefits, fees, royalties as a result of approval by NBA will be deposited in the National Biodiversity Fund (NBF) which will be used for conservation and development of areas from where resource has been accessed, in consultation with the local self government concerned.

Under the EPA, the rules and procedures for the manufacture, import, use, research and release of GMOs as well as products made by the use of such organisms were notified by MoEF through their Notification No. 621 in official Gazette of Government of India on December 5, 1989. These rules and regulations cover the areas of research as well as large scale applications of GMOs and products made them from throughout India. The rules also mandate that every institution engaged in GMO research establish an Institutional Biosafety Committee (IBC) to

oversee such research and to interface with the RCGM in regulating it. Brief details of the relevant regulations as well as guidelines are described below.

7.2.1.1 Recombinant DNA Guidelines, 1990

With the advancement of research work initiated in biotechnology by various Indian institutions and industry, the Department of Biotechnology of the Ministry of Science and Technology (DBT) formulated and released Recombinant DNA Guidelines in 1990. These guidelines were further revised in 1994. These revised guidelines included guidelines for large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research. The issues relating to genetic engineering of human embryo, use of embryos and fetuses in research and human germ line, and gene therapy have been excluded from the scope of these guidelines.

For research activities, the guidelines have been classified into three categories based on the level of the associated risk and requirement for the approval of competent authority.

- Category I activities include those experiments involving self cloning using strains and also inter-species cloning belonging to organism in the same exchanger group which are exempt for the purpose of intimation and approval of competent authority;
- Category II activities which require prior intimation of competent authority and include experiments falling under containment levels II, III and IV (details of each containment level provided separately in the guidelines), large scale use of recombinants made by self cloning in systems belonging to exempt category;
- and Category III activities that require review and approval of competent authority before commencement include experiments involving toxin gene cloning, cloning of genes for vaccine production, and other experiments as mentioned in the guidelines.

The levels of risk and classification of the organisms within these categories have been defined in these guidelines. Appropriate practices, equipment and facilities necessary for safeguards in handling organisms, plants and animals in various risk groups have been recommended. The guidelines employ the concept of physical and biological containment and the principle of good laboratory practices. For containment facilities and biosafety practices, recommendations from the WHO laboratory safety manual on genetic engineering techniques involving microorganisms of different risk groups have been incorporated therein.

For large scale experiments, the guidelines categorize experiments beyond 20 liters capacity for research and industrial purposes as large-scale experiments/operations. The guideline gives principles of occupational safety and hygiene for large-scale practice and containment. Safety criteria have also been defined in the guidelines. Physical containment conditions that should be ensured for large-scale experiments and production have been specified in the guidelines.

For release to the environment, the guidelines specify appropriate containment facilities depending on the type of organisms handled and potential risks involved. The guidelines require the interested party to evaluate rDNA modified organism for potential risk prior to application in agriculture and environment like properties of the organism, possible interaction with other disease causing agents and the infected wild plant species.

7.2.1.2 Guidelines for research in transgenic plants, 1998

In 1998, DBT issued separate guidelines for carrying out research in transgenic plants, the Revised Guidelines for Research in Transgenic Plants. These also include the guidelines for toxicity and allergenicity of transgenic seeds, plants and plant parts.

These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research use.

The genetic engineering experiments on plants have been grouped under three categories.

- Category I includes routine cloning of defined genes, defined non-coding stretches of DNA and open reading frames in defined genes in E.coli or other bacterial/fungal hosts which are generally considered as safe to human, animals and plants.

- Category II experiments include experiments carried out in lab and green house/net house using defined DNA fragments non-pathogenic to human and animals for genetic transformation of plants, both model species and crop species.

- Category III includes experiments having high risk where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, plants and animals by dispersing new genetic traits the effects of which cannot be judged precisely. In addition, this also includes experiments conducted in green house and open field conditions having the risks mentioned above.

The guidelines include complete design of a contained green house suitable for conducting research with transgenic plants. It provides the basis for generating food safety information on transgenic plants and plant parts.

7.2.1.3 Drugs and Cosmetics Rules (8th Amendment), 1988

In India, all recombinant products are considered to be new products as per the current Drugs and Cosmetics Rules. The Ministry of Health and Family Welfare (Department of Health), Government of India, issued a notification vide GSR No. 944 (E) dated September 21, 1988 indicating in detail the requirement of the activities for enabling the import or manufacture of biological and biotechnological products.

Recombinant products approved by marketing for one company will be considered to be a new product when introduced by another company if there is a change in the host, the vector, the gene construct or even the process of production and purification. The reasons are that the new hosts or the vectors or the gene constructs are likely to incorporate newer molecules or fragments of DNA and proteins in final product, and therefore the safety questions associated with them require to be resolved. On similar grounds, the different methods of processing of biological products may also assume importance with regard to resolving the safety issues specially, if the host line is implicated with reasons of safety from its contents of nucleic acids and/or proteins; in addition the processing techniques may also incorporate processing materials into the final product like salts, solvents, sugars etc.

All new drugs to be imported or to be produced locally for marketing purposes in India require the permission of the Drug Control Authorities. The Drug Controller General of India (DCGI)

may approve the import or local manufacture, provided he is satisfied with the information provided by applicants on the clinical trials data.

7.2.1.4 Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics, 1999

DBT issued a set of guidelines for preclinical and clinical evaluation of rDNA vaccines, diagnostics and other biological material in 1999 to help in the production of relevant data for submission to the DCGI. The guidelines specially are on safety, purity, potency and effectiveness of the project.

7.2.1.5 Drug Policy, 2002

The Government of India has recently issued Drug Policy, 2002 and it has reference to recombinant DNA products. Clause 12.1 of the policy states that bulk drugs produced by the use of rDNA technology, bulk drugs requiring *in vivo* use of nucleic acid as the active principles and specific cell/tissue targeted formulations require an industrial license for production. Furthermore, in the subsequent paragraphs i.e. 12.2 and 12.3, all the above products need be approved for foreign investments as well as foreign technology agreements.

7.2.1.6 Seed Policy, 2002

In the recently announced Seed Policy, 2002, there is a separate section (No. 6) on transgenic plant varieties. It states that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations on guidelines of the EPA, 1986. Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986. Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests required for environment and bio-safety clearance by the EPA before any variety is commercially released in the market. After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act. After commercial release of a transgenic plant variety, its performance in the field will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture. It has also been mentioned that transgenic varieties can be protected under the legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.

7.3 Institutional context

The 1989 Rules also lay down the institutional framework for regulating activities relating to use of GMOs in India. As per the rules, two central committees were to be established with research to be overseen by the Review Committee on Genetic Manipulation (RCGM) established under the DBT. Approvals for large scale releases and commercialization of GMOs are given by the Genetic Engineering Approval Committee (GEAC), established under the Ministry of Agriculture. In addition to these two central committees, the 1989 Rules mandate that every institution engaged in GMO research establish an Institutional Biosafety Committee (IBCS) to oversee such research and to interface with the RCGM in regulating it. In addition, state Biotechnology Coordination Committees are to be set up in each state, together with District Level Committees, to ensure that there is a process of monitoring and information exchange between districts, states and the central government in regulating GMO activities. Presently there are six competent authorities. A brief description of their responsibilities is as described below.

7.3.1 The Recombinant DNA Advisory Committee (RDAC)

This committee constituted by the DBT takes note of developments in biotechnology at national and international levels. The RDAC prepares recommendations that are suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This Committee prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990, which was adopted by the Government for conducting research handling of GMOs in India.

7.3.2 Institutional Biosafety Committee (IBSC)

All research institutions which carry out work on GMOs are required to have an IBSC. The IBSC is the nodal point for interaction within the institution for implementation of the guidelines. All the IBSCs have to induct one DBT nominee. The activities of IBSC also include training of personnel on biosafety and instituting health monitoring program for laboratory personnel. The directives are to carry out medical checks including pathological tests done periodically on persons involved in the work/experiments.

7.3.3 Review Committee on Genetic Manipulation (RCGM)

This committee is based in the DBT and has the responsibility to monitor safety related aspects of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The RCGM includes representatives of: (a) DBT, (b) the Indian Council of Medical Research (ICMR), (c) the Indian Council of Agricultural Research (ICAR) ,(d) the Council of Scientific and Industrial Research (SCIR),(e) other experts in their individual capacity. The RCGM may nominate and appoint other organizations to the committee on an as needed basis. It oversees the preparation of guidelines specifying procedures for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high-risk category and controlled field experiments will be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines. The RCGM establishes procedures restricting or prohibiting production, sale, importation and use of such genetically engineered organism of cells as are mentioned in the Schedule.

7.3.4 Genetic Engineering Approval Committee (GEAC)

This committee is based in the MOEF. It reviews and issues approval of activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production when they meet established environmental guidelines. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.

The composition of the Committee includes:

(i) Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology

(ii) Members: Representative of concerned Agencies and Departments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy

(iii) Expert members: Director General Indian Council of Agricultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity.

(iv) Member Secretary: An official of the Department or Environment, Forest and Wildlife.

The committee may co-opt other members/experts as necessary.

The committee or any person's authorised by it shall have powers to take punitive action under the Environment (Protection) Act.

An Example of GMO Approval: Commercial Cultivation Bt cotton

Bt cotton has been sown in six states in India namely Gujarat, Madhya Pradesh, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu. The GEAC accorded approval to MAHYCO for conducting large-scale field trials in June 2000. MAHYCO approached GEAC in May 2001 requesting approval for commercial cultivation of Bt cotton. As the large scale field trials conducted by MAHYCO in Kharif 2000 could not reflect the true values because of late sowing, GEAC decided that the trials be repeated by the company. In addition, it was also decided that the Indian Council of Agricultural Research (ICAR) also conduct large-scale field trials under their Advanced Varietal Trials of the All India Coordinated Cotton Improvement Project.

The Monitoring and Evaluation Committee (MEC) set up by the DBT evaluated the large scale field trials conducted by MAHYCO. The MEC constituted 10 monitoring teams comprising scientists, representatives from State Agricultural Universities, experts from ICAR, IARI, DBT, MOEF etc, The monitoring teams visited 62 locations in central and southern states between the last week of September and last week of December 2001 and monitored the trials. The environmental safety assessment of Bt cotton hybrids include: pollen escape outcrossing, aggressiveness and weediness, effect on non-target organisms, presence of Cry 1AC protein in soil, effect of Cry1 AC protein on soil microflora, confirmation of the absence of Terminator Gene, and baseline susceptibility studies. MAHYCO conducted these studies as per the Protocol approved by the RCGM functioning in the Department of Biotechnology.

7.3.5 State Biotechnology Coordination Committee (SBCC)

There shall be a State Biotechnology Coordination Committee (SBCC) in the States wherever necessary. The SBCCs have authorization to inspect, investigate and take punitive action in case or violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The SBBC shall review periodically the safety and control measures in the various industries/institutions handling genetically engineered Organisms/Hazardous microorganisms. The composition of the Coordination Committee shall be:

(i)	Chief Secretary	-	Chairman
(ii)	Secretary, Department of Environment	-	Member Secretary
(iii)	Secretary, Department of Health	-	Member
(iv)	Secretary, Department of Agriculture	-	Member
(v)	Secretary, Department of Industries and Commerce	-	Member
(vi)	Secretary, Department of Forests	-	Member

(vii)	Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering	-	Member
(viii)	State microbiologists and Pathologists	-	Member
(ix)	Chairman of State Pollution Control Board	-	Member

The Committee may co-opt other members/experts as necessary.

7.3.6 District Level Committee (DLC)

There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications in the environment.

The DLC or any other persons authorised on its behalf shall visit the installation engaged in activity involving genetically engineered organisms and/or hazardous microorganisms and prepare an information chart which details potential hazards and risks associated with each of these installations. It will then coordinate activities with a view to meeting any emergency. The DLC shall regularly submit its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee.

The District level Committee shall comprise of:

(i)	District Collector	- Chairman
(ii)	Factory Inspector	- Member
(iii)	A representative of the Pollution Control Board	- Member
(iv)	Chief Medical Officer (District Health Officer)	– Member (Convenor)
(v)	District Agricultural Officer – Member	
(vi)	A representative of the Public Health Engineering Department	- Member
(vii)	District Microbiologists pathologist (Technical expert)	- Member
(viii)	Commissioner Municipal Corporation	- Member

The Committee may co-opt other member/s/experts as necessary.

In order to contain possible hazards to environment from the release of GMOs, the MOEF has notified the 'Rules for the manufacture, use, import, export and storage of hazardous Micro-organisms/Genetically Engineered Organisms or Cells. These Rules are being implemented through a three tiered mechanism:

- Institutional Biosafety Committees (IBPSCs) at the institutional level.
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Approval Committee (GEAC)

It is a requirement that IBSCs be set up by R &D institutions handling LMOs, in order to monitor the research activities at the institutional level. The IBSC is comprised of the director of the institution, the scientist undertaking rDNA work, a medical expert and a nominee of the DBT. The IBSC assists the institution to prepare an on-site emergency plan. The other functions of IBSC include training of personal on biosafety.

The RCGM is functioning in the DBT. Its functions are:

- To review the reports in all approved ongoing projects involving high risk category and controlled field experiments research in four areas namely human and animal health care, agriculture, industry and environmental management.

- To periodically visit the site of experimental facilities where projects with biohazard potential are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.

- To issue clearance for import/export of etiologic agents and vectors, germplasm, organelle, etc. needed for experimental work/training and research.

The RCGM is headed by an eminent scientist and has representation from MOEF, the Ministries of Agriculture and Health and DSIR. In addition, there are six experts as members. The RCGM meets three to four times in a year.

