IMPLEMENTATION COMPLETION MEMORANDUM (ICM)

Revised Template version 5/18/06

A. BASIC TRUST FUND INFORMATION

Most basic information should be automatically linked to SAP TF Master Data and IBTF

TF Name: GEF Mid-size project **"Capacity Building for Implementation of the Cartagena Protocol on biosafety"**
TF Number: **GE-PO-79856-WBTF52427-IN**
Task Team Leader Name/TF Managing Unit: **Eija Pehu/SASAR (on cross support from ARD)**
TF Amount *(as committed by donors):* **1 million USD**
Recipient of TF funds *(Bank/Recipient, if Recipient state name of recipient government and implementing agency):* **India, Ministry of Environemnt and Forests**
Type of TF*(Free-standing/ programmatic/ new TF for an ongoing program)*: **GEF Program on Biosafety Capacity Building/Demonstration Projects (12 countries)**
Single/Multi Donor: **Single**
Donor(s) Name(s): **Global Environment Facility**
TF Program Source Code:
Purpose of TF *(Co-financing/Investment financing/ Debt Service/ Advisory Activities-Bank/Advisory Activities-Recipient, etc)*: **Biosafety Capacity Building for Implementation of the Cartagena Protocol on Biosafety**
TF Approval/IBTF Clearance Date**: March 12, 2003**
TF Activation Date**: July 23, 2003**
TF Closing Date(s): **June 30, 2007**
Date of ICM Submission to TFO:
Cost and Financing Table: Annex 1.

Grant for Capacity Building for Implementation of the

Cartagena Protocol Project

B. TRUST FUND DEVELOPMENT OBJECTIVES AND DESIGN

1. Original (and Revised) Trust Fund Development Objectives

Provide original statement of objectives from the approved/cleared IBTF. If original objectives have been changed, explain the timing and nature of the revisions, their justification and approval authority given.

The Development Objective is to strengthen institutional capacity for implementing the Cartagena Protocol on Biosafety in India.

2. Original (and Revised) Trust Fund Activities/Components

Provide original activities/components to be financed by the Trust Fund. If original activities/components have been changed, identify them, and explain the nature of the revisions, their justification and approving authority.

Component 1: Strengthening of institutional and legal framework to improve capacity and coordination in decision-making within and across ministries.

Component 2: Improved capacity for risk evaluation and management.

Component 3: Strengthening laboratories/institutions for analytical detection of LMOs

Component 4: Biosafety Claearing House and enhanced information sharing and public awareness

Component 5: Project coordination and monitoring unit

3. Outcome Indicators

Provide original performance benchmarks to be measured in the assessment of outcome If none were established, explain why not.

Original indicators*/Indicators added in 2005:*

Component 1: Biosafety capacity established in key institutions
Four training programs conducted for policy makers

Component 2: Training program designed.
Training courses to stakeholders conducted.
Downloads of risk assessment report from MOEF web-page
Training.Needs Assessment used by other organizations

Component 3: Equipment provided.
Technical training courses conducted.
LMO detection protocols developed and validated.
Downloads of the rice biology document from NPBGR web-site
Number of hits in the GMO database of NRCPB

Component 4: Central Clearinghouse design finished.
Equipment purchased.
Web-page running.
Data capture working.
Competent personnel recruited.
BCH-India live and fully functional
Number of hits in the project web-site

Component 5: Coordination unit created
Annual workplans prepared.
Steering committee meets regularly
Operational guidebook published and in use

4. Other Significant Changes in Trust Fund Design
Describe and explain the rationale for any changes made in design, scope and scale, implementation arrangements and schedule and funding allocation

The above addition of indicators was done early 2005 as the Bank was moving strongly towards outcome monitoring in 2004-05 and as the program content became clearer during implementation.

The funding allocation to category 'training' was doubled from 200 000 to 400 000 USD following a re-assessment of the human power needs among different stakeholders as determined by the Training Needs Assessment. The funds were re-allocated from goods, consultancy and human-power categories.

