



PROJECT EXECUTIVE SUMMARY

GEF COUNCIL SUBMISSION

AGENCY'S PROJECT ID: P091269
GEFSEC PROJECT ID: 2689
COUNTRY: Brazil, Mexico, Colombia, Peru, Costa Rica
PROJECT TITLE: Latin America: Multi-Country Capacity-Building in Biosafety
GEF AGENCY: World Bank
OTHER EXECUTING AGENCY(IES): International Center for Tropical Agriculture (CIAT), Bogota Colombia.
DURATION: 3 years
GEF FOCAL AREA: Biodiversity
GEF OPERATIONAL PROGRAM: OP13 (Conservation and sustainable use of biodiversity important to agriculture); OP1 (Arid and Semi-Arid Zones); OP2 (Coastal, Marine and Freshwater Ecosystems); OP3 (Forest Ecosystems); and OP4 (Mountain Ecosystems).
GEF STRATEGIC PRIORITY: Biodiversity focal area Priority 3 (Capacity-building for the implementation of the Cartagena Protocol on Biosafety)
Pipeline Entry Date: Pipeline 19, February 2005
ESTIMATED STARTING DATE: January 15, 2007

FINANCING PLAN (US\$)	
GEF PROJECT/COMPONENT	
Project	5,000,000
PDF A	n.a.
PDF B	260,000
PDF C	n.a.
<i>Sub-Total GEF</i>	5,260,000
<i>CO-FINANCING*</i>	
CIAT	1,415,000
Governments (Brazil, Colombia, Costa Rica, Mexico and Peru)	9,330,200
<i>Sub-Total Co-financing:</i>	10,745,200
<i>Total Project Financing:</i>	16,005,200
FINANCING FOR ASSOCIATED ACTIVITIES IF ANY:	
LEVERAGED RESOURCES IF ANY:	

*Details provided under the Financial Modality and Cost Effectiveness section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN:

The project will use GEF funding to strengthen country capacity in science-based risk assessment and management, in order to facilitate implementation of relevant provisions in the Cartagena Protocol on Biosafety, adopting a multi-country approach as a cost-effective mechanism for longer-term sustainability and to exploit economies of scale; and build/consolidate long-term collaboration between governments, scientific institutions and civil society, and the donor community, on biosafety.

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT(S):

Brazil: Carlos Eduardo Costa, General Coordinator for Social Operations, Ministry of Planning, Budget and Management, Secretariat for International Affairs. (March 7, 2005)


Colombia: Carmen Elena Aravalo Correa, Vice Minister, Ministry of Environment, Housing and Territorial Development. (February 16, 2005)

Costa Rica: Ricardo Ulate, International Affairs Adviser, Ministry of Environment and Energy, National Forestry Financing Fund (January 31, 2005)

Mexico: Claudia Grayeb Bayata, Director for International Financial Institutions, Ministry of Finance and Public Credit, Operational Focal Point (August 4, 2005)

Peru: Carlos Loret de Mola, President, National Environmental Council (CONAM), (January 28, 2005)

Approved on behalf of the World Bank. This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for work program inclusion.


Steve Gorman
GEF Executive Coordinator, The World Bank
Date: March 24, 2006

Jocelyne Albert
GEF Regional Coordinator
Latin America and the Caribbean

Tel. and email: (202) 473-3458
Jalbert@worldbank.org

PROJECT SUMMARY

- a) Project rationale, objectives, outcomes/outputs and activities.

Rationale:

1. Concern is mounting over the accelerating adoption of Genetically Modified Organisms (GMO) in Latin America without sufficient, scientifically-sound, biosafety assessment, management or decision-making instruments. The region is falling behind in its capacity to implement biosafety regulation in compliance with international standards and treaties. The LAC region has been adopting GMO at a faster rate than any other region of the world. Just under half of all countries currently growing commercial, transgenic crops are in this region, and in 2004, Latin America grew 30% (23 million hectares) of the total global area of transgenic crops, second only to the United States (48 million ha).
2. Tropical Latin America and the Caribbean (LAC) Region are among the world's richest areas of biodiversity, harboring the center of origin of landrace/weedy/and wild relatives¹ of many important crops. Around one-third of all crop plants grown world-wide were domesticated from the biodiversity of this region. Mesoamerica, the Andean region and the Amazon were the centers of origin or diversification of maize, beans, potato, sweet potato, tomato, cassava, groundnut, pineapple, cotton, cacao and chili pepper, among others. All five countries selected for participation in this project – Brazil, Colombia, Costa Rica, Mexico and Peru – have centers of mega-biodiversity, as defined by the Convention on Biological Diversity (CBD).
3. Potential, negative impacts on biodiversity of the unregulated use of GMO could have major medium- and long-term implications for the regional and global environment, for human/animal health and for international trade and competitiveness. Health and environmental concerns are reflected in widespread public mistrust of GMO crops, especially in Europe and Latin America. Further, the global economy has prompted the formation of trading blocs (in Latin America currently there is Mercosur, Andean Pact, CARICOM, CAFTA and NAFTA, with FTAA under negotiation), which are shaping regional commerce. These have implications for the future of biotechnology-derived products, and for the export opportunities and expansion of countries lacking capacity to comply fully with the Cartagena Protocol (CP) on biosafety.
4. LAC countries have received little attention and funding despite their biodiversity, importance in the global biosafety arena, and expanding commercial cultivation of transgenic crops. This is in contrast to Asia and Africa, which have received major funding in recent years to establish functional biosafety systems (e.g., USAID is currently supporting two mega-projects on biosafety for these regions valued at about US\$30 million each). Establishing biosafety capacity in the LAC region is complex due to the (a) unique and difficult problems faced by mega-diverse countries addressing potential environmental risks, and (b) range of technical topics and research areas involved which encompass the biological, socio-economic, health, legal and political arenas. Adding to this complexity is the need to comply with the latest international agreements on biosafety designed to protect biodiversity, the environment and animal/human health, and to regulate trans-boundary movement and use of these crops. Together, these create an urgent and relatively high-risk situation which needs to be addressed at the national and regional levels.
5. Many countries in Latin America have the advantage of already having established regulatory frameworks, though they need to strengthen the safeguards aspects. The participating countries acknowledge that their biosafety legal frameworks for the regulation, management and deployment of GMO are not sufficient. Technical, legal, policy and political obstacles are hindering their full compliance with the Cartagena Protocol. The countries defined these obstacles during project formulation as weak

¹ Landrace plants are older, often farmer-developed strains of a species, ideally-suited to the environment where they live, and bred through traditional methods of natural selection without the influence of modern breeding practices.

technical capacity in biosafety risk assessment and risk management, and in biosafety cost-benefit analysis. As well, there is inadequate availability and dissemination of science-based information to support planning and policy-making on biosafety and to temper broad public concern about transgenic crops.

6. GEF support for this multi-country approach is needed to assist countries on safeguards aspects of the Cartagena Protocol. All five countries have established legal frameworks for implementing the CP; with GEF financing, they will be able to implement the safeguard aspects. The CP, Article 22, calls for parties to cooperate in capacity building with the emphasis on technical and scientific training in the proper, safe management of biotechnology, in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety.

7. *Project Strategy:* The proposed project would finance a biosafety capacity-building operation in five Latin American countries. Total project cost is estimated at \$17.9million, including country and donor contributions. The GEF would contribute US\$5.0 million channeled through the Colombia-based, International Center for Tropical Agriculture (CIAT). The project's multi-country design maximizes economies of scale by exploiting the comparative advantages of participating countries and designated specialist entities as either Net Donors/Providers or Net Recipients of capacity. At completion, it is expected that all five countries will have a more transparent and predictable regulatory environment, and enough capacity and effective coordination between the responsible agencies/entities to assess and manage risks, costs and benefits associated with the use and trans-boundary movement of LMO, and to contribute to a better-informed public discourse. The proposed project is consistent with the World Bank's Country Assistance Strategy (CAS) objectives for the five countries, which show marked similarities across development pillars and sector goals, seeking, inter alia, to harmonize inclusive economic growth with environmental sustainability.

8. *Objective:* The project's Global Environmental Objective is to strengthen capacity in the five participating countries to implement the Cartagena Protocol (CP) on biosafety.

9. *Outcomes:* Principal project outcomes will include: (a) Adoption and use by all targeted institutions in the five countries, of standardized biosafety risk assessment and risk management mechanisms developed by the project; (b) Increased science-based awareness and understanding of biosafety on the part of targeted communicators, opinion-makers and the general public; and (c) Networks established among the five participating countries to promote inter-country and inter-institutional cooperation on biosafety and the environment.