The Genetic Engineering Approval Committee (GEAC) is functioning under the MOEF and is authorized to examine and issue the clearance from the view point of environmental safety on a case by case basis for :

- activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from environmental angle.
- Proposals relating to the release of genetically engineered organisms and products into the environment including experimental field trials.
- Production, sale, import or use of substances and products including food stuffs and additives including processing aids containing or consisting genetically engineered organisms or cells or micro-organisms.
- Import, export, transport, manufacture, process, use or sale of any hazardous micro-organisms or genetically engineered organisms/substances or cells.
- Scale up or pilot operations for facilities using genetically engineered organisms/micro-organisms mentioned in the schedule.

The GEAC is chaired by the Additional Secretary of the MOEF. An expert nominated by the DBT is the Co-Chairman of GEAC. The other members include representatives from ICAR, CSIR, ICMR, Drug Controller of India, Department of Agriculture & Cooperation(??), Ministry of Commerce & Industry, Ministry of Health & Family Welfare, Ministry of Food Processing Industries, Ministry of External Affairs, Department of Atomic Energy, Ministry of Science and Technology, Ministry of Industry and Central Pollution control Board. In addition, three experts are members of GEAC. Thirty three meetings of the GEAC have been held so far. The composition and functions of Indian Competent Authorities can be found in Annex 1.

7.3.7 The Rules also provide for constitution of committees like State Biotechnology Co-ordination Committee (SBCC) which is to monitor research as well as commercial applications of GMOs in the states and District Level Committee (DLC) which monitors research and applications in GMOs including accidental releases at the district level. The SBCC which is required to be constituted by all the State Government, is headed by the State Chief Secretary, and the Secretary, Department of Environment is also a Member. Other members of the SBCC include Secretaries in the Departments of Health, Agriculture, Industries, Commerce, Forests and Public Works; Chief Engineer, Department of Public Health Engineering, chairman of State

Pollution Control Board, and microbiologists and pathologists experts in the State. The SBCC has powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the appropriate State Government department. The DLC is headed by the District Collector. Other members include: factory inspector, representative of the State Pollution Control Board, District Medical Officer, District Agricultural Officer, representative of Public Health Engineering Department, District Microbiologists/Pathologists, and Commissioner, Municipal corporation. The function of the DLCs is to monitor the safety regulations in installations engaged in the use of LMOs and its applications in the environment. The DLCs are also authorized to coordinate activities for meeting any emergency.

Both MoEF and DBT seek advise of experts in the field of genetic engineering and molecular biology who are represented in GEAC and RCGM. Besides, agency representatives like experts from Indian Council of Agricultural Research (ICAR), CSIR, ICMR, Drug Controller of India, Department of Agriculture & Cooperation, Ministry of Commerce & Industry, Ministry of Health & Family Welfare, Ministry of Food Processing Industries, Ministry of External Affairs, Department of Atomic Energy, Ministry of Science and Technology, Ministry of Industry and Central Pollution Control Board are members of GEAC. All the proposals received by GEAC are scrupulously referred to a panel of experts and their views are considered before taking a final decision. All proposals are considered on a case-by case basis and on merit. In order to evaluate proposals, DBT has issued following guidelines:

- Recombinant DNA Safety Guidelines, 1990
- Recombinant DNA Safety Guidelines and Regulations, 1990
- Revised Guidelines for Safety in Biotechnology, 1994
- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines for generating pre-clinical and clinical data for rDNA vaccines, diagnostics and other Biological species, 1999.

A Monitoring and Evaluation Committee has been established at DBT to monitor and evaluate results of large scale field trials transgenic crops. In addition, ICAR also evaluates the transgenic crops through its All India Coordinated Project. The Government is following a policy of case by case approval of transgenic crops. Introduction of any new technology requires careful evaluation and long term sustainable benefits. Extensive Rules and guidelines have been framed for evaluating environmental and health safety aspects of genetically modified organisms. Any company involved in the use of genetic engineering techniques has to obtain approval of the RCGM for conducting testing under laboratory conditions and confined field conditions. Thereafter approval of GEAC is required for large-scale field trials and introduction to environment.

In India, a number of recombinant pharmaceutical products have been imported/manufactured and marketed. As regards, GM crops, the ICAR and a number of private sector companies are in various stages of developing and field testing transgenic tobacco, rice, mustard, cotton, potato, tomato, brinjal, cauliflower, cabbage, chilli and bellpepper after the necessary approval of RCGM. Of the genetic modifications attempted, the vast majority are intended to confer pest resistance. Another focus of genetic transformations has been the production of higher value hybrids in crops such as mustard. Notwithstanding the fairly extensive research effort underway, no transgenic crop has yet been approved for commercialization in India. Contained field trails are underway or have been completed for tobacco (by the Central Tobacco Research Institute), mustard and tomato (by Pro-Agro-PGS), cotton (by Mahyco) and brinjal and tomato (by the Indian Agricultural Research Institute. As on date Mahyco's transgenic cotton modified to be

resistant to the cotton bollworm became the first crop to receive approval of large scale field tests by GEAC.

In order to handle the issues relating to human health and environment from transgenic crops and other areas the composition of GEAC was expanded to include representatives from DARE, Dept. of Agriculture & Cooperation, CSIR, Ministry of External Affairs, Ministry of Commerce & Industry, Ministry of Health, and Ministry of Food Processing & Industries.

7.3.8 Ministry of Agriculture

The Department of Agriculture and Cooperation of the Ministry of Agriculture is responsible for the formulation and implementation of national policies and programmes aimed at achieving rapid agricultural growth through optimum utilization of the country's land, water, soil and plant resources. The Department undertakes all possible measures to ensure timely and adequate supply of inputs and services such as fertilizers, seeds pesticides, agricultural implements and also provides agricultural credit, crops insurance and ensures remunerative returns to the farmer for his agricultural produce. The Department is entrusted with the responsibility of collection and maintenance of a wide range of statistical and economic data relating to agriculture, required for development planning, organising agricultural census, assisting and advising the States in undertaking scarcity relief measures and in management of natural calamities e.g. flood, drought, cyclone, etc.

The Ministry of Agriculture has enacted the 'Plants Fruits and Seeds (Regulation of Import into India) Order' (1989) under the Destructive Insects and Pests Act (1914). The PFS Order, as it is commonly called, inter alia provides for regulating import of seeds/planting material of fruits subject to plant quarantine regulations.

7.3.9 The National Research Center on Plant Biotechnology (NRCPB)

The National Research Center on Plant Biotechnology (NRCPB) is a premier research center of the country for carrying out research and teaching in the frontier areas of plant biotechnology. It is making steady progress in several areas of the plant biotechnology including isolation and characterization of new genes and promoters, development of transgenic, DNA Fingerprinting, molecular breeding and biological nitrogen fixation. The Center is making global impact by contributing to the International Rice Genome Sequencing Project (IRGSP). Postgraduate teaching and training of scientists from the National Agricultural Research System (NARS) are the main strength of this center and it is continuing to train manpower in the area of agricultural biotechnology.

7.3.10 The National Bureau of Plant Genetic Resources (NBPGR)

The National Bureau of Plant Genetic Resources (NBPGR) has its Headquarters at New Delhi, functions under Indian Council of Agricultural Research (ICAR). The Bureau is headed by the Director, who draws guidelines from the Crop Science Division of ICAR, Bureau's Management Committee, Research Advisory Committee and Germplasm Advisory Committees. The Bureau has four Divisions and two units at its Headquarters in New Delhi and 11 regional/ base/ satellite stations located in different phyto-geographical zones of India. Besides this, a National Research Centre on DNA Fingerprinting (NRC on DNAF) and an All India Coordinated Research Project (AICRP) on Under-utilized Crops are also located at the Bureau. The NRC on DNA Fingerprinting has developed laboratories for molecular fingerprinting of released varieties and genetic stocks of crop plants of India. It has the objectives of standardization of molecular marker systems for DNA profiling and their application in variety identification, DUS testing and essential derivation. The Plant Exploration and Collection Division of NBPGR has the objectives to plan, coordinate and conduct explorations for collecting germplasm. Germplasm Evaluation

Division is entrusted with the prime responsibility of characterization and evaluation of all the indigenous and exotic germplasm collections for their field performance and other important traits like resistance to biotic/ abiotic stresses and phyto-chemical attributes along with maintenance and regeneration. This Division has an experimental farm located at Issapur, New Delhi, covering an area of 40 ha. Germplasm Conservation Division is vested with the task of conservation of germplasm of various crop plants, and to undertake basic research on various aspects of seed storage and longevity. NBPGR also has the Tissue Culture and Cryopreservation Unit, with the main objective to conserve economic plants, for which conventional methods of storage are unsuccessful or inadequate, through *in vitro* and cryopreservation techniques. Plant Quarantine Division has been vested power by Plant Protection Advisor to the Government of India, under the Plants, Fruits and Seeds Order (PFS, 1989) of the Destructive Insects and Pests (DIP) Act (1914), to carry out quarantine processing of the plant germplasm including transgenics imported for research purposes. Germplasm Exchange Unit has the responsibility of introducing genetic resources of diverse crop plants and their wild relatives under phytosanitary conditions. It distributes the same within the country, and also exports the germplasm with requisite phytosanitary certification.

At NBPGR a DBT sponsored project entitled, "National Containment/ Quarantine Facility for Transgenic Planting Material" Phase I with a budget outlay of Rs. 258.66 Lakhs was initiated in April, 1999 for three years (1999-2002) with objectives of restricting the introduction of exotic pests and pathogens in imported transgenic planting material by proper quarantine processing of the material as stipulated by Government of India Notification No. GSR/1067 (E) dated 05.12.1989 issued under PFS Order, 1989 of DIP Act, 1914. The activities of the project included establishment of a National Containment (Level-4) for facilitating the processing of transgenic planting material from quarantine aspect; developing molecular probes/ markers as and when required for evaluation of transgenic planting material; and training of human resource in the area of biosafety. The project is continuing as Phase II with a budget outlay of Rs. 65.88 Lakhs for two years (2002-04).

The Containment Facility was established on turn-key basis by M/S Gauri International, Australia. The facility (CL-4) is ready to handle potentially hazardous genetically modified plant material to prevent their direct contact with the environment. It has been built in a way that no viable biological material/ pathogen / pollen can enter or leave the building. Growing transgenic planting material in containment would ensure their isolation from the gene pool represented by sexually compatible plants to prevent the escape of transgenes to avoid environmental interactions of the genetically modified plants. It would help to prevent or limit the contact of exotic/ transgenic planting material with environment.

A total of 863 imported samples of different transgenic crops comprising soybean (359 samples) with CP4 EPSPS*, nptII* and *aad* genes for *Roundup Ready 1445* from USA; 262 samples of rice from UK, Belgium and the Philippines (having *Bt* gene i.e. *Cry 1 Ac*; *Bt* gene i.e. *Cry 1 Ab/Cry 19c* and *Bar* gene; and *Bt* gene (*Cry 1 Ab*), *Xa21* and *PR* genes, respectively), cotton (12) with *Bt* gene i.e. *CryX* from USA and cotton (7) with C*ry 1A, npt II* and *Gus* genes from China; *Brassica napus (*10) having *Osmads 1* gene from Belgium, *Brassica juncea* (175) having *Barnase Barstar* and *Bar* gene from Australia and Belgium, and chickpea (34) having *Bean alpha A1* gene from Australia and Scotland and corn (4) with *Cry1A(b)* from USA were subjected to quarantine processing. Among these, 141 samples of soybean were rejected due to presence of downy mildew fungus (*Peronospora manshurica*), which causes serious losses, and also not yet known to occur in India. The remaining soybean samples were grown under containment and expression of soybean mosaic virus was recorded in 15 lines by using ELISA test. Harvest of disease free plants was released to indentors. One hundred twenty six samples of *Brassica juncea* were found

infected with *Alternaria brassicae, A. brassicicola, Phoma lingam* and *Xanthomonas campestris* pv. *campestris.* The fungi viz., *Fusarium dimerum* and *Tricochonis padwickii* known to cause grain discoloration and stack burn on paddy, respectively, were intercepted on paddy samples from the Philippines. All the samples of paddy and *Brassica* were given prophylactic hot water treatment at 52^0C for 30 min. against bacteria, fungi, nematode and other seed-borne pathogens. Samples of chickpea, soybean and cotton were subjected to X-ray radiography to detect the hidden infestation of bruchids.

Designing of molecular probes for testing of transgenic material with Polymerase Chain Reaction (PCR), Southern Hybridization and Northern Hybridization has been standardized for *Kanamycin, Bar, Barnase and Barstar* genes. Molecular probe for detection of a component of terminator genes (*cre* sequences) has been designed. Threshold level (minimum detectable copy number) for detection of transgenes varied with the size and complexity of the genome. Detection of *npt II* gene in transgenic *Glycine max* (CP4 EPSPS, *aad* and *npt II*) and *barnase* and *barstar* genes in transgenic *Brassica juncea* (*bar*, *barnase* and *barstar*) has been confirmed. Presence of CaMV 35S promoter has been confirmed in transgenic rice, maize and chickpea using specific primers. For the detection of transgenes, primers have been designed and synthesized for scorable/ selectable markers such as *gus, hpt* and *npt,* for promoters such as CaMV 35S, Nos and CaMV35S/ Nos and transgenes such as *bar, barnase, barstar*, CP4 EPSPS, *cry 1 A(c)* and *cre* sequence of terminator gene. A medium-term storage module of the National Gene Bank has been allocated with double lock and key system for storing the imported transgenic material for reference.

7.3.11 Ministry of Health

The new Drug Policy, 1994 stipulates certain regulations for drug and other biological products produced using biotech intervention. The licensing authority is vested with the Drug Controller of India.

At present the following Acts and Rules made there under that govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India.

- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)

7.4 Project linkage to national priorities, action plans and programmes:

As recombinant DNA technology allows isolation and manipulation of DNA sequences *in vitro*, it is possible to produce organisms capable of synthesizing or modifying any number of useful proteins. The practical reach of rDNA technology has considerably enlarged due to the possibilities to express virtually any kind of coding sequence from any possible source. Sequences from mammals or any other animals, plants, fungi, bacteria or even sequences synthesized in vitro can be introduced into and expressed in almost any other organisms. These spectacular advances made in the area of recombinant DNA technology are being successfully used in various sectors such as agriculture, health care, process industry and environment management.

There are four primary areas in healthcare in which recombinant DNA technology is being used i.e. production of medicines or therapeutics, vaccines, diagnostics and gene therapy. Traditional agriculture includes improvement of crops by selecting and sowing the seeds from plants with beneficial characteristics such as higher yields, better nutrition and resistance to diseases. By breeding plants with these good characteristics, plant breeders combined the genetics of those plants long before the science of genetic was understood. The recombinant DNA technology however allows plant breeders to select genes that produce desired traits and move them from not only one plant to another but from other organisms as well. The process is far more precise and selective than traditional breeding. Application of recombinant technology is primarily for the production of transgenic plants with higher yield potential, increased resistance to stresses, less use of chemical pesticides and improved nutritional content. Tissue culture technique applied in conjunction with rDNA technology has led to the development of transgenic plants in the shortest possible time with the target genes transferred into them.

Although, several commercially important crops such as maize, soybean, tomato, cotton, potato, mustard, rice etc. have been utilized for incorporating transgenic traits, the traits that have been targeted for genetic transfer to plants could be classified broadly as herbicide tolerance, insect resistance, disease resistance, product quality improvement, ability to grow in harsh environment, and plant based pharmaceuticals. To improve the productivity-to-cost ratio, it is now possible to modifying genes to increase enzyme productivity in microorganisms commonly used in manufacturing thereby making it possible to manufacture the desired enzyme in commercial quantities. The technique of genetic engineering is also used to make other microbial enzymes that are too expensive or even impossible to cultivate. The process uses renewable resources as a raw material feedstock.

8. Environmental Context

India is one of the 12-mega biodiversity countries of the world. The country is divided into 10 bio-geographic regions. Over 47,000 species of plants and 81,000 species of animals have been recorded by the Botanical Survey of India and the Zoological Survey of India, respectively. India is also alone of the 8 primary centers of origin of cultivated plants and is rich in agricultural biodiversity. India is equally rich in traditional and indigenous knowledge, both coded and informal. The wide variety in physical features and climatic situations have resulted in a diversity of ecological habitats like forests, grasslands, wetlands, coastal and marine ecosystems and desert ecosystems, which harbour and sustain the immense biodiversity. With only 2.4% of the total land area of the world, the known biological diversity of India contributes 8% to the known global biological diversity. Currently available data place India in the tenth position in the world and fourth in Asia in plant diversity. In terms of the number of mammalian species, India ranks tenth in the world; in terms of the endemic species of higher vertebrates, it ranks eleventh. It stands seventh in the world for the number of species contributed to agriculture and animal husbandry. Release of LMO without proper evaluation and biosafety investigations may adversely affect the native biodiversity of the country. Hernce, appropriate risk assessment and risk management procedures are required to be put in place to commensurate and strengthen the existing biosafety framework.

The vast majority of applications of environmental biotechnology use naturally occurring microorganisms (bacteria, fungi, etc.) to identify and filter manufacturing waste before it is introduced into the environment. Some more advanced systems using genetically modified microorganisms are being tested in waste treatment and pollution prevention to remove difficult-to-degrade materials. Some microorganisms, for example, feed on toxic materials such as methylene chloride, a variety of detergents, creosote, pentachlorophenol, sulfur and polychlorinated biphenyls (PCBs) and are thus being used in bioremediation. Recombinant

technology helps in improving the efficiency of these microorganisms and thus wider and cost-effective use.

9. Public Information

Recently the MOEF in collaboration with DBT has conducted eight workshops to increase public awareness on LMO and biosafety issues including the provisions of the Cartagena Protocol. stakeholders which participated in these workshops included government agencies, NGOs, scientists and other experts, the general public, and representatives from industry. The GEF Project will enhance and broaden the stakeholders' participation through seminars, workshops, training and the Biosafety Clearing House (BCH).

10. Baseline Capacity and Identified Gaps

India played a very active role in the preparation of provisions of the CP. India is one of the 12 megadiversity countries associated with the agrobiodiversity and it attaches great importance to the development of sound biotechnology for harnessing this potential while at the same time recognizing the importance of biosafety. After entry into the force of the CP, there would be an increased movement of the LMOs. There is a need for enhancing the capacity in the context of the CP. Information sharing protocols and additional data capacity are needed to keep pace with the expected increase in trans-boundary movement of LMOs. There is an information system on biosafety including the biotechnology information system and this system needs to be strengthened and converted into the nodes of the Biosafety Clearing House.

Although a good start has been made towards developing a regulatory framework for LMOs, there is a need to systematically review this framework to determine if there are specific gaps based on the provisions of the CP. The expected outcomes of the present GEF project are an important step for closing these gaps and builds on current government efforts.

11. Barriers to fully Implement the Cartagena Protocol

A number of significant barriers that prevent the full implementation of the CP in India have been identified and are described below:

11.1 Institutional, Legal & Policy

India has already put in place a regulatory framework for dealing with LMOs. This regulatory framework oversees the development of LMOs from laboratory research to contained use to open field trials and large scale field trials before release into environment. Guidelines have been developed for field evaluation of environmental risks and to some extent food safety. India has scientific manpower trained in various aspects of molecular biology, ecology, immunology, microbiology, virology, agronomic evaluation etc. As discussed earlier, there are R & D institutions with some expertise for conducting research in this area. There is a need to strengthen this capacity for effective implementation of the CP and to meet the challenges that are emerging with the rapidly changing biosafety scenario. All LMOs are required to be assessed on a case by case basis for their risks to the environment taking also into consideration human and animal health. For better appreciation of the risks associated with LMOs and an understanding of the transgene sequence and trait, promoter, host plant and its pollination biology, their interactions with other species is essential. Moreover, there is also need to build capacity in assessing socio-economic risks associated with introduction of GMOs including impact on labor markets, possible land holding consolidation and poverty. Another important area to include in the training is Intellectual Property Rights and their impact on access to technology by the poor producers and also the issue of Indigenous Knowledge in relation to IP.

The emerging scenario of transgenic crops and GM foods calls for the upgrading of institutions, training of scientists in advanced evaluation techniques, including analytical detection methods, and strengthening of institutions for addressing issues of environmental and food safety. Environmental risk assessment capacities include study of extent of pollen/gene flow, likelihood of hybridisation, presence of close relatives, invasiveness of engineered crop, susceptibility to diseases and pests, stability of the transgenic genome, resistance to abiotic stresses etc. Food safety evaluation includes capabilities of determination of composition and assessment of the quality of LMOs**,** compositional analysis and near equivalent studies of major ingredients to assess substantial equivalence, toxicity and allergenicity implications of LMOs handling procedures for allergenic substances etc. For environmental risk assessment and evaluation of food safety, a series of protocols are to be developed to address specific safety issues and effect on non-target species including on soil microorganisms.

For the acceptance of LMOs by the society, scientific assessments alone cannot form the basis of decision making. Many other aspects, especially socio-economic factors need to be considered and national capacity for doing socio-economic analysis of LMOs should be built. Awareness building programmes to increase participation of all stakeholder groups along with public education materials can also play an important role.

11.2 Technical and information barriers

India has a well-developed information sharing systems on environment, health, agriculture and biotechnology sectors. However, there is a need for developing integrated information systems through networking of institutions and databases, exclusively working on biosafety.

12. Human Resources

India has professionals with good knowledge of safe production, use and handling of LMOs. Besides the Government sectors, private and public sector laboratories have some expertise in evaluating the potential risks and benefits of LMOs. Capacity must be improved at all levels of government in order to fully meet the legal requirements of the CP.

13. GEF Alternative Course of Action

A GEF intervention would complement and strengthen baseline activities in India by ensuring that key required capacities for implementation of the CP are developed and/strengthened.

13.1 Project Objectives

13.1.1 Development objective

The development objective of the project is to assist India to fully implement the obligations under the CP related to the transboundary movement of LMOs. This includes the assessment, management and long term monitoring and documentation of the risks to the sustainable use of biodiversity and to human health potentially posed by the introduction of LMOs. The major objectives for GEF support would be to improve capacity across ministries and among key stakeholders to analyze, inform, and make decisions to reduce potential risks related to LMOs, increase benefits to society, and protect biodiversity.

13.1.2 The immediate objective

The immediate objective is that at the end of the three year capacity building project there will be sufficient capacity in the country and effective coordination between the responsible agencies to

assess and manage risks associated with the transboundary movement of LMOs. This will be achieved through the strengthening of the biosafety framework with the necessary regulations, enhanced technical capacity and enforcement and monitoring capacities as well as a well managed information and coordination network. Within three years, the country will build sufficient capacity to assess and manage risks associated with the trans-boundary movement of LMOs through the strengthening of the legal and regulatory frameworks, enhanced institutional capacity and effective communication strategies. Knowledge and methodologies on Biosafety will be shared and transferred to the state agencies through training programmes conducted across the country. The projects specific objectives are to:

a. strengthen institutional capacity for coordination and decision making across ministries, specialized agencies and in state government in areas related to biosafety and the CP.

b. strengthen technical capacity to assess, manage and monitor risks associated with biosafety through the provision of training for core capacity development in relevant stakeholder ministries, specialized agencies and in state governments. Sector specific issues to be addressed include:

   - Agriculture – identify preservation, inspection and monitoring of laboratory work and field trials, safe handling of GMO materials and quarantine, extension and training of farmers.
   - Environment – biodiversity conservation, pollen transfer, effect on non-target species, insect resistance management strategies.
   - Biotechnology – Gene constructs, development of protocols for evaluation of safety, development of guidelines and training materials.
   - Health and food processing - food safety evaluation compositional analysis for assessment for substantial equivalence.
   - Commerce- monitoring and regulating trade in commercial food, feed and industrial products.
   - Socio-economic risk and impact assessment.

c. establish the biosafety database system and Biosafety Clearinghouse Mechanism (BCH);
d. support centers of excellence and a network for research, risk assessment, and monitoring; and,
e. establish the Project Coordination and Monitoring Unit (PCMU).

13.2 Project Strategy

13.2.1

The main activities of the project are focused on the identification, regulation and management of the risks derived from the trans-boundary release and utilisation of LMOs, that might prevent adverse risks to the conservation and sustainable use of biological diversity, taking also into account potential risks to human health. This national approach to capacity building contemplates risk assessment and management, monitoring and evaluation, legal and regulatory reform/strengthening, broad social participation and a dissemination strategy in the context of the Advanced Informed Agreement. GEF is requested to participate in strategic elements of this approach over the medium-term horizon (3 years) permitting the longer-term consolidation of the

strategy. The GEF-financed portion of the project includes training and risk management components that will ensure sustainability and information exchange over the long-term. The project concentrates GEF funds in the areas of trans-boundary risk assessment and management as these are considered to be vital to the implementation of a large-scale communication campaign. Consolidated capacities in these two areas will also help detect additional gaps in the legal framework and will help fine tune possible strategies for its modification.

Given India's size and GEF/GOI budget limitations, it was necessary to be very selective in choices regarding project activities. Training will be undertaken at two levels: (i) a more general type training for policy makers and regulatory agencies. This training will be carried out in a decentralized cost effective fashion in the India's four regions. It is expected that this training will achieve 100% coverage of all institutions which have legal authority for biosafety; (iii) training for scientists and managers in risk evaluation. This training will also attempt to achieve 100% coverage. In addition, the project will target improvements for analytical evaluations and certification services at 4 laboratories. Details on specific project activities can be found in the following section.

13.2.2 Strategic considerations for program design.

Design of this program for capacity development will recognize a number of strategic concerns:

- Biosafety is a rapidly changing field as more is learnt about the science and its interaction with biodiversity and consumer concerns. Any program will necessarily be one step in a continuous program of capacity development. The need is large and priorities for this program must be carefully identified.

- Biosafety is a highly technical area that requires considerable scientific skill. On the other hand, it also requires broad understanding and ready access to information from the public at large, especially producer and consumer groups.

- The issues of Biosafety and risk assessment are crosscutting and no single ministry or sector can have sole responsibility for decision-making. For this reason, capacity development must be sustainable. This requires essential capacity building for personnel, infrastructure and equipment with major concentration on upgrading skills and knowledge of current staff through training and information sharing.

- Many international development and technical agencies are working on agricultural biotechnology related biosafety. To draw on this experience, the project management will be in touch with other agencies working on biosafety, such as UNIDO, UNEP, ISNAR (and other CGIAR centers), and relevant bilateral agencies to compare their methodologies and lessons learnt in biosafety capacity building and risk assessment.

Component 1: Strengthening the institutional and legal framework to improve capacity and coordination in decision making at he Federal and State levels and in relevant specialized agencies.

In order to improve capacity and coordination in decision making on issues relating to LMOs, the GEF resources will be used to strengthen institutional framework within as well as across the concerned Ministries, including MoEF, DBT, Ministry of Agriculture (MoA) Ministry of Food

Processing Industries (MoFPI) Ministry of Health and Family Welfare (MoH&FW), Ministry of Commerce and Industries (MoC&I). This component will be achieved interalia through training for core capacity development in relevant Ministries and State Agencies and other specialized organizations including oversight and review bodies (NPBGR, NRC on DNAF etc.). Training modules which comprise the training program will include:

- Agriculture – inspection and monitoring of laboratory experiments and field trials, safe handling of GMO materials and quarantine, extension and training of farmers; training in IPR and Indigenous Knowledge for policy makers.