C. OUTCOME

1. Relevance of TF Objectives, Design and Implementation
Discuss how the Trust Fund objectives, design and implementation are proved relevant to current global/regional/country priorities and the Bank's sector strategy
The PDO of strengthening capacity to implement the Cartagena Protocol on Biosafety using the project approach of strengthening selected laboratories for technical capacity and providing training across institutions and stakeholder groups tailored by the training needs assessment are well in line with global and national priorities. In terms of global priorities the project adopted the guidance from the GEF supported biosafety projects in selecting the components with the specific view of improving capacity for Cartagena Protocol complience. Early 2000 witnessed a very dynamic era of national biotechnology

development as well as international interest to bring GM-crops to the Indian market. India signed the Cartagena Protocol on biosafety in 2003; the need for strong regulatory capacity was reaffirmed in 2004 in the report of a committee led by Dr. M.S. Swaminathan and again in the National Biotechnology Strategy of 2006. The Bank's Reaching the Rural Poor strategy of 2003 emphasises safe access to modern technologies and countries' capacity to make informed decisions of technology choices. Within the India CAS, the project fits well into the protection of biodiversity goal.

2. Achievement of TF Development Objective

Discuss and rate the extent to which the Trust Fund development objectives have been met, with linkage to outcome indicators. This includes an assessment as to whether the actual output/deliverables were successfully completed, compared to the expected output, for each activity/component of the Trust Fund. For activities where the output is a report or a dissemination event such as a workshop, conference, training, or study tour, discuss and rate the Quality, Presentation and Dissemination. Applicable reports and/or documents are to be attached to the ICM

COMP1:INSTITUTIONAL/MINISTERIAL CAPACITY:

Biosafety capacity established in key ministries: MOEF's capacity has been strengthened. The capacity of the key committees GAEC, RGCM, SBCC, DLCC and IBSC (all the committees include representatives from several ministries) has been strengthened through tailored training events.

Four training programs conducted for policy makers: exceeded: 1 brainstorming to members of key approval committees; 3 orientation courses in regulation; and training workshops in 7 states.

Rating: Satisfactory

COMP2: RISK ASSESSMENT COMPETENCE:

Training program designed. Yes, the training needs vs. stakeholder groups matrix developed, see appendix 2.

Training courses to stakeholders conducted. In total 53 training events conducted, see Appendix 3. for the training program.

Trainee satisfaction surveys: 80% of courses surveyed; 70% were rated excellent.

Downloads of risk assessment report from MOEF web-site: the completion of this report was delayed and completed in October 2007, thus statistics not yet available.

*Training.Needs Assessment used by other organizations***:** Yes, the State Agricultural Universities are using the document to develop their biosafety programs.

Rating: Highly Satisfactory

COMP3: STRENGTHENING OF LABORATORIES:

Equipment provided: All equipments purchased, delivered and in use.

Technical training courses conducted. Yes, all 4 of the technical institutes have developed and delivered training courses based on the project supported activities.

LMO detection protocols developed and validated.Yes, protocols developed for 7 commercial events.

Downloads of the rice biology document from NPBGR web-site. Used by RCGM sub-committee on rice developing risk assessment protocols and rice-specific standard protocols for field trials. Used by scientists doing rice research. Over 500 downloads from the web-site.
Number of hits in the GMO database of NRCPB*:* 2400 hits the first year
Rating: Satisfactory

COMP4: BIOSAFETY CLEARING HOUSE.
Central Clearinghouse design finished.
Equipment purchased.
Web-page running.
Data capture working.
Competent personnel recruited. Yes, to all of the above.
BCH-India live and fully functional. Yes, see http://indbch.nic.in
Number of hits in the project web-site: 1000/month
Rating: Highly Satisfactory

COMP5: PROJECT COORDINATION AND MONITORING UNIT.
Coordination unit created: yes, core staff from 2003, fully staffed spring of 2005
Annual workplans prepared*:* yes.
Steering committee meets regularly: Multistakeholder Steering Committee was set up in 2004; has held three meetings.
Operational guidebook published and in use: yes, completed in 2004 and made available to executing institutions.

Rating: Moderately Satisfactory

Hyperlinks to the reports produced by the project are listed in Appendix 5.

Overall assessment: The project has clearly made an impact to building capacity in LMO biosafety and improved India's capacity to comply to the Carthagena Protocol. Progress was most significant in components 2, 3 and 4, which met or exceeded the targets set. Especially impressive has been the actions in assessing training needs, developing the training program and its implementation; development of the LMO detection protocols and in establishing a fully functional BCH-India. Progress was also made in Component 1 in inter-ministerial cooperation through training of central and state level approval committees, which have members from different ministries. For Component 5, there were some initial delays in getting the PCMU fully functional and in establishing the Steering Committee.