10. *Components/Activities:* The project comprises the following components: (a) Strengthening technical capacity in knowledge generation for biosafety risk assessment and management; (b) Strengthening biosafety decision-making capacity; and (c) Public awareness on biosafety for communicators, opinion-makers and the general public. Costs by component are summarized in Table 1 and component content is described immediately following.

Table 1: Project Components by Financier (US\$ '000)

COMPONENTS	GEF		CIAT		BRAZIL		MEXICO		COLOMBIA		COSTA RICA		PERU		TOTAL	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
1. Strengthening Technical Capacity in Knowledge Generation for Biosafety Risk Assessment and Management																
1.1 Strengthening of Technical Capacity for Environmental Risk Assessment and Management	3,737.9	35.4	1,265.0	12.0	2,600.0	24.6	450.0	4.3	1,055.2	10.0	1,350.0	12.8	100.0	0.9	10,558.1	67.1
1.2 Strengthening of Technical Capacity for Socioeconomic Impact Assessment	305.3	13.9	50.0	2.3	495.0	22.5	1,300.0	59.2	45.0	2.0	-	-	-	-	2,195.3	13.9
Subtotal Strengthening Technical Capacity in Knowledge Generation for Biosafety Risk Assessment and Management	4,043.2	31.7	1,315.0	10.3	3,095.0	24.3	1,750.0	13.7	1,100.2	8.6	1,350.0	10.6	100.0	0.8	12,753.4	81.0
2. Strengthening Biosafety Decision Making Capacity	563.3	33.6	50.0	3.0	840.0	50.1	-	-	35.0	2.1	150.0	8.9	40.0	2.4	1,678.3	10.7
3. Public Awareness on Biosafety for Communicators, Opinion Makers, and the General Public	393.5	30.0	50.0	3.8	720.0	54.8	-	-	110.0	8.4	-	-	40.0	3.0	1,313.5	8.3
TOTAL PROJECT COSTS	5,000.0	31.8	1,415.0	9.0	4,655.0	29.6	1,750.0	11.1	1,245.2	7.9	1,500.0	9.5	180.0	1.1	15,745.2	100.0

11. Budget allocations for project regional coordination including project monitoring and evaluation (M&E) are mainstreamed within Component 1, subcomponent 1.1. Allocations are defined in detailed project cost tables but not shown in summary cost tables, as above. Total costs of regional coordination of the project are estimated at US\$0.6 million. See also Project Brief C.3 and Annexes 7 and 8 for reference to project coordination activities and specifically to monitoring and evaluation.

12. Component 1: Strengthening technical capacity in knowledge generation for biosafety risk assessment and management (US\$12.75 million of which US\$4.04 million GEF).

Activities in this component aim to strengthen regional technical capacity using selected, target crops (cassava, cotton, maize, potato and rice)² as models for developing risk assessment, management and cost-benefit analysis methodologies for transgenic products. The project will finance the following subcomponents and related inputs:

1.1 Strengthening technical capacity for environmental risk assessment and management: Financing will be used to develop baseline information, tools, strategies and methodologies for assessing, monitoring and managing gene flow in crop biodiversity (using the five selected crops as models), and the potential effects on non-crop (non-target) organisms. In *gene flow* activities, national Centers of Excellence in the project countries and CIAT, will pool resources and best practices to assess and monitor the gene-flow in crop biodiversity by: (a) compiling and generating baseline data for tracking and monitoring gene introgression and persistence of novel traits in crop-biodiversity; (b) generating and testing the use of GIS-referenced databases for mapping the distribution of crop/landrace/weedy/wild populations, and gene flow analysis; (c) adaptation and regional standardization of methodology for large scale monitoring of gene flow; and (d) developing crop management strategies and operational guidelines to minimize trans-gene flow.

In activities related to the potential *effects on non-crop (non-target) organisms*, the designated national Centers of Excellence and CIAT will carry out: (a) adaptation and regional standardization of methodologies for evaluating effects on non-target organisms; and (b) development of crop management strategies and operational guidelines to minimize effects on non-crop (non-target) organisms. The subject of unintended effects on non-target organisms will be studied by using existing insect-, herbicide- and (if available) disease-resistant crops. The study will include a review of the considerable literature already available on the subject, and will design experiments which extend the evaluation to the high-biodiversity areas in the participating countries, with the goal of providing decision-makers with locally developed and relevant information.