- Environment – pollen transfer, out crossing/hybridisation, effect on biodiversity, effect on non-target species.

- Biotechnology - Gene constructs, development of protocols for evaluation of safety, development of guidelines and training materials.

- Health and Food processing – food safety evaluation, compositional analysis for assessment for substantial equivalence.

- Commerce- monitoring and regulating trade in commercial food, feed and industrial products.

- Socal sector – LMOs impact on labor markets, land consolidation and poverty.

- Training and awareness for policy makers in relevant Ministries.

- Minimum infrastructure and equipment to support core capacity.

- Training to develop capacity to support implementation of international agreements (e.g. CBD, Cartagena Protocol, Codex Alementarius) and to effectively participate in negotiation of new agreements or amendments.

- Mechanisms for information sharing at the national and state level.

A Steering Committee will be set up in the MOEF to oversee the implementation of Cartagena Protocol specifically for institutional framework. This committee and the Project Coordination and Monitoring Unit (PCMU) will interact with all stakeholder Ministries/Agencies for prioritisation of programmes and their implementation.

To insure wide participation, four regional training programs will be organized encompassing India's four geographic zones to insure full national coverage.

Component 2: Improving capacity for risk evaluation and management

GEF resources will be used specifically for training experts in molecular genetics to detect and track LMOs presented under AIA. The capacity developed will increase India's potential to monitor in-country movements of LMOs. GEF support will also be used to develop field capacity to monitor possible gene flow between introduced LMOs and semi domestic and wild relatives. This training will allow supervision of the implementation of biosafety measurers and over the medium term to identify potential gene flow, as well the effect on non-target species. Data on transboundary shipments of LMOs at points of entry would be registered, collected and validated by Customs through ad-hoc methodologies designed with the help of GEF resources. The training will also include a module on socio-economic impact assessment of LMOs.

The outcome will be achieved through activities such as:

- Operational manuals to guide scientists in managing field trials, and training in their implementation.
- Access to and provision of risk-related ecological and environmental information to all stakeholders.
- Training for scientists and research managers in risk evaluation procedures in selected institutions.
- The development and adaptation of methodologies for risk evaluation and management of GMOs.
- Training and capacity building for the monitoring of GMOs after release.
- Training and capacity building in socio-economic impact assessment.

The training programs would be oriented for capacity building for techniques and monitoring methodologies for risk evaluation of GMOs. It is envisaged that eight training courses/workshops encompassing four zones of the Country would include about 1600 participants. All the outputs generated from this project would be utilized by all the stakeholders and also would be disseminated across the Country.

Component 3: Strengthening laboratories/institutions for analytical evaluation of GM ingredients and for certification services.

This outcome will be achieved through:

- Identification of laboratories/institutions for analytical evaluation of GM ingredients.
- Training the personnel for certification services.
- Infrastructure and equipment for the identified laboratories/institutions.
- Risks related to LMOs, including labelling issues, traceability etc.

Based on criteria established during the project preparation process, four laboratories have been selected for strengthening:

(1) Central Food Technological Institute, Mysore, Karnataka
(2)National Bureau of Plant Genetic Resources (NPBGR), New Delhi
(3)National Research Center on Plant Biotechnology (NRCPB), a member center of IARI
(4) G.B. Pant University of Agriculture and Technology, Pantnagar, Uttaranchal

These organisations/laboratories would be strengthened by providing equipment to the laboratories so as to develop their capacities to evaluate and mitigate risks. The equipment needs would be identified by the PCMU in consultation with these institutions.

1. Central Food Technological Research Institute (CFTRI), Mysore

The department undertakes research and development in the area of food-related biotechnological processes of economic importance to India, with emphasis on biochemical engineering investigations necessary for efficient process development. The thrust over the years has been on

the development of fermentative, enzymatic and similar bio-technological processes on laboratory scale; pilot plant trials for scaling them up; and technology transfer to industry. The facilities in the department and the experience and expertise available here have turned it into a major centre in India for R&D work related to the food fermentation industry in particular, and the food processing industry in general. Other major areas which have been addressed include the following:

Food- Microbiology

- Micro-organisms and their metabolites for food, feed and fuel
- Industrial alcohol (Ethanol)
- Food spoilage and food poisoning micro-organisms like mycotoxins
- Bio-degradation of chemical pollutants
- Anaerobic Microbiology

Plant Cell Biotechnology

The department focuses on plant biotechnology in the specialised areas of Algal Biotechnology and Tissue/Cell Culture of Plants as also Molecular Biology and Genetic Engineering. The major emphasis inter alia is on:

- Development of health foods, food additives and natural products from plant cell/ microalgal cultures.
- Improvement of plants for production of food-value metabolites in cell cultures, and for better processing characteristics
- Immobilization of plant cells and algal cells for biotransformation of low-value compounds into high-value end products.
- Field-testing of tissue-culture-derived plants.
- Nutritional quality analysis, feed formulation, evaluation of mycotoxigenesis and food safety.
- Tissue culture of bioactive plants for extraction of pyrethrin, thiophene.

2. National Bureau of Plant Genetic Resources (NBPGR), New Delhi.

National Bureau of Plant Genetic Resources (NBPGR) is the nodal organization in India for exchange, quarantine, collection, conservation, evaluation and the systematic documentation of plant genetic resources. To act as the nodal institute at national level for acquisition and management of indigenous and exotic plant genetic resources for food and agriculture, and to carry out related research and human resources development, for sustainable growth of agriculture. The objectives of NBPGR are**:**

- To plan, organize, conduct and coordinate exploration and collection of indigenous and exotic plant genetic resources.
- To undertake introduction, exchange and quarantine of plant genetic resources.
- To characterize, evaluate, document and conserve crop genetic resources and promote their use, in collaboration with other national organizations.
- To develop information network on plant genetic resources.
- To conduct research, undertake teaching and training, develop guidelines and create public awareness on plant genetic resources

3. National Research Center on Plant Biotechnology (NRCPB), IARI

The NRCPB is the premier research center in India for carrying out research and teaching in the frontier areas of plant biotechnology. It is making steady progress in several areas of the plant biotechnology including isolation and characterization of new genes and promoters, development of transgenic, DNA Fingerprinting, molecular breeding and biological nitrogen fixation. The Center is making global impact by contributing to the International Rice Genome Sequencing Project (IRGSP). Postgraduate teaching and training of scientists from the National Agricultural Research System (NARS) are the main strength of this center and it is continuing to train manpower in the area of agricultural biotechnology.

The NRCPB has pioneered the development of Brassica varieties using biotechnological tools. Use of inter-specific hybridization, plant tissue culture and somaclonal variation techniques has led to the release of two mustard varieties Pusa Jai Kisan and Pusa Gold which are very popular among the farmers. In a further development in quality enhancement yellow seeded high yielding mutant of mustard have been developed from the variety Pusa Jai Kisan. The Center has also developed two types of cytoplasmic male sterility lines.

A major emphasis of the Center is to develop transgenic crops with resistance to biotic and abiotic stresses including insect pests, drought, salinity and temperature. The Center has been focusing its effort on the development of Bt-transgenic crops.

In development of transgenic Bt-rice, the NRCPB has produced two gene transgenic lines of rice incorporating cry1Ac and cry1Aa genes under different promoters. These two gene transgenic lines will offer better protection against yellow stem borer as well as help delay the development of resistance in the insect populations. The first generation Bt transgenic rice lines are already going through limited field trials at the IARI after approval of RCGM A novel approach to control insect pests and diseases is to use the ubiquitous endophytic bacteria. *Bacillus subtilis*, endophytic to the stem of maize has been transformed with the gene for the Bt insecticidal protein Cry1Ab and there was a significant reduction (up to 33 %) in the infestation by corn borer in the maize plant treated with these transgenic endophytic bacteria.

The NRCPB is working to produce transgenic crop plants, which will offer much greater stress tolerance than is possible by conventional breeding to accumulate the existing genes within the gene pool of the crop. Transgenic potato containing osmotin gene has been produced and these tubers are now in the third generation. A number of putative transgenic tomato plants containing codA and osmotin genes have also been produced. Annexin, a protein that has been shown to provide protection against water stress tolerance and Center has produced a number of transgenic tobacco plants over expressing annexin to successfully verify these findings.

The Center also has a programme to produce transgenic plants to prevent post- harvest losses during storage. Promoter regions of the ripening related genes LeACS1A, LeACS3 and LeACS6 and cDNAs for expansin gene LeExp1 have been PCR amplified and cloned. In addition to the major transgenic programmes the Center has developed protocols for transformation and regeneration in mustard (*Brassica juncea*), mung bean (*Vigna radiata*), and chick pea (*Cicer arietinum*) using different model genes and promoters.

Marker assisted selection and molecular breeding are playing increasingly important role to speed up the selection process for difficult characters by the plant breeders. The main areas where work is in progress include DNA fingerprinting of rice, wheat and mustard, mapping and tagging of quantitative trait loci (QTLs) and genes in mustard and rice. DNA fingerprints based on the SSR and AFLP analysis have been developed for rice, wheat and mustard varieties. In the year 2000,

India became a partner in the international effort to produce a high quality sequence of the rice genome and make it available in the public domain for free access by all the rice scientists. The work is spearheaded by International Rice Genome Sequencing Project (IRGSP), which is a consortium of ten countries including Brazil, China, France, India, Japan, Korea, Taiwan, Thailand, UK and USA. India is sequencing the long arm of chromosome 11 and the work is being shared equally between Delhi University South Campus and the NRCPB-IARI. The region allocated to India covers about 14 mega bases of genomic DNA covering a map distance between 57.3 and 110.9 cM. During the reporting period the NRCPB has submitted its first lot of rice genome sequences to the GenBank and so far the tally is at 550 kb of high quality sequence data.

4. G. B. Pant University Of Agriculture And Technology, Pantnagar, Uttaranchal.

The G. B. Pant University of Agriculture and Technology, Pantnagar is the premier agricultural university in the country. It is credited with ushering Green Revolution in India by introducing in late 1960 an integrated concept of seed production, processing and distribution. The University is a multi faculty university with nine faculties *e.g.,* College of Agriculture, College of Agri-Business, Management, College of Basic Sciences and Humanities, College of Fishery Science, College of Home Science, College of Technology and College of Veterinary Sciences. The University besides having a strong programme in traditional disciplines in agriculture and allied sciences, has a strong interdisciplinary programme in Biotechnology. The University is one of the Centers established by NBPGR and State Government for plant genetic research, quarantine and has Head, Department of Plant Pathology identified as the Residential Quarantine Nodal Officer for NorthZone. University has been strengthened with facilities such as P2 containment, transgenic glass houses, quarantine facility, medium term storage facility. The University in its Biotechnology programme has also added facilities for ELISA, Bioseparation, Plant Tissue Culture, Molecular Marker Lab etc. It has also assisted in nutritional evaluation of Bt cotton. The experts from University are participating in Monitoring and Evaluation Committee, RCGM. The University has an Institutional Biosafety Center. The University has been identified by Uttaranchal Government as hub of Biotechnology activities in the State. In the future, a Biotechnology Park and an Advanced Center of Biotechnology will be established in Pantnagar. It will be there that all these facilities and expertise will be available.

Component 4: Biosafety Clearing House and Enhanced information sharing and public awareness

Targeted information needs to be simple and reliable and should make best use of the different available media options under an overall strategy. GEF resources would be used to design a targeted information campaign on potential risks and benefits of LMOs. This information would be reviewed during project implementation to take into account the results of capacity building efforts in outputs 1 and 2. Replication efforts would ensure that lessons learned and scientific and technical innovations on biosafety efforts would be directly incorporated into the human resource preparation efforts over the mid and long term. Norms and guidelines, the abstracts of each risk evaluations, final decisions and reports of the procedure for the AIA (Art. 20) will also be included in the Biosafety Clearing House.

The outcome will be achieved interalia through:

- Support for establishing the national node for the Biosafety Clearing House and linkages with associated websites and list servers of relevant Ministries.

- Activities to improve information sharing and networking (workshops, exchange visits etc.).
- Training in information management, website construction etc.
- Stakeholder workshops with farmer groups, consumers, NGOs etc. on introduction and release of GMOs.
- Development of relevant materials on GMOs for key stakeholders.

The BCH would hire staff, procure equipment and software, and establish a local information network. Training would be imparted to the BCH staff for discharging their duties so as to achieve the objectives of the Project and so also to achieve the objectives of the CP. This would involve the detailed design of the information components including Web Page along with the design of information capturing mechanisms. The BCH would design and manage the database, prepare the Manual and operational design, information gathering and also implement the information system targeted at stakeholder departments and Ministries. The BCH would also impart training for the capacity enhancement of stakeholder departments and Ministries.

Component 5: Project Coordinating and Monitoring Unit (PCMU)

A PCMU under Project Director, Shri Desh Deepak Verma, JS in-charge and Project Coordinator, Dr. Manoranjan Hota, Joint Director will be created and supported within the MoEF to administer the project. The tasks of the PCMU will include overall project management, coordination with other Ministries, reporting and evaluation. The PCMU will also prepare work plans, budgets, and terms of reference for subcontractors and consultants, and will be responsible for maintaining financial accounts and records according to World Bank's guidelines for nationally executed projects.

14. RISKS AND SUSTAINABILITY

14.1 Risks

Project risks have been envisaged and the following table summarises likely risks and describes abatement measures within the scope of the project.

RISK	ABATEMENT MEASURES
Fragmentation of institutional mandates may make project implementation difficult.	A Steering Committee will constituted to provide appropriate guidance to project implementation and will approve annual work plans and ensure that participating institutions stay focussed on project objectives and outputs. Capacity building exercises in the Steering Committee gradually increase and thereby help participating institutions improve overall biosaftey policy and program implementation. Project timetable will insure that project as envisaged.