Rating: For all the components 'Satisfactory'; for the Programmatic Components I-IV 'Highly Satisfactory'

This Biosafety project in India was evaluated internally by QAG in the Bank and in the Biosafety program evaluation carried out by GEF. Both noted the high technical quality

and supervision of the India project. The programmatic targets set for the project were met and in many instances exceeded.

3. Efficiency

Describe the degree to which the Trust Fund activities have been efficiently implemented, in terms of their associated costs, implementation times and economic and financial returns.

There were initial delays in getting the PCMU established and personnel recruited, which delayed the implementation of the project activities somewhat. Once the PCMU was fully functional it adequately managed and coordinated the activities and the use of the funds to achieve the project development objective.

Rating: Moderately Satisfactory

4. Development Impacts, including those that are Unintended/Unrelated to TF Objectives

Discuss all other outcomes and impacts achieved under the Trust Fund (including unintended, positive and negative). Where relevant, discuss how the Trust Fund has contributed to the development/strengthening of relevant institutions, mobilization of other resources, knowledge exchange, recipient policy/program implementation, replicable best practices, introduction of new products, New Forms of Cooperation with Other Development Institutions/NGOs, etc., which would not have been achieved in the absence of the Trust Fund.

1) The Biosafety project published a quarterly newsletter of 2000 hard copies and posting in the project web-site. This has been an effective tool to inform stakeholders on current issues, upcoming events, key resource person interviews, etc. It has started to develop a virtual network of interested stakeholders with impact beyond the information provision role anticipated. It has also profiled the work of MOEF as the expert ministry in biosafety. 2) The key idea in the development of the training program was to develop core curriculum for biosafety and to pilot test that for a subsequent scale up by national or other resources. The state and district level training courses are an example of those that will be scaled out with national funding. There are also multiplier effects through the inclusion of the training modules into mainstream curriculum of different agencies (e.g. Customs Officer training will now include biosafety) and State Agricultural Universities. The training materials developed have been made available through libraries and many of the courses are now running with national funding. 3) The World Bank team from preparation through implementation support included high level international expertise, which has subsequently been used by several other key players in GM-biosafety/foodsafety organizations (DBT, Ministry of Health, MOA) with a significant contribution for the development of LMO biosafety in India.

5. Overall TF Outcome

Justification for overall outcome rating, taking into account the Trust Fund's relevance, achievement of each TF development objectives, efficiency and development impact. (Rating Scale would be consistent with the six point scale used in ISR/ICR: Highly

Satisfactory (HS), Satisfactory (S), Moderately Satisfactory (MS), Moderately Unsatisfactory (MU), Unsatisfactory (U) and Highly Unsatisfactory (HU))
Rating: Satisfactory
The biosafety capacity building project was highly relevant. It came at the time when India's biotechnoloy research was gearing up and when international interest to bring LMO products to the market was high, while having rather limited capacity to deal with this new technology, especially assessment of its potential risks. The PDO of strenghthening capacity to comply to Cartagena protocol obligations and the different component objectives were met satisfactorily with appropriate and efficient use of resources.

D. Risk to Development Outcome

1. Follow-On Results and/or Investment Activities

Identify and provide a description of the role played by this TF that led to those follow-up activities or investments checked below. (Check all that are applicable):

Activity/Investment:
__X___ Recipient/Other Investment; __X___ Grant Project/Program; _____ Bank Project; _____ IFC Financial Project/Activity

The core courses developed and piloted are being scaled out by national resources; the BCH is kept running by national resources; and the services of the strengthened laboratories will be commissioned by various clients. The international expertise brought to play by the project is having continuous impact in contributing to the development of GM related biosafety/foodsafety sectors in India. This project has laid the foundation to the next biosafety project funded from the national GEF framework on biodiversity.

2. Replicability
Describe and rate the extent to which the Trust Fund has generated useful lessons and methodology that are replicable in other sectors and/or regions.