For decisions about field trials of transgenic crops, regions where the risk of crossing to wild relatives is minimal will be identified. For decisions about commercial release, the extent to which transgenic crops might interact with their sexually compatible wild relatives would be one of the considerations in a risk assessment/decision. A searchable database containing this basic information will be produced and will be a valuable tool in environmental risk assessment and for disseminating best practice. The project will evaluate widely-used approaches/tools for gene

² These crops were chosen based on: (a) economic importance in the region and local socio-economic needs; (b) centers of diversity of maize, cassava and potato are in this region; (c) relative commercial weight of crops developed by the public and private sectors, respectively; (d) need for collaboration on knowledge generation and gaps in smart breeding for output traits (mostly private sector) versus input traits (public sector); and (e) potential implications for local/regional biodiversity.

flow control (e.g., spatial and temporal isolation, use of male sterility) in the five target crops in the environmental and agricultural context of the participating countries. It is not intended to do experimental work with these approaches, but rather to validate existing approaches. The current status of such approaches in each crop and their ability to work in the field (as proven by scientific literature) will be assessed.

Outputs will include: (a) adapted databases for tracking and monitoring gene introgression and persistence, and for mapping the distribution of crops/landrace/weedy, wild populations; (b) crop management strategies and operational guidelines to minimize trans-gene flow; (c) adapted, standardized methodologies for large-scale monitoring of gene flow; (d) regionally-adapted and standardized methodologies for evaluating effects on non-crop (non-target) organisms; and (e) project-generated knowledge in (a) to (d) downloaded to depositories and websites in Country, regional (CIAT) and Montreal BCHs, and available for use..

1.2 Strengthening technical capacity for socio-economic cost-benefit assessment. This subcomponent responds directly to provisions of the CP to improve understanding of the socio-economic costs and benefits associated with the use of transgenic crops in tropical Latin America and to improve regional capacity to conduct related analysis. Project country partners and CIAT will collaborate on the following activities related to this sub-component: (a) adaptation of existing methods and tools for socio-economic impact assessment of GMOs to the specific environment of the tropics; and (b) development of skills for analyzing the potential costs and benefits of GMOs in centers of crop diversity. It is unlikely that a standard socio-economic assessment methodology will be appropriate for all countries given that the decisions countries face will differ depending on the specific GMO product and the social, economic and environmental characteristics of the country. Nonetheless, countries with similar characteristics will benefit from having standard methods for carrying out impact assessments that will allow them to share results, especially among countries with limited human and financial resources in this field.

The potential costs and benefits of genetic modifications of the five project crops in the five target countries will also be analyzed. Specific types of impacts to be assessed will be determined in collaboration with the national-level project participants. Differences by agro-ecological zone, and by farmer and consumer characteristics, will also be taken into account. The results per se, will be valuable inputs to policy-making, and will also serve as examples of how assessments can be done and as a baseline against which to monitor future progress in the case of GMO deployment. Many of the methods for assessing GMO impacts are not substantially different from those used to assess other agricultural technologies and can therefore be applied directly if data are available. In some cases, it may be necessary to develop or adapt existing methods. The need for methods development will be determined via consultations with project partners. The project will compile inventories of the types of data and information needed for socio-economic analysis of GMOs, and to the extent possible, actual data sets that partners and others can use. For environmental and economic analysis, spatially disaggregated data will be most appropriate. During the course of the project, the capacity of national partners to conduct such analyses will be built both via training and via participation in the analyses.

Outputs include: (a) adapted methodologies and tools for socio-economic impact assessment of GMOs in the tropics; (b) adapted methodologies and tools for analyzing potential

costs and benefits of GMOs in centers of biodiversity; and (c) project-generated knowledge in (a) and (b) downloaded to depositories and websites in Country, regional (CIAT) and Montreal BCHs, and available for use/reference.