Industry advances continue to outpace government capacity	During project supervision, these issues will be identified and recommendations made to address them. The Biosafety Clearing House (BCH) will monitor these developments and recommend appropriate reallocation of resources.

14.2 Sustainability

This capacity-building project is designed to form the first part of a longer-term national effort to consolidate the Biosafety framework. Each of the proposed activities addresses gaps or barriers that have been identified during the project preparation process. Capacity building activities have been designed to strengthen not only the capabilities of the focal point to the CP, but also of key Ministries, agencies and scientific research institutions. The Steering Committee's role as the key technical focal point for the project will help to insure that decision-making will be cross-sectoral and produce synergies among key governmental and – non-governmental organizations. Financial sustainability is evident in the level of counterpart funding. The results of the project in terms of institutional strengthening and development should lay the groundwork for the allocation of additional resources in the future.

15. STAKEHOLDER PARTICIPATION

Broad-based public consultations on biosafety issues include representatives from all sectors in India. Over the last few years MoEF has organized 8 workshops addressing various stakeholders, policy makers, scientific community, and civil society. The GEF project will carefully assess the lessons learnt from these workshops and will also learn from the discursive process that follows the Berkeley Systems Approach. Experience will also be incorporated from the regional Science and Technology consultations the World Bank has engaged in this past year regarding participation, framing of the questions, ground rules and facilitation of multistakeholder consultations. The GEF project will also broaden stakeholder participation and public information provision by including key representatives of each of these sectors in the capacity building component through courses and publications, and through the dissemination of information via the BCH mechanism. Through the BCH mechanism, participation will be supported which will target farmers and other rural organizations and consumer associations. Additionally the BCH will offer the opportunity to create forums on relevant/important biosafety subjects for the purpose of obtaining input from the public at large and feedback on the projects outcomes, particularly at the institutional level. Opportunities will be provided to NGOs, academics and the research community to publish opinions and to disseminate them to the public. Finally, the BCH will disseminate information to different citizen groups interested in Biosafety.

Project design has benefited from interministerial consultations, as well as discussions with NGOs, experts, farmers organizations and industry. Stakeholders involved in project preparation include:

a) Ministry of Environment and Forests
b) Ministry of Agriculture
c) Department of Biotechnology
d) Ministry of Commerce & Industry
e) Ministry of Health Family Welfare
f) Indian Council for Agricultural Resources
g) National Bureau of Plant Genetic Resources
h) Non-governmental organizations (environmental, consumers, producers)

i) Other stakeholders (farmers etc.)

Workshops will be organised involving not only technical experts and government officials, but also key representatives of society (i.e. NGOs, consumer association, the press) to ensure a collective foundation for reaching a broad understanding and endorsement of priority biosafety issues. Such consultation with diverse stakeholders would be fundamental to implementation of this project.

16. International priorities

The current project responds to the commitment of the Cartagena Protocol to provide support to capacity building in implementation of the protocol, especially with respect to safe transboundary movement of LMOs.

17. Linkages to World Bank Programmes

The current WB GEF portfolio falls within the focal areas of climate change and biodiversity and includes initiatives under Operational Programs for: (i) Energy Conservation and Energy Efficiency; and (ii) Forest Ecosystems.

The WB's India GEF portfolio is comprised of 2 projects. There is also one project under preparation not including the proposed Capacity Building for Biosaftey. A brief summary of those projects is described below.

Under implementation:

1. *Energy Efficency-Full*-Sized *GEF*. The project will establish an energy efficiency service capacity in IREDA to help overcome market barriers to energy efficiency services for small and medium enterprises in India. Components will comprise: (a) technical assistance to IREDA to develop capacity to deliver energy efficiency services; (b) line of credit to finance private energy efficiency demonstration sub-projects; and (c) an energy efficiency service awareness campaign. (GEF Approval December 1997; WB Approval June 2000; project start up January 2001).

2. *Ecodevelopment. Full-Sized GEF.* Project integrates conservation & development objectives in 7 threatened, priority sites representative of India's varied ecosystems. It supports improved protected area management, emphasizing joint management with local communities; the design and financing of village development plans and agreements that address the negative interactions of local communities on biodiversity and vice-versa; and research (biological and policy), education, and institution-building to improve knowledge of, and support and capacity for, ecodevelopment and conservation activities. (GEF Approval May 1995; WB Approval September 1996; project start-up December 1996)

Under preparation:

1. Solar Thermal Power. Full- Sized GEF. Project involves (a) construction by the priv. Sector of a solar thermal/fossil-fuel hybrid power plant of about 140MW incorporating a parabolic trough solar thermal field of 35MW to 40 MW; and (b) technical assistance package to support commercialization of solar thermal technology.

The World Bank is also supporting a major project on agriculture in India, namely the National Agricultural Technology Project (NATP), being implemented by the Ministry of Agriculture. This project has some GMO component. This GEF funded project will further strengthen the capacity to deal with the LMOs and to implemented the Cartagena Protocol on Biosafety.

18. Implementation Arrangements

18.1 Project Execution

The GOI recently completed the preparation of a National GEF Strategy. This Strategy was endorsed by GOI in January this year. The strategy has proposed the establishment of an Inter-Ministerial GEF Coordination Committee to serve as the apex coordination body on GEF in India. This body will clear project entry into India's GEF pipeline and oversee status of implementation and allocate project responsibility to the various implementing agencies. This will provide an opportunity for improved coordination among Implementing Agencies.

The Ministry of Environment and Forests (MoEF) is the technical focal point for the GEF in India. The capacity building project on biosafety is the first of its kind which will be implemented by the GOI with support from the international donor community. It will be implemented by the technical and scientific division of the MoEF in association with other concerned Ministries and Departments as well as the International Cooperation Division of the MoEF. A Global Environment Cell (GEC) with UNDP assistance has been set up in the Ministry to facilitate implementation of GEF assistance. At present UNDP, UNEP, UNIDO, FAO, ADB WB are engaged in a number of projects/programmes relating to environment. However, none of these projects is working on biosafety issues. In order to coordinate various donors, MoEF holds regular meetings in the country.

Project execution will be the responsibility of the Biosafety Capacity Building Cell of the MOEF which is the GEF focal point in India. The Cell would constitute a PCMU for this purpose. This Cell would have the responsibility for the operational planning, administration, budget approval, annual plans and monitoring of project progress under the supervision of a Steering Committee represented by all the stakeholder Ministries/organizations viz. Ministry of Environment and Forests, Ministry of Agriculture, Ministry of Health, Department of Biotechnology, Ministry of Commerce, Ministry of Finance, etc.

18.2 Project Steering Committee

The MoEF will set up a Steering Committee under the Chairpersonship of the Additional Secretary in-charge, MoEF with representatives from relevant stakeholder Central Ministries/ Departments as its members.

The Steering Committee will approve an operational manual which will be submitted to the Bank for no objection and will ratify the commitments of each of the participating institutions, establish criteria for the functioning of the Committee and define procedures for decision making within the Committee as well as the first Annual Operating Plan. Taking into account the actual institutional context, the Committee will define the rules governing its functions, responsibilities, and outputs of each participating institution in the context of the projects objectives.

18.3 Project Co-ordinating and Monitoring Unit (PCMU)

A PCMU under Project Director, Shri Desh Deepak Verma, JS in-charge and Project Coordinator, Dr. Manoranjan Hota, Joint Director will be created and supported within the MoEF to administer the project. The tasks of the PCMU will include overall project management, coordination with other Ministries, reporting and evaluation. The PCMU will also prepare work plans, budgets, and terms of reference for subcontractors and consultants, and will be responsible for maintaining financial accounts and records according to World Bank's guidelines for nationally executed projects.

19. Incremental Costs Assessment

This project both complements existing activities described in the section on the current situation (baseline course of action) and adds new activities (alternative course of action) to the baseline that are required to meet the requirements of the Cartagena Protocol and achieve global environmental benefits. The detailed Incremental Cost Assessment can be found in Annex II.

20. Monitoring, Evaluation and Dissemination

Monitoring and evaluation of the project will be based on indicators presented in the project logframe. The relevant data for the analysis of these indicators will be collected during the different project activities, and in the reports prepared by the PCMU and participating ministries and agencies. The PCMU will prepare monthly status reports and results will be used to fine tune implementation strategies and schedules of the project components.

The PCMU will develop a project monitoring system. Quarterly revision of the results of the operative plan of the project will also take place in order for the advances and results of the project to be shared between the beneficiaries of the project and the Project Steering Committee. These revisions will be used to provide quarterly information to the World Bank. The web page, multimedia presentation and videos will also provide needed information on which to evaluate the project's progress and will be updated on a regular basis.

Results of project monitoring and evaluation activities will serve as a basis for the recommendations on changes in project implementation. It is hoped that these results will prove useful as a reference point for the implementation of other similar projects.

In addition, the Bank will undertake periodic supervision such as annual, mid-term and final performance evaluation.

21. Lessons learned

India participated in all of the negotiations leading up to the signing of the Protocol, and established working contacts with a wide range of countries. The compromises agreed to in order to move forward with the CP allowed India to understand the needs and priorities of other signatories in biosafety. More recently, India has participated in diverse meetings in the biosafety context (IPCC, CBD-Cancun, Mexico) and has used these opportunities to exchange ideas and strategies with countries in the region as well as other megadiverstiy countries. This experience provided the India authorities with an informal network of decision-makers and experts during the design and implementation of the country's biosafety framework.

ANNEX I

PROJECT LOGICAL FRAMEWORK

Each of these five main components has intermediate outputs expected which will be reached by diverse activities carried out by the main participants of the project.

Objective	Activities	Success Indicator	Unit of Measurement	Number of units	Way of Verifying
1. Project set up	Establishment of a Project Coordination and Monitoring Unit (PCMU). Formation of a Steering Committee.	Coordination Unit created. Created	Coordination unit.	1	Work Plan for coordination
2.Development of Institutional capacity	Design and creation of capacity on biosafety among key stakeholders/ Ministries.	Capacity on Bio safety, working in each one of the different institutions.	Number of stakeholders/ Ministries participating.	3	Action Plan on training
	Design of a training program oriented to capacity building for techniques and monitoring	Designed program based on the conceptual framework	Number of designed courses and exchanges.	1	Defined program
	Strengthening of laboratories by providing equipment to the laboratories to evaluate and mitigate risks (3 Organisations as listed out)	Equipment provided	Number of projects assessed for risks.	8	Action Plan for risk management
	○ Four training programmes for the policy makers so to enhance their capacities to implement the Cartagena Protocol.	Four training programmes	Trainings held	50	Action Plan on Training

	Training courses (8 modules x 4 workshops x 50 participants = 1600)	(8 modules x 4 zones x 50 participants = 1600)	Trainings held	1600	Action Plan on Training
3. Establishment of Biosafety Clearing House					
	Physical location of the BCH	Preparation of Directorate/Central Clearing Unit	Directorate/Central Clearing Unit adapted and established	1	Direct verification in situ Direct verification, and proof of purchase
	Hiring of staff	Hired personnel	Formation of the team	2	Contracts/loan from other Divisions
	Equipment and Software acquisition	Technical infrastructure purchased and functioning	List of equipment (to be identified)	-	Direct verification and permits.
	Local network connection	Connection working	Connection	1	Internet
	Identification and detailed design of the information components that the BCH will have	Structured components	Components	10	Written procedures
	Web Page design	Web page running on the internet	Web Page	1	data bases
	Detailed design of information capturing mechanisms	Standardized mechanisms of capture and exchange	Exchange and capture protocol	1	Document
	Design and management of data base	Data base working with proper information	Data base		Database
	Manual and operational design.	Clear manual published	Manual	1	Proceedings and reports
	Information gathering	Capture mechanisms and information exchange	Systemized information		Documents
	Connectivity to other stakeholder departments and Ministries.	Internet connection established	Connection	72	Database and exchange of information

	Training and capacity enhancement of stakeholder departments and Ministries	Online meeting and exchange of information.	Exchange of information	More than 72	Database and exchange of information
	Training for BCH staff	Personnel with the capacity for information sharing required for the BCH	No. of courses and trainings	2	Proceedings of the event
	Spreading information tools	Tool kit designed	KIT	1	
	Use of the results of risk analyses research	Level of the results for risk analyses	Number of attended requests and referrals of information use.	To be defined	

ANNEX II

INCREMENTAL COST ASSESSMENT

India has well-developed scientific manpower who are trained in molecular biology, immunology, microbiology, virology, plant pathology, and agronomic evaluation. There are several R&D institutions and adequate infrastructure for which project activities would be complementing the existing activities. The project would be complementing mainly in three areas in which India has expertise and experience: (i) development and strengthening of legal and regulatory framework and institutional structures; (ii) skills in biotechnology biosafety process applications; and (iii) human resource strengthening and development.

Incremental Cost Assessment

The total cost of the project will be US$ 4,080,418. The total baseline costs are US$ 1,010,418. The incremental costs to be provided by GEF will be US$ 1,000,000. The Government of India will contribute US$2,070,000 to the project's incremental costs. A summary of the project's incremental costs are provided in Table 1. The GOI's incremental costs of US$ 2,070,000 will include a cash contribution of US$1,000,000. The Table 2 provides a summary of the GOI incremental costs (cash vs. in kind).

Baseline Scenario

In the absence of additional GEF funding, a number of activities related to the project's components would be undertaken. The estimated cost of the Baseline investment is US$1,010,418.