The India project is one of two national implementation projects that Bank has been involved with. The India experience and knowledge products will be shared with the teams implementing the two new regional projects (West Africa, Latin America).
Rating: Satisfactory

3. Overall Risk to Development Outcome

Rate how likely, and for how long, the outcomes will be sustained after completion of Trust Fund activities, and the likelihood that some changes may occur that are detrimental to the achievement of the TF development objectives. These may include factors such as technical, financial, economic, social, political, environmental, government ownership/commitment, other stakeholder ownership, institutional support, governance and natural disasters exposure. (Rating Scale would be consistent with the four point scale used in ISR/ICR: Negligible to Low (L), Moderate (M), Significant (S) and High (H))

This Biosafety project was the first concerted effort to build capacity in LMO related biosafety and laid a significant foundation and built scientific and social capital for future efforts in this sector. The diagnostic work on assessing training needs of different stakeholders and development of a comprehensive training program, from which various courses can be scaled out and replicated is likely to have a long lasting impact. The four laboratories strengthened are now on their way to become centers of excellence in their regions and sectors, and will be able to build on their competence in this dynamic area. There is political commitment to biotechnology and related biosafety; and the sector is developing fast in India with new GM events reaching the advanced field testing and commercial approval stage. Civil society is actively involved to make sure all pre-cautions are observed, but there is strength in the system to allow dialogue while maintaining the national policy direction. Overall risk is estimated to be: **Low.**

E. PERFORMANCE

1. Bank

Rate and justify rating on how well the Bank carried out its specific responsibilities assumed under the Trust Fund. If the TF financed Secretariat functions, describe how well the Secretariat carried out its roles and responsibilities, and its exit strategy, if any. If the Bank is executing Recipient work on behalf of Recipient, describe how well the rationale for Bank execution (as specified in the IBTF) was realized. (Rating Scale would be consistent with the six point scale used in ISR/ICR: Highly Satisfactory (HS), Satisfactory (S), Moderately Satisfactory (MS), Moderately Unsatisfactory (MU), Unsatisfactory (U) and Highly Unsatisfactory (HU))

The Bank conducted four preparatory missions to design the program with MOEF in consultation with DBT and other stakeholders. From the design point of view, this project was a special case as the design elements and the choice of the national executing agency were already predetermined by the requirements of the Cartagena Protocol as part of the CBD. The project required one year extension and in hindsight it would have been better to delay effectiveness to allow the internal finance management procedures to be in place in MOEF. During implementation the Bank conducted regular implementation support missions twice a year. The Bank team included high level, international experts, whose inputs were invaluable and had national impact. The resident FM and procurement specialists in the Bank office provided frequent and timely support to the project team. .

Rating: Satisfactory

2. Recipient (for Recipient-executed TFs only)
Rate and justify rating on how well the different tasks that were expected from the Recipient under this Trust Fund were carried out. (Rating Scale would be consistent with the six point scale used in ISR/ICR: Highly Satisfactory (HS), Satisfactory (S), Moderately Satisfactory (MS), Moderately Unsatisfactory (MU), Unsatisfactory (U) and Highly Unsatisfactory (HU))

The recipient of the GEF grant was MOEF, within which the PCMU established for the project was responsible of its management, both programmatic and financial. There were initial delays in getting the PCMU fully functional, but once the staffing was completed it performed the project tasks efficiently. There were some limitations to the work of the Steering Committee. It could have met more regularly and taken a stronger guidance and oversight role of the programmatic aspects of the project.

Rating: Moderately Satisfactory

F. LESSONS LEARNED / RECOMMENDATIONS

Describe the most significant positive and negative lessons learned from the success or failure of the grant activity and, as appropriate, make constructive recommendations for each stakeholder involved (Donor/Bank/Recipient/Development Community)—based on the assumption these stakeholders might decide to undertake a similar activity at a future time.

Positive lessons: Bringing in high level international expertise at this critical early stage of agricultural biotechnology commercialization in India was very important and productive. To carry out a training needs assessment among different stakeholders was very helpful in designing an inclusive, structured training program addressing the specific training needs of each stakeholder. For the Bank the India operation was very important to make an opening into this new regulatory area of modernizing agriculture sector.

Negative lessons: The timing of effectiveness could have been delayed to allow time for MOEF to get all the FM procedures in place. A multistakeholder steering committee is a good choice in such a cross-sectoral activity, but it is also important to empower the members to give their contributions and to follow-up agreed actions.

Recommendations to the recipient: This project was the first step in building GMO related biosafety. But the work has only begun. MOEF could take the activities that worked well and scale them out in the next phase. Of special value would be to build the capacity of state and district level committees. It is very important to continue the

development of the risk assessment guidelines to arrive at standard protocols for different crops and events. Of special importance is to develop high quality environmental assessment protocols. Further focus on the decentralized State and District level committees and their capacity is recommended as well as support to research supporting biosafety regulation.