13. ***Component 2: Strengthening biosafety decision-making capacity (US\$1.67 million of which US\$563,300 GEF)***. The objective is to assist partner governments to implement Articles 14 (bilateral, regional and multilateral agreements and arrangements) and 22 (capacity building) of the Cartagena Protocol, specifically their emphasis on regional approaches. It will build biosafety capacity for decision-making entities (competent authorities) and for practitioners (public and private research community) using the knowledge generated by this project in a collaborative effort across the region. The project will finance the following subcomponents and related inputs:

2.1 Training in environmental risk assessment, management and communication for competent authorities and practitioners: This subcomponent will allow all core participants in the regulatory process to work on the basis of standardized, tested procedures and similar level of technical expertise. Core participants include the implementing bodies of national biosafety frameworks (i.e. national biosafety committees) and the biotechnology research and development (R&D) community (i.e. transgenic crop developers, plant breeders, other relevant agricultural science professionals, especially those working in public sector research). A high quality decision-making process on the biosafety aspects of environmental release of transgenic crops is only possible if all these groups are equally proficient in the principles and application of biosafety assessment and biosafety management. More uniform and higher quality participation will also bolster confidence in the system on the part of other stakeholders (e.g., consumers, environmental interests).

Training under 2.1 will be provided at the regional, national and sub-national levels, exploiting the expertise derived from this and other GEF-funded projects. Special attention will be given to strengthening wherever possible, international cooperation and regional standard-setting. The project will identify the key decision-makers and practitioners to be trained, initially by projecting best existing practice, and subsequently by using systematically, the outcomes of Component 1. A key *output* will be science-based briefing documents in accessible, non-technical language for non-specialist members of relevant national authorities.

2.2 Training in socio-economic cost/benefit assessment for competent authorities and practitioners: Training in socio-economic cost/benefit assessment will strengthen the capacity for and promote a common approach to, this type of assessment. The project will evaluate existing materials, identify gaps and propose course development plans. The project will produce, test-run, evaluate and disseminate courses deemed through review to be of high quality. Key decision-makers and biosafety practitioners working with socio-economic issues will be contacted and introduced to the objectives of the project to secure their participation in training courses. The project will also provide them through targeted training courses and materials, with the outcomes of the socio-economic analysis subcomponent of the project.

Outputs will include: (a) decision-making entities (e.g., competent authorities, implementing entities of national biosafety frameworks) and practitioners (e.g., agricultural science professionals, transgenic crop developers and users) trained and proficient in the core

principles and application of biosafety assessment and biosafety management; (b) competent authorities and practitioners trained to understand and use common methodologies to conduct cost-benefit assessment of biosafety products for planning purposes.

14. ***Component 3: Training in biosafety for communicators and opinion-makers to improve public awareness (Total US\$1.31 million of which US\$393,000 GEF).*** The objective of this component is to promote public awareness and stimulate informed public debate on biosafety based on quality information generated by biosafety specialists in target countries, through the mechanism of engaging national research organizations, policy-makers, communicators and opinion-makers, based on comprehensive information linking biosafety and biotechnology. This component will finance communications specialists to develop information materials on biosafety and information campaigns, and insert them into the public debate/discourse at various levels, e.g., through press briefings with national science writers/journalists and other opinion-makers. Inputs financed by the project are as follows:

Communication specialists contracted by the project will develop communication strategy/plans, develop and test information materials on biosafety, and design information campaigns to insert science-based messages into the public debate/discourse at various levels, e.g., through press briefings with national science writers/journalists and other opinion makers, information events, publications and other media. Impact evaluation activities, i.e., measuring the effectiveness of these activities using standard media assessment methods, would also be financed.

In the public awareness activities, the project is actively seeking a paradigm shift in the public debate, by linking biosafety to biotechnology at every opportunity. This is not the case today and it has created a situation where the potential benefits of biotechnology and its potential risks (including biosafety and socio-economic uncertainties) are debated separately. In trying to unite these disparate (but complementary) elements in the public debate and in the policy process, the project follows the original intention of the Biodiversity Convention, article 19, which links the benefit potential of biotechnology and the need for safety in its deployment. The component seeks to ensure that communicators, opinion-makers and the broad public (including civil society interests) have better access to more balanced, science-based information in all project countries through the media and other information intermediaries. Currently, available information is unsuitable for an informed discourse and coverage is poor.

Outputs will include: (a) audience-tailored, science-based information modules and awareness-building tools prepared by communications specialists, based on knowledge generated under Component 1 and targeted to social communicators and opinion makers with a broad public audience; and (b) delivery of science-based information through various media, to targeted audiences.

b) Key indicators, assumptions and risks (from Results Framework)

15. Key indicators related to the Global Environmental Objective include:

- All targeted