As stated above, India has a established base of agricultural universities and institutional network with adequate infrastructure. This R&D infrastructure has contributed to the development of stable, disease-free cultivars that have contributed to increased food production. In many of these institutions people get trained as well as would get trained in various specific areas pertaining to Cartagena Protocol. Furthermore, India already has a comprehensive legal and institutional framework to manage LMOs. Key institutions such as the DBT and NBPGR oversee the development of LMOs from research stage to contained use, large-scale commercialisation and subsequently monitoring and evaluation in the field. Guidelines have also been prepared for food safety. There are detailed procedures for involving the State Govt authorities as well as the scientists from State and Central Govt institutions as has been described elsewhere in the project document. The existing regulations adequately bring closer the scientific personnel, the government officials as well as the legal system while considering the evaluation of LMOs for introduction in the environment.

Strengthening the legal framework and institutional mechanisms for biosafety management in India(US$143,750)

Activities will include the continued support for institutions which comprise the current institutional setup for biosafety management (MOEF, DBT, RDAC, RCGM, GEAC, relevant ministries and state and district government etc.). Some training and information exchange related to the provisions of the CP are planned.

Capacity building for risk evaluation, assessment and management (US$47,917)

The MOEF, DBT, NBPGR, IARI and CFTRI are the main organizations for risk evaluation, assessment and management. An operational system is in place with a small cadre of trained professionals. Over the next 3 years, the GOI will support the basic the human resources and infrastructure for risk assessment at these facilities (US$380,000). This support follows recommendations of the Asia Regional Workshop on Risk Assessment and Risk Management for implementing the Cartagena Protocol on Biosafety (IUCN) which was carried out in 2001.

Capacity building on risk assessment methodology will include comparative analysis to the risks of existing technologies from environmental, public health and socio-economic points of view. Information on these analyses will also feed into the public awareness materials developed by the project.

Strengthening of laboratories for analytical evaluation of the GM ingredients and certification services (US$795,834)

The development of infrastructure including building, farms, laboratories, and logistical support as well as manpower will continue at all the four specified laboratories (US$795,834). The four institutions selected to participate would continue to work on activities related to biosafety including interchange with other institutions throughout the country and overseeing biosafety issues involving risk assessment and risk management. The labs have basic equipment to undertake research and testing in molecular biology**.** ICAR and some private companies are currently undertaking evaluations on GM crops including: mustard, tobacco, potato, brinjal, cauliflower, cabbage and bell pepper. However, the required analytical and certification services for the transboundary movement of LMOs as specified in the CP are not yet available.

Establishing the biosafety database system and Biosafety Clearing House Mechanism (US$22,917)

The NBPGR has built up a database system on the import and distribution of all LMOs and GMOs in the country and would continue to work on activities related to an information database apart from networking with the other institutions who will participate in the project. The NBPGR in association with DBT will further strengthen the database containing various trial data of GMOs, accumulation of dossiers, maintenance of registers for the transboundary movement of LMOs conforming to the Cartagena Protocol. The database is accessible to various regulatory authorities as well as governmental organisations and ministries. (US$380,000)

Project Coordination & Monitoring Unit (US$ 0.00)

No baseline activities have been undertaken or are under implementation for this component. Funds associated with the baseline for this activity are tied to the approval of the GEF project.

Benefits of the baseline. Benefits achieved by the baseline will permit the GOI to make some progress in meeting its obligations under the CP, especially in institutional, database development and management, and risk assessment and risk management. However the scope and number of activities financed will be limited. The baseline does not permit the increase in institutional capacity and the development and implementation of the biosafety clearinghouse mechanism. Under the baseline, very few resources will be available for new laboratory equipment and supplies and the establishing dissemination and outreach programs.

GEF Alternative

Since India is a signatory to the CP and has already ratified it, it gives utmost importance to the relevance of implementation of Cartagena Protocol on biosafety. The need for capacity building and institutional strengthening are considered to be the key priorities. In other words there should be an approach for societal acceptance of the technologies involved in the use of LMOs and in this context the efforts would continue for capacity building for the risk management and risk assessment with the successful as well as careful use of transgene technology. The GEF alternative would be built up on the existing baseline scenario supporting a number of incremental activities needed to achieve the goals of the CP. The cost of such GEF alternative has been slated at US$4,080,418..

Strengthening institutional mechanisms for biosafety management in India:(Total Cost:US$ 643,750. Incremental cost US$500,000 of which the GEF US$200,000 and the GOI US$ 300,000).

The proposed alternative for the strengthening mechanisms would provide means to speed up the entire process of the implementation of Cartagena Protocol within a stipulated timeframe through the strengthening of the institutional mechanisms and refinement of the legal and regulatory framework. It is also proposed that various institutions would be further networked to facilitate decision making in the transboundary movement of LMOs through locally developed scientific protocols, some of which are already in place. The proposed programme would provide some better means for the dissemination, diffusion and absorption of the results of scientific assessments to various stakeholders within the country apart from various NGOs, LMO producers as well as private sector units. This would be made possible further through awareness programmes to be conducted via workshops, seminars with a proper bench marking. Training programs related to the provisions of the CP and biosafety management would be implemented at both the national and state levels to all concerned stakeholders.

Capacity building for risk evaluation, assessment and management (Total Cost: US$647,917. incremental cost US$600,000 of which the GEF US$200,000 and GOI US$400,000).

The alternative will help establish a fully operational system for risk assessment, monitoring and management. Training will be targeted at scientists and research managers in government. Training programs will include: research and production of LMOs, characterisation of various protocols, effect of LMOs on the environment as well as on health of human and animals. The training will also include standardisation of various methodologies with the coverage of various grey areas which often constitute a minor percentage of suspected risks in light of the present scientific developments which would be capable of allowing to find precise answer to various risks associated with LMOs. The major concerns with the use of LMOs would be adequately addressed on the basis of sound scientific experiments with the further development of existing guidelines and procedures.

Strengthening of laboratories for analytical evaluation of the GM ingredients and certification services (Total Cost: (Total Cost US$2,095,834. Incremental cost US$1,300,000 of which GEF US$300,000 and GOI US$1,000,000).

The existing strength of India in the analytical evaluation and certification services is inadequate in light of the available LMOs/GMOs and the products thereof. The GEF alternative will help the

GOI to build up the analytical evaluation system and certification services conforming to the Cartagena Protocol. With GEF support the project will purchase 4 Polymerase Chain Reactors (one for each lab @ $10,000 per reactor), one DNA sequencer ($50,000) and one Oligonucleotide Synthesizer ($50,000). In addition, certification services are further required for various ancillary exercises like cost benefit analysis, relevance of LMOs to societal needs as well as in relation to addressing the problems of hunger or meeting the nutritional requirements. The project will support the purchase of laboratory equipment and other equipment required for the evaluations.

Establishing the biosafety database system and Biosafety Clearing House Mechanism: (Total Cost:US$422,917. Incremental cost US$400,000 of which GEF US$200,000 and GOI US$200,000).

The alternative would further augment and expand the base of the biosafety database system in the existing as well as the associate institutions to further establish the biosafety clearing house mechanism. The GOI is aware of the BCH requirements and will develop this component with close attention to CBD guidelines. The project will support the purchase of necessary hardware(computers, scanners, network equipment) and specialized software required to build the database and build and manage the BCH.

Project Coordination & Monitoring Unit (Total Cost:US$270,000.Incremental cost US$ US$270,000 of which GEF US$ 100,000 and GOI US$ 170,000).

The alternative will allow the establishment of the PCMU at the MOEF.

Benefits of the GEF Alternative. The GEF alternative will enable India to move more quickly in building the scientific and institutional capacity necessary for meeting its obligations under the CP. The alternative will also strengthen the infrastructure facilities for risk assessment and risk management measures to be undertaken by various ministries on different GMOs and further the information sharing facilities. The gap areas like coordination between state and central governments and information sharing among them in implementation of present legal set up will be addressed.

Table 1: Incremental Cost Matrix (US$)

Component	Baseline	Increment (GEF)	Increment (GOI)	GEF Alternative
Project Coordination and Monitoring Unit	0.00	100,000	170,000	270,000
Strengthening Institutional mechanisms for Biosafety Management in India	143,750	200,000	300,000	643,750
Capacity Building for risk evaluation, assessment and management	47,917	200,000	400,000	647,917

Strengthening of laboratories for analytical evaluation of the GM ingredients and certification services	795,834	300,000	1,000,000	2,095,834
Establishing the Biosafety Database System and Biosafety Clearing-House Mechanism	22,917	200,000	200,000	422,917
Total	**1,010,418**	**1,000,000**	**2,070,000**	**4,080,418**

Table II: Government of India Increment (US $)

Component	Cash	In-kind
Project Coordination and Monitoring Unit	0.00	170,000
Strengthening Institutional mechanisms for Biosafety Management in India	0.00	300.000
Capacity Building for risk evaluation, assessment and management	0.00	400,000
Strengthening of laboratories for analytical evaluation of the GM ingredients and certification services	1,000,000	0.00
Establishing the Biosafety Database System and Biosafety Clearing-House Mechanism	0.00	200,000
Total	**1,000,000**	**1,070,000**

ANNEX III(a)

STAP ROSTER TECHNICAL REVIEW

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PROJECT NAME: Capacity Building for Implementation of the Cartagena Protocol
Duration: 3 years
IMPLEMENTING AGENCY: Ministry of Environment And Forests
Requesting Country: India
ELIGIBILITY: Ratified the Cartagena Protocol 17 JANUARY, 2003
GEF FOCAL AREA: Biodiversity
GEF Programming Framework: Enabling Activity

Review by Klaus Ammann,

Member of the STAP Roster Biodiversity

March 9, 2003

Introduction

First a general statement by the reviewer, which is out of the context of his review, which will concentrate on procedure, implementation, technical and scientific aspects.

The project focuses on the implementation of the Cartagena Biosafety Protocol, which has been ratified by India on January 17 2003. India must meet now many obligations as a state having ratified the protocol, and it is certainly of high priority to become more active for the Indian Government. There is no doubt that time is short, and if India wants to avoid unwelcome frictions in the so important process in modernizing its agriculture, then time is very short and India needs to invest a lot of efforts in human and financial resources. So – any attempt of the government and his bodies involved should be per se taken very serious and financial help put in place as expediently as possible.

The below project has therefore to be scrutinized with special attention also for its implementation strategy, whether results will be obtains expediently enough. In addition, the reviewer feels a responsibility to review the project in a particularly critical manner, since he considers it a very important task of the Indian government.

In order to follow up as closely as possible the Guidance for Reviews provided by STAP, I first will answer the following questions (adapted from the evaluation of biodiversity projects), each of which will make the head of a paragraph:

1. Is there sufficient background information about the legal context ?

There is no doubt that the project gives a fully comprehensive account on information about the environmental politics and environmental legislation to make the project work: There is an elaborate list of government bodies documented in the introduction, obviously written by an author who has deep insight in the governmental system in India. In chapter 7 there is a full account given on the background about India's environmental politics, which starts as early as 1927 and also documents a balanced view, the main strategy is documented in one of the first sentences: "strives to achieve a balance between development and conservation", putting the finger right at the beginning on the problem.
The project gives a professional account on what is in place and what still has to be established. The legal context (7.2.1.) is well described and the goals appropriately defined, and if India can achieve those goals of the biosafety protocol, the future will be a balance between biosafety and development in the best sense. In particular the project covers in a comprehensive way on how biodiversity conservation is organized. The role of the National Biodiversity Authority (NBA) is clearly defined, financial compensation which stems from the Biosafety Protocol

2. Is there sufficient background information about the technical context ?

The second chapter is written, as if the project author had a full account on the present day regulation in mind to write. This is unusual and again is proof of professional insight and experience. The guidelines are precisely described and meet e.g. European standards and 'even' Swiss standards. Swiss regulatory agencies could learn from India in the way the regulators differentiate between escaped genes causing "cause significant alterations in the biosphere" and others which do not. It is interesting to read the account and – to be honest – it should influence also the Swiss regulation, which is often too strong in my view –which does not mean, that the author has a basically permissive view on biosafety, on the contrary, the project documents with those lines a balanced view.
Also the drug part is comprehensively described regarding regulation, the seeds part as well, there is even a monitoring installed after LMO seeds are commercialised.
The reviewer gets the impression, that India will do a good and balanced job for the commercialisation, but it has to be stated, that only this project will put India in a position to really come to terms:

"After the transgenic plant variety is commercially released, its seed will be registered

and marketed in the country as per the provisions of the Seeds Act. After commercial release of a transgenic plant variety, its performance in the field will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture. It has also been mentioned that transgenic varieties can be protected under the legislation in the same manner as non-transgenic varieties after their release for commercial cultivation."

3. Has there an Adequate Institutional Context been described ?
Here also the project authors have delivered excellent work, again they show a thorough scholarship in the field and build confidence that nothing is just for some political reasons brushed under the table. It is an extensive account on the several committees with regulatory power and with precision the complicated structures and thus complicated regulation process is fathomed out. Here you also can easily see the reason for the delays and the slow work in regulation, but this is not a problem specific to India, I would say bluntly that the situation in Europe is worse.The various institutions are:

The Recombinant DNA Advisory Committee (RDAC, the Institutional Biosafety Committee, the Review Committee on Genetic Manipulation (RCGM), the (IBSC) Genetic Engineering Approval Committee (GEAC), the State Biotechnology Coordination Committee (SBCC). Also the State and District level, not to underestimate in their influence, are in Detail described with all the structures and procedures, again the reviewer witnesses that the project authors are closely in touch with the situation in India.

Also on the ministerial level, details are sufficient: The Ministry of Agriculture, the National Research Centre for Agricultural Biotechnology, the National Bureau of Plant Genetic Resources are not merely described, but also the texts are illustrated with lots of concrete examples about activities of the named Institutions.

4. Is the environmental context adequately weighted ?
In contrast to the previous chapters these paragraphs are a bit short, summary statements are made and certainly this does signal that more should be done in future, the project writers are aware of this.

Already here I would draw the attention of the project leaders to get in contact with other institutions such as UNIDO, which is building up a regulatory decision making system which will work on a global level and be a great help: It will contain an electronic decision making tree which is combined with a compendium with the relevant information on all regulatory matters.

There is one important institution I am missing here: The highly influential Swaminathan Foundation, but this omission can have an explanation in the fact that actually this foundation is a private one. But still I would suggest that in many activities of the project, Swaminathan and his institution could play an important role.

5. Is public the activity on information adequately described ?
Unfortunately yes, there is still a lot to be done, and even the 8 events described are not really impressive, since in one of those events in Chennai the writer of this expertise has

been present and there was not much of a public debate, and it is also clear to me that a real scientific exchange of ideas and counter ideas is probably much more difficult in India than in Europe. But more thoughts below when the comments on the proposed project activities come up.

6. Are the gaps and the baseline capacities critically analysed ?
This is clearly the case, the authors have done a rigorous job, they have identified a number of significant barriers which hinder the implementation of the Cartagena Protocol. And it is by all means not a defensive strategy what the authors see, when they describe lacunas: Important seems for them the enforcement of Research and Development of local institutions, so that more sophisticated regulatory activity can put in place. It is rewarding to realize that the authors of the project also have a realistic view on the work which has to be done in the field of public perception: "For the acceptance of LMOs by the society, scientific assessments alone cannot form the basis of decision making. Many other aspects, especially socio-economic factors need to be considered."
But also technical and human resources gaps are identified. And from now on in the project text it gets really exciting, the authors glide with their marvellous impetus unwillingly into the project formulation, action plan style becomes obvious.

7. Is the project strategy adequately described ?
The list of actions they propose is long, adequate, the only lacuna I can discover is that there is not enough emphasis put on discursive processes, where a *real dialogue* is initiated.

It is also clear to the project authors that priorities have to be set, and that realistically enough they see that the high degree of fragmentation of agencies involved will be a serious risk, which can only be overcome, if special attention to good project management and project coordination is paid.

In the next chapter 13 the authors come to terms and make some priority decisions:
It is also clear that the emphasis will be put on the negative side of modern plant breeding, and one has to admit that there is logic in this. Still, the expert would like to see at least a few baseline thoughts: Risk cannot be determined by focussing solely on the new technologies, it is of utmost importance that risk evaluation is done in a cross checking with other strategies in agriculture, namely the classic, pesticide focussed agriculture and also aspects of organic farming. Also the social and cultural aspects should not be forgotten. In many ways, the present day risk assessment philosophy does not meet scientific standards, and by this the expert does not mean the strict science, but that science is always building up on comparisons, on the zero-comparison for instance. How can you evaluate the risks of Bt crops when you do not evaluate the classic pesticide oriented agriculture at the same time and work on data sets also on this side ?

Scientific approaches in risk assessment in modern agriculture should be unbiased and take into account baseline data. It is possible, that the project authors include such thoughts without saying it in expressis verbis when they describe monitoring systems and field trials without going into the details.

It may also be included in another priority point under Biotechnology:

- "Biotechnology – Gene constructs, development of protocols for evaluation of safety, development of guidelines and training materials."

In point f) it would be possible to seek help with UN agencies working since some time on this: UNIDO, UNEP.

It is also rewarding to understand, that India can build up on a number of existing activities, but as the project authors rightly point out, all those institutions and specialists need the project implementation in order to get on time to results really needed. The expert can also approve the lines on the Strategic considerations regarding the project 13. 2.2

8. Is the project output balanced and does it fit to the introductory chapters ?
After those preliminary remarks to the project strategy it is no surprise, that the expert comes to positive judgements regarding the output and the above question 8.

Output 1
Again the expert thinks, the wording for monitoring and field trials mean automatically, that baseline comparison is included, although not specifically mentioned. In the eyes of the expert this is a must. Also it should be mentioned, that MOEF hosting the activities, should actively include the views of other ministries from the agriculture and health sector in the planning process and later in staging an evaluation process for all introduction, research, monitoring and commercialisation.

Output 2
Doubtless India needs a boost in strengthening the institutions on all levels, not only in the light of institutional weaknesses, but also in the light of innovation, since with the Cartagena protocol India is meeting new obligations, just as well as the other nations.
Training courses are extremely important, again here UNIDO and UNEP could help.

Output 3
Although India has considerable resources in biotechnology research and capacity in analytical lab work, there is no doubt that the country needs to upgrade this capacity in the light of the rapid new development.

And if you realize how many biotech generated crops are in the pipeline (just have a look a the impressive listing of National Research Centre on Plant Biotechnology (NRCPB), IARI p. 23, then you know how much upgrading regulation needs.

Output 4
All efforts will be in vain, if not Output 4 comes into full force: A Biosafety Clearing House and Enhanced Information Sharing and Public Awareness need to be funded by the project with important sums. The expert wants to emphasize the point about the stakeholder workshops, where farmers, scientists, consumers, NGO's etc have ample

tome to exchange their views and come to terms about decisions. (Consensus is often not possible, but decision making processes need time and good professional structures for an efficient exchange of knowledge, for documenting the process and last but not least encourage and select the best experts and stakeholders. This should be done in the spirit of a discursive process, in the best tradition of the Berkeley Systems Approach, see http://www.academia-engelberg.ch/ the homepage, and the discursive process **http://www.academia-engelberg.ch/en/activities_spirit_disc.html**.

Output 5
It is with pleasure for the expert to see that the project authors have rightly seen that management and stakeholder structures are of a decisive importance. After all the CBD wants to see such structures and India has committed itself to comply. We will see a decisive enhancement of the processes, provided they are funded through this project, and it is particularly rewarding to see that the regulatory decision making processes will become much more transparent than they were up to now.

"Opportunities will be provided to NGOs, academics and the research community to publish opinions and to disseminate them to the public. Finally, the BCH will disseminate information to different citizen groups interested in Biosafety"

It would be advisable to give equal weight to governmental and non-governmental organizations such as Universities, Consumer groups etc. I think also the private companies should have their voice, the expert does not approve to the moves in the United Kingdom to leave the private companies outside the important committees and stakeholder processes.

It is also good to see that the project authors have a realistic view on the obstacles, most of them can be minimized through professional project management and good communication.

Implementation measures, are they realistic ?
I can answer this question positively, since both project authors have a very intimate knowledge of the present day structure and their weaknesses and from there they build up realistic scenarios.

Are the baseline views correct and can they serve as a nucleus for the project ?
Also here I have nothing but positive answers as an expert. And it nicely illustrates the importance of the support by the World Bank. Finally it will also help to link even better the Indian biosafety specialists to the global network of growing expertise in those new fields.

Is there any area weakness, gap in the project?
I do not think that there are any decisive gaps in the project, except maybe for the fact that stakeholder processes should be more precisely described, and it should be made clear, that those structures should have s strong touch of a discourse and need to be designed as participative processes.

Are there any controversial aspects about the project?
Again the expert can confirm that he did not find any controversial aspects in the project, there are no points which need basically some clarification, and it would be good if the project could start expediently.

Full support of project proposal by expert K.Ammann
Overall I want to state, that I found the project to be written in a professional manner and alone from those lines I am fully confident, that the project management can be delegated to the two project authors without any hesitation. The two personalities have proven with this text that they have a thorough knowledge of the Indian structures and they also have a deep understanding about the science behind.

St. Louis, Missouri Botanical Garden

Prof. Dr. Klaus Ammann,
on sabbatical leave

ANNEX III(b)

WORLD BANK RESPONSE TO STAP REVIEW

Introduction

First a general statement by the reviewer, which is out of the context of his review, which will concentrate on procedure, implementation, technical and scientific aspects.

The project focuses on the implementation of the Cartagena Biosafety Protocol, which has been ratified by India on January 17 2003. India must meet now many obligations as a state having ratified the protocol, and it is certainly of high priority to become more active for the Indian Government. There is no doubt that time is short, and if India wants to avoid unwelcome frictions in the so important process in modernizing its agriculture, then time is very short and India needs to invest a lot of efforts in human and financial resources. So – any attempt of the government and his bodies involved should be per se taken very serious and financial help put in place as expediently as possible.

The below project has therefore to be scrutinized with special attention also for its implementation strategy, whether results will be obtains expediently enough. In addition, the reviewer feels a responsibility to review the project in a particularly critical manner, since he considers it a very important task of the Indian government.

In order to follow up as closely as possible the Guidance for Reviews provided by STAP, I first will answer the following questions (adapted from the evaluation of biodiversity projects), each of which will make the head of a paragraph:

1. Is there sufficient background information about the legal context ?

There is no doubt that the project gives a fully comprehensive account on information about the environmental politics and environmental legislation to make the project work: There is an elaborate list of government bodies documented in the introduction, obviously written by an author who has deep insight in the governmental system in India. In chapter 7 there is a full account given on the background about India's environmental politics, which starts as early as 1927 and also documents a balanced view, the main strategy is documented in one of the first sentences: "strives to achieve a balance between development and conservation", putting the finger right at the beginning on the problem.
The project gives a professional account on what is in place and what still has to be established. The legal context (7.2.1.) is well described and the goals appropriately defined, and if India can achieve those goals of the biosafety protocol, the future will be a balance between biosafety and development in the best sense.
In particular the project covers in a comprehensive way on how biodiversity conservation is organized. The role of the National Biodiversity Authority (NBA) is clearly defined, financial compensation which stems from the Biosafety Protocol

Response: No response required.

2. Is there sufficient background information about the technical context ?

The second chapter is written, as if the project author had a full account on the present day regulation in mind to write. This is unusual and again is proof of professional insight and experience. The guidelines are precisely described and meet e.g. European standards and 'even' Swiss standards. Swiss regulatory agencies could learn from India in the way the regulators differentiate between escaped genes causing "cause significant alterations in the biosphere" and others which do not. It is interesting to read the account and – to be honest – it should influence also the Swiss regulation, which is often too strong in my view –which does not mean, that the author has a basically permissive view on biosafety, on the contrary, the project documents with those lines a balanced view.
Also the drug part is comprehensively described regarding regulation, the seeds part as well, there is even a monitoring installed after LMO seeds are commercialised.
The reviewer gets the impression, that India will do a good and balanced job for the commercialisation, but it has to be stated, that only this project will put India in a position to really come to terms:

"After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act. After commercial release of a transgenic plant variety, its performance in the field will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture. It has also been mentioned that transgenic varieties can be protected under the legislation in the same manner as non-transgenic varieties after their release for commercial cultivation."

Response: No response required.

3. Has there an Adequate Institutional Context been described ?
Here also the project authors have delivered excellent work, again they show a thorough scholarship in the field and build confidence that nothing is just for some political reasons brushed under the table. It is an extensive account on the several committees with regulatory power and with precision the complicated structures and thus complicated regulation process is fathomed out. Here you also can easily see the reason for the delays and the slow work in regulation, but this is not a problem specific to India, I would say bluntly that the situation in Europe is worse.The various institutions are:
The Recombinant DNA Advisory Committee (RDAC, the Institutional Biosafety Committee, the Review Committee on Genetic Manipulation (RCGM), the (IBSC) Genetic Engineering Approval Committee (GEAC), the State Biotechnology Coordination Committee (SBCC). Also the State and District level, not to underestimate in their influence, are in Detail described with all the structures and procedures, again the reviewer witnesses that the project authors are closely in touch with the situation in India.

Also on the ministerial level, details are sufficient: The Ministry of Agriculture, the National Research Centre for Agricultural Biotechnology, the National Bureau of Plant Genetic Resources are not merely described, but also the texts are illustrated with lots of concrete examples about activities of the named Institutions.

Response: No response required.

4. Is the environmental context adequately weighted ?
In contrast to the previous chapters these paragraphs are a bit short, summary statements are made and certainly this does signal that more should be done in future, the project writers are aware of this.

Already here I would draw the attention of the project leaders to get in contact with other institutions such as UNIDO, which is building up a regulatory decision making system which will work on a global level and be a great help: It will contain an electronic decision making tree which is combined with a compendium with the relevant information on all regulatory matters.

There is one important institution I am missing here:
The highly influential Swaminathan Foundation, but this omission can have an explanation in the fact that actually this foundation is a private one. But still I would suggest that in many activities of the project, Swaminathan and his institution could play an important role.

Response: The Bank project team has advised the MOEF of these comments and suggestions. MOEF will contact UNIDO and the Swaminathan Foundation to obtain the information.

5. Is public the activity on information adequately described ?
Unfortunately yes, there is still a lot to be done, and even the 8 events described are not really impressive, since in one of those events in Chennai the writer of this expertise has been present and there was not much of a public debate, and it is also clear to me that a real scientific exchange of ideas and counter ideas is probably much more difficult in India than in Europe. But more thoughts below when the comments on the proposed project activities come up.

Response: The bank project supervision team will pay special attention to stakeholder participation and public information programs. The MOEF has been advised that that these aspects need strengthening. Lessons from the eight consultations conducted by MOEF as well as the discursive process basing on Berkeley Systems Approach and the experience of the Science and Technology consultation the Bank has recently engaged in will be reviewed and discussed with the project management to develop the consultation processes.

6. Are the gaps and the baseline capacities critically analysed ?
This is clearly the case, the authors have done a rigorous job, they have identified a number of significant barriers which hinder the implementation of the Cartagena Protocol. And it is by all means not a defensive strategy what the authors see, when they describe lacunas: Important seems for them the enforcement of Research and Development of local institutions, so that more sophisticated regulatory activity can put in place. It is rewarding to realize that the authors of the project also have a realistic view on the work which has to be done in the field of public perception: “For the acceptance of LMOs by the society, scientific assessments alone cannot form the basis of decision making. Many other aspects, especially socio-economic factors need to be considered.”

But also technical and human resources gaps are identified. And from now on in the project text it gets really exciting, the authors glide with their marvellous impetus unwillingly into the project formulation, action plan style becomes obvious.

Response: No response required.

7. Is the project strategy adequately described ?

The list of actions they propose is long, adequate, the only lacuna I can discover is that there is not enough emphasis put on discursive processes, where a *real dialogue* is initiated.

It is also clear to the project authors that priorities have to be set, and that realistically enough they see that the high degree of fragmentation of agencies involved will be a serious risk, which can only be overcome, if special attention to good project management and project coordination is paid.

In the next chapter 13 the authors come to terms and make some priority decisions:
It is also clear that the emphasis will be put on the negative side of modern plant breeding, and one has to admit that there is logic in this. Still, the expert would like to see at least a few baseline thoughts: Risk cannot be determined by focussing solely on the new technologies, it is of utmost importance that risk evaluation is done in a cross checking with other strategies in agriculture, namely the classic, pesticide focussed agriculture and also aspects of organic farming. Also the social and cultural aspects should not be forgotten. In many ways, the present day risk assessment philosophy does not meet scientific standards, and by this the expert does not mean the strict science, but that science is always building up on comparisons, on the zero-comparison for instance. How can you evaluate the risks of Bt crops when you do not evaluate the classic pesticide oriented agriculture at the same time and work on data sets also on this side ?

Scientific approaches in risk assessment in modern agriculture should be unbiased and take into account baseline data. It is possible, that the project authors include such thoughts without saying it in expressis verbis when they describe monitoring systems and field trials without going into the details.
It may also be included in another priority point under Biotechnology:

- "Biotechnology – Gene constructs, development of protocols for evaluation of safety, development of guidelines and training materials."

In point f) it would be possible to seek help with UN agencies working since some time on this: UNIDO, UNEP.

It is also rewarding to understand, that India can build up on a number of existing activities, but as the project authors rightly point out, all those institutions and specialists need the project implementation in order to get on time to results really needed. The expert can also approve the lines on the Strategic considerations regarding the project 13. 2.2

Response:

On multistakeholder consultations, see response to question 5

Fragmentation of agencies: One of the goals of the inter-ministerial steering group of the project will be to create a forum for exchange of views and consensus building by the different participating ministries. Expert input to facilitate these consultations will be supported by the project.

Baseline risks and comparative analysis: Capacity building on risk assessment methodology will include comparative analysis to the risks of existing technologies from environmental and socio-economic points of view. Information on these analyses will also feed into the public awareness materials developed by the project.

Cooperation with other agencies:The project management will be in touch with other agencies working on biosafety, such as UNIDO, UNEP, ISNAR (and other CGIAR centers), and relevant bilateral agencies to compare their methodologies and lessons learnt in biosafety capacity building and risk assessment.

8. Is the project output balanced and does it fit to the introductory chapters ?
After those preliminary remarks to the project strategy it is no surprise, that the expert comes to positive judgements regarding the output and the above question 8.

Output 1
Again the expert thinks, the wording for monitoring and field trials mean automatically, that baseline comparison is included, although not specifically mentioned. In the eyes of the expert this is a must. Also it should be mentioned, that MOEF hosting the activities, should actively include the views of other ministries from the agriculture and health sector in the planning process and later in staging an evaluation process for all introduction, research, monitoring and commercialisation.

Output 2
Doubtless India needs a boost in strengthening the institutions on all levels, not only in the light of institutional weaknesses, but also in the light of innovation, since with the Cartagena protocol India is meeting new obligations, just as well as the other nations.
Training courses are extremely important, again here UNIDO and UNEP could help.

Output 3
Although India has considerable resources in biotechnology research and capacity in analytical lab work, there is no doubt that the country needs to upgrade this capacity in the light of the rapid new development.

And if you realize how many biotech generated crops are in the pipeline (just have a look a the impressive listing of National Research Centre on Plant Biotechnology (NRCPB), IARI p. 23, then you know how much upgrading regulation needs.

Output 4

All efforts will be in vain, if not Output 4 comes into full force: A Biosafety Clearing House and Enhanced Information Sharing and Public Awareness need to be funded by the project with important sums. The expert wants to emphasize the point about the stakeholder workshops, where farmers, scientists, consumers, NGO's etc have ample tome to exchange their views and come to terms about decisions. (Consensus is often not possible, but decision making processes need time and good professional structures for an efficient exchange of knowledge, for documenting the process and last but not least encourage and select the best experts and stakeholders. This should be done in the spirit of a discursive process, in the best tradition of the Berkeley Systems Approach, see http://www.academia-engelberg.ch/ the homepage, and the discursive process http://www.academia-engelberg.ch/en/activities_spirit_disc.html.

Output 5

It is with pleasure for the expert to see that the project authors have rightly seen that management and stakeholder structures are of a decisive importance. After all the CBD wants to see such structures and India has committed itself to comply. We will see a decisive enhancement of the processes, provided they are funded through this project, and it is particularly rewarding to see that the regulatory decision making processes will become much more transparent than they were up to now.

"Opportunities will be provided to NGOs, academics and the research community to publish opinions and to disseminate them to the public. Finally, the BCH will disseminate information to different citizen groups interested in Biosafety"

It would be advisable to give equal weight to governmental and non-governmental organizations such as Universities, Consumer groups etc. I think also the private companies should have their voice, the expert does not approve to the moves in the United Kingdom to leave the private companies outside the important committees and stakeholder processes.

It is also good to see that the project authors have a realistic view on the obstacles, most of them can be minimized through professional project management and good communication.

Response: The MOEF has been advised that training in Component 1 needs to be developed to lay the groundwork for inter-ministerial cooperation in biosafety. In addition, the MOEF should examine the training programs in biosafety undertaken by UNEP and UNIDO for possible inclusion. MOEF has been advised of the STAP experts views on stakeholder participation and of the methodology used in the Berkeley Systems Approach. Non- governmental organizations concerned with biosafey should have representation on the Project Steering Committee.

Implementation measures, are they realistic ?

I can answer this question positively, since both project authors have a very intimate knowledge of the present day structure and their weaknesses and from there they build up realistic scenarios.

Response: No response required.

Are the baseline views correct and can they serve as a nucleus for the project ?
Also here I have nothing but positive answers as an expert. And it nicely illustrates the importance of the support by the World Bank. Finally it will also help to link even better the Indian biosafety specialists to the global network of growing expertise in those new fields.

Response: No response required.

Is there any area weakness, gap in the project?
I do not think that there are any decisive gaps in the project, except maybe for the fact that stakeholder processes should be more precisely described, and it should be made clear, that those structures should have s strong touch of a discourse and need to be designed as participative processes.

Are there any controversial aspects about the project?
Again the expert can confirm that he did not find any controversial aspects in the project, there are no points which need basically some clarification, and it would be good if the project could start expediently.

Response: No response required.

ANNEX IV

TIMETABLE OF ACTIVITIES

Activities	TIME (annual trimesters of the project)											
	YEAR 1				YEAR 2				YEAR 3			
	1	2	3	4	5	6	7	8	9	10	11	12
ESTABLISHMENT OF PROJECT COORDINATION AND MONITORING UNIT (PCMU)												
Establishment of the PCMU	◄►											
Operationalize unit		◄	—	—	—	—	—	—	—	—	—	►
INSTITUTIONAL CAPACITY												
Design and creation of Biosafety capacity.	◄►											
Adjustment to the capacity building program for the development of knowledge nodes.		◄►										
Risk assessment and management			◄	—	—	—	—	—	—	—	—	►
Training on LMO's Biosafety Level 1			◄	—	—	—	—	—	—	—	—	►
Biosafety on microorganisms –LMO's								◄	—	—	—	►
Proceedings of the courses				◄	—	—	—	—	—	—	—	►
Biosafety guides		◄	—	—	—	—	—	—	—	—	—	►
Strengthening of laboratories by providing equipment to the laboratories to evaluate and mitigate risks			◄	—	—	—	—	—	—	—	—	►
Biosafety Clearing House-information exchange mechanism												
	◄►											
Physical location of BCH	◄►											
Hiring of human resources	◄►											
. Purchase of servers	◄►											
. Purchase of computers	◄►											
. Purchase of printers	◄►											
Purchase of software	◄►											
Purchase of supplies, maintenance and materials	◄►											
Connection to local network	◄►											
Identification and detailed design of the information components for the BCH.		◄	—	►								
Web page design.												
Detailed design of the mechanisms to capture and exchange information.		◄	—	►								
Database design and management				◄	—	►						
Design of the operational manual of BCH				◄	—	►						
Information gathering				◄	—	—	—	—	—	—	—	►
Evolution of the gathered information.					◄	—	—	—	—	—	—	►
Design of dissemination tools.				◄	—	—	—	►				
Launching of BCH				◄	—	►						

ANNEX V

MATRIX SHOWING THE LINKAGE AMONG ACTIVITIES, THE CARTAGENA PROTOCOL AND THE NATIONAL BIOSAFETY FRAMEWORK

ACTIVITY	LINKAGE TO THE NATIONAL BIOSAFETY FRAMEWORK	LINKAGE TO CARTAGENA PROTOCOL (ARTICLES)
▪ Evaluate the existing regulatory instruments and develop others which will ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology. ▪ Creation of a high level interinstitutional mechanism – Steering Committee	▪ A legal proposal for the creation of the Steering Committee. ▪ Elaborate and develop a plan for intersectorial coordination related to information on LMOs and their derivatives. ▪ Propose strategies for the incorporation of the legal framework and related policies into the decision making process for sector projects and programs which are focused on LMOs and biosafety.	2(2), 8(2), 11(2), 9(3), 10(1), 16(3) 16 (4), 17 (1), 18(2a), 18 (2b), 18(2c), 21 (1,6) 21(2), 21(3,5), 21(4), 25(1), 25(2)
▪ Eight regional workshops including training courses for trainers targeted at policy makers, NGOs, media, consumer and producer groups focus on contained, deliberate release and commercial use of LMOs. will be organized with the aim to train and sensitise the risk assessment and management for the LMO/GMOs. ▪ specialised training of selected technical personnel. ▪ Establish a network of laboratories which will promote strategic alliances among national research organizations	Promote the development of institutional capacity on biosafety and establish mechanisms for risk management including: ▪ Evaluation and analysis of information related to LMOs ▪ Monitoring, and control of use of LMOs ▪ Increasing public awareness and participation	15(1,2), 16(1), 16(3), 17(1), 20(3) (c, e), 25 (3), 33
▪ Establishment of infrastructure and logistics for design and maintenance of information network ▪ Creation of roaster of experts	▪ Propose and develop mechanisms for the effective interchange of scientific, technical, legal and administrative information or other information deemed relevant at the national, regional or international level. ▪ A national system of information on	20, 23(1a) 23(1b) 23(2) 23(3)

	biosafety that includes mechanisms related to the provisions of the Cartagena Protocol (ie Biosafety Clearing House) ▪ Training in the efficient management of information	
▪ Establish a network for research, risk assessment ▪ Improve laboratory facilities and support laboratories including molecular biology for risk assessment and monitoring on LMOs	▪ Promote the development of institutional capacities in the area of biosafety among key institutions with responsibilities for overseeing matters related to LMOs. In this context establish mechanisms for: ▪ Creation of research groups on Biosafety to provide technical support for decision making at the sectorial level ▪ Risk management ▪ Evaluation and analysis of information on LMOs ▪ Creation of a national data base ▪ Control and monitoring of LMOs ▪ Building the required infrastructure for control and monitoring	15(1,2), 16(1), 16(3), 17(1), 20(3) (c, e), 25 (3), 33

ANNEX VI

COMPOSITION AND FUNCTIONS OF INDIAN COMPETENT AUTHORITIES

Competent Authority	Composition	Functions
Recombinant DNA Advisory Committee (RDAC)	As determined by the Department of Biotechnology – to consist of experts in their individual capacity	To review biotechnology developments at national and international levels; to recommend suitable biosafety regulations for India.
Genetic Engineering Approval Committee (GEAC):	Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology Members: Representative of concerned Agencies and Departments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy: Expert members: Director General Indian Council of Agricultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity. Member Secretary: An official of the Department or Environment, Forest and Wild life.	This committee shall function as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.
Review Committee on Genetic Manipulation (RCGM)	The Review Committee on Genetic Manipulation shall include representatives of (a) Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.	This committee shall function in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms
Institutional Biosafety committees (IBSC)	Head of the Organization;scientists engaged in rDNA work, Biosafety or Medical Officer, Nominee, Department of Biotechnology	To oversee rDNA research activities; to seek RCGM approval for category III risk; to ensure adherence with biosafety guidelines; to prepare an emergency plan; to inform DLC, SBCC & GEAC about relevant experiments.

State Biotechnology coordination committee (SBCC)	Chief Secretary, State Government: Secretaries, Department of Environment, Health, Agriculture, commerce, Forests, Public Works, Public Health; chairman, State Pollution Control Board ; State microbiologists and pathologists; Other experts in individual capacity	To periodically review safety and control measures in institutions in handling GMOs, to inspect and take punitive action in case of violations through the State Pollution control Boards or the Directorate of Health; to act as nodal agency at the state level to assess damage, if any, from release of GMOs, and to take on site control measures.
District-Level Committee (DLC)	District Collector, Factory Inspector; Pollution Control Board Representative; chief medical Officer; district Agricultural Officer, Public Health Department Representative; District microbiologists/pathologists; Municipal Corporation Commissioner; other experts in individual capacity	To monitor safety regulations in installations; to investigate compliance with rDNA guidelines and report violations to SBCC or GEAC; to act as nodal agency as district level to assess damage, if any, from release of GMOs and to take on site control measures.