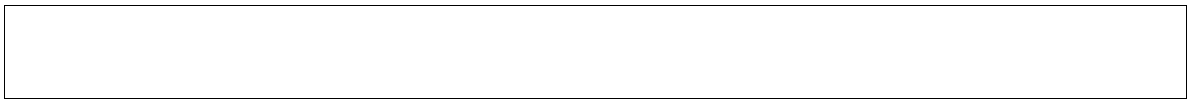
Recommendation to the Bank: use this operation to guide new interventions in the area of GM related biosafety. Where possible blend the biosafety support with regular research and extension oriented agricultural services projects to address the trade-off between economic growth and environmental safety. In India, the Bank could explore a continuing support with DBT to the National Biotechnology Regulatory Agency (see Annex 4 for a way forward).

G. ICM PROCESSING AND COMMENTS

1. Preparation
TTL at Approval: Eija Pehu
TTL at Closing: Eija Pehu
Comment of TTL at Closing:
Prepared by (if other than TTL):
Date Submitted to Approving Manager: Nov 21, 2007

2. Approval
Manager: Adolfo Brizzi
Date Approved by Manager:
Manager's Comment:

3. TFO Evaluation of ICM Quality
TFO Reviewer:
TFO Rating on the Quality of ICM *(Satisfactory or Unsatisfactory):*
Comment and Justification for Rating Given by TFO:



Annex 1.

Category	Category Description	USD
(1)	Consultants' services	163,739.09
(2)	Training	448,490.57
(3)	Goods	164,631.16
(4)	Incremental operating costs	108,646.81
TOTAL DISBURSED		**885,507.63**
Cancelled as of October 31, 2007		114,492.37
Total Grant		**1,000,000.00**

Annex 2.

TRAINING NEEDS MATRIX

TRAINING NEEDS	***MAJOR TARGET GROUPS***												
(KEY COMPETENCES – KNOWLEDGE AND SKILLS REQUIRED	***Decision/ Policy-makers***	***Government Regulators***	***Scientists/ Technical, Advisors & Experts***	***Enforcement Officials***	***Customs Officials***	***Lawyers***	***Economists***	***Data/ Information Managers***	***Researchers & Technicians***	***Graduate & Undergraduate Students***	***Interest groups (Consumer groups, farmers, NGOs) Associations***	***Mass Media / Extension workers***	***General public, Politicians***
General biosafety/ biotech knowledge	✓	▯	▯	▯	▯	▯		▯	▯	▯	▯	▯	▯
Molecular biology skills									▯	▯			
Biosafety Research / field trial techniques (e.g. buffer zone, isolation distance etc.)		▯	▯						▯	▯			
Risk Assessment & Management	▯	▯	▯	▯			▯	▯	▯	▯			
Audit of Risk Assessment reports and Risk Management plans			▯	▯					▯				
Safety requirements and procedures for intentional and unintentional LMO releases	▯	▯	▯	▯					▯				
Tools for monitoring the handling, transport, packaging and use of LMOs	▯	▯	▯	▯	▯				▯				
Compliance requirements under the CPB	▯	▯	▯	▯		▯		▯	▯	▯	▯	▯	▯
Harmonization of biosafety related sectoral laws/ policies including international agreements	▯		▯	▯		▯				▯	▯	▯	▯
Regulatory training (legal, policy, enforcement, inspection, etc.)	▯	▯	▯	▯	▯	▯							
Preparation and presentation of LMO export or release applications/ dossiers			▯			▯			▯				
Review of applications and the accompanying dossiers			▯	▯		▯							
Administrative practices (including handling of requests for LMO imports or releases)		▯						▯					
Decision making practices, including assessment and integration of socio-economic considerations	▯	▯	▯	▯									
Drafting/use of technical manuals & guidelines			▯	▯	▯	▯		▯	▯				
Procedures to be applied to LMO transboundary movements	▯	▯	▯	▯	▯	▯		▯		▯			

(including information on neighboring countries)													
Documentation requirements for LMO shipments													
LMO detection & quantitative analysis													
Cost/ risk benefit analysis													
Systems for identification of LMOs including traceability procedures													
Public awareness and participation													
Data and information management, including use of the BCH													

Annex 3.

Publications/Documents of the Project:

1. *Biosafety Information Kit*
2. *Project Implementation Guide Book*
3. *Capacity Building on Biosafety :Training Needs Assessment*
4. *Biosafety : Issues and Challenges*
5. *Rice Biology Document*
6. *Crop Biotech & Biosafety*
7. *Documents for SBCC, DLC & IBSc*
8. *Biosafety and Mass Media*
9. *Proceedings of the International Conference on the Implications of the Cartagena Protocol on Biosafety*
10. *Training Manual on Biosafety concerns of transgenics and detection of LMOs*
11. *Training Manual on National training Workshop on Biosafety and Web resources in GMOs*
12. *Training Manual on Biosafety Issues and Web Resources in GMOs*
13. *Training Manual on Molecular Testing and Diagnostic Methods for Transgenic Crops*
14. *Training Manual on Biosafety issues in the Management of Genetically Modified Crops*
15. *Training Manual on Biosafety Measures for monitoring of Deliberate and unintended release of Transgenic Crops*
16. *Critical Control points in Genetically Modified Seed Production*
17. *Technical Bulletin of GM Crops Database: An Interactive Web Resource*
18. *Training Programme for Legal Practitioners & Legal Officers on the Implementation of the Cartagena Protocol on Biosafety in India*
19. *Document on Launching Workshop on Biosafety*
20. *Environmental Risk Assessment, socio-Economic Considerations and Decision-Making Support for LMOs in India*
21. *Pre-market Biosafety and Risk Assessment of GM crops and GM-derived Products*
22. *Biosafety News Letters*
23. *Documentary on GEF – World Bank Capacity Building Project*

Key web-sites developed by the project:

http://indbch.nic.in/ , Biosafety Clearing House, India

http://envfor.nic.in/divisions/csurv/biosafety/default.htm, Biosafety Information web-site

http://envfor.nic.in/divisions/csurv/biosafety/default.htm, Biosafety Project web-site

Annex 4.

WAY FORWARD TO SUPPORT BIOSAFETY REGULATORY FRAMEWORK IN INDIA

Introduction

In India, the regulation of all activities related to GMOs and products derived from GMOs was initiated with the notification of *Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989*[1] (commonly referred to as *Rules, 1989*) under the provisions of *Environment (Protection) Act, 1986* through the Ministry of Environment and Forests (MoEF). The *Rules, 1989* are very broad in scope, essentially capturing all activities, products and processes related to or derived from biotechnology. They created six competent authorities, the two most important of which are the Review Committee on Genetic Manipulation (RCGM) administered by the Department of Biotechnology, Ministry of Science and Technology (DBT, MoST) and the Genetic Engineering Approval Committee (GEAC) administered by MoEF. RCGM authorizes imports of recombinant products for research purposes; authorizes multi-location confined, field trial experiments of genetically modified (GM) crops; authorizes pre-clinical trials of recombinant pharmaceuticals; and provides technical support to GEAC, including assessment of data provided from laboratory, greenhouse and field trial experiments with GM crops. GEAC is the apex decision-making body and authorizes large-scale field trials of GM crops and the commercial release of biotechnology-derived products.

MoEF's Role in Biotechnology Regulation and Capacity Building

In 2005, the regulatory framework for recombinant pharmaceuticals was reviewed and the recommendations and procedures outlined in the resulting report[2] were adopted by the Government of India in 2006 with the publication of "Notification Regarding Adoption of the Recommendations of the Task Force on r-Pharma under the Chairmanship of Dr R A Mashelkar, DG-CSIR with Effect from 1.4.2006[3]". Under this Notification, the regulatory authority of GEAC as regards the approval process for recombinant pharmaceuticals has been limited to assessing the potential environmental risks and benefits associated with the application of living modified organisms (LMOs) in pharmaceutical development. Given that the GEAC sits within MoEF, this revision in its responsibility was considered to be more consistent with the Ministry's role as the GoI lead for the Convention of Biological Diversity and the Cartagena Protocol on Biosafety. Product safety, efficacy, clinical trials and market authorization of recombinant drugs are now vested with the Drug Controller General of India.

[1] See Acts and Rules at http://dbtbiosafety.nic.in.
[2] MoEF. (2005). Report of the Task Force on Recombinant Pharma. Ministry of Environment and Forests (MoEF), New Delhi.
[3] See Stepwise procedures for the development of r-DNA pharmaceutical(s) under Steps Involved at http://dbtbiosafety.nic.in/

Consistent with its revised policy to limit GEAC's mandate to the regulation of organisms or products where the end product is a LMO, MoEF recently notified its decision to rescind Rule 11[4] of *Rules, 1989*. This remains a very controversial decision by MoEF as it now exempts biotechnology-derived food stuffs from regulation in India, which is inconsistent with how these products are regulated elsewhere. While India's new *Food Safety and Standards Act, 2006* captures GM foods under its definition of foods that will be subject to regulation, implementing regulations (rules) for this Act have yet to be notified and the Food Safety and Standards Authority that will implement the Act is not yet in operation.

Further changes to MoEF's role in the Indian biotechnology regulatory framework are forthcoming. Two national reviews of the biotechnology regulatory system[5] and the recently published National Biotechnology Development Strategy[6] have all recommended the creation of an autonomous, statutory National Biotechnology Regulatory Authority (NBRA). The NBRA is to be established by DBT and its regulatory mandate will encompass biotechnology products and processes in the agricultural, human health, industrial and environmental sectors. It is anticipated that DBT will draft a new act to create and empower the NBRA as there is no legislation within the Ministry of Science and Technology that could be amended to provide the NBRA with statutory authority. It is anticipated that the new "National Biotechnology Regulatory Act" will end up replacing part or all of the *Rules, 1989* consequently diminishing the role of MoEF in biotechnology regulation.

For the near term, MoEF will continue to have a lead role in the regulation of biotechnology as pending the establishment of the NBRA existing regulatory mechanisms will "continue till a full-fledged body is created with the required infrastructure and fully functional autonomy[7]". Additionally, because of its position as the national competent authority for functions pursuant to the Cartagena Protocol on Biosafety, it is expected that MoEF will continue to participate in international negotiations related to the Protocol and facilitate national dialogue on related issues such as liability and redress and capacity building. MoEF's obligations as the focal point for the Biosafety Clearing House are also likely to remain unchanged.

Over the life of the GEF-World Bank project "Capacity Building for Implementation of the Cartagena Protocol on Biosafety", MoEF has developed a number of useful training curricula that should continue to be disseminated through awareness-raising programs, training

[4] Rule 11 addresses the regulation of foods derived from biotechnology and it states "Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engi-neered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee."

[5] MoEF. (2005). Report of the Task Force on Recombinant Pharma. Ministry of Environment and Forests (MoEF), New Delhi; MoA. (2004). Report of the Task Force on Application of Agricultural Biotechnology. Ministry of Agriciulture (MoA), New Delhi.
[6] http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf
[7] http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf

workshops, as well as alternative modes of distribution such as distance learning. MoEF should endeavour to ensure that its resource materials remain up-to-date and that the communications tools developed during the GEF-World Bank project, such as the Biosafety Information website[8], remain current. In absence of a significant commitment on the part of MoEF to support such capacity building activities, it is unlikely that the Ministry will be able to maintain its existing role as a significant provider of biosafety capacity building expertise. Based on a review of the training programs developed under the GEF-World Bank project, it is apparent that most of that expertise lies outside of MoEF and so the Ministry, should it wish to remain active in national and international biosafety fora, may wish to pursue both intra- and extra-ministerial capacity building.

Looking to the Future

Donor support to continue to build biosafety capacity in India may be best directed to providing resources that can be applied to the establishment and operation of the newly proposed NBRA. While the development of the NBRA it is still in its very early stages, it is understood that DBT has identified institutional and human resource capacity building as key components of the new Authority. This is likely to include the need for support in the following areas: drafting of new legislation; strengthening of institutional relationships with key central government ministries and, very importantly, with state governments and organizations that are likely to play an increasingly important role in biotechnology regulation; technical training for risk assessors; and training in communications, outreach and stakeholder engagement.

Given that the mandate of the NBRA may extend to agricultural, forest and fisheries biotechnology (including aquaculture), applications of biotechnology to human health, and industrial and environmental biotechnology (*e.g.*, bioremediation), significant resources will be required to ensure that the required capacities for effectively and efficiently regulating products and processes are put in place. Additional to this, is the need to ensure that the regulations, standards and guidance that the NBRA provides to the biotechnology community is consistent with international best practices. The World Bank is well positioned to provide both financial and multi-lateral policy support to DBT to assist the Department as it works to establish a new regulatory framework that will allow India to access the benefits of biotechnology while still ensuring that human and environmental safety are properly addressed.

[8] http://envfor.nic.in/divisions/csurv/biosafety/default.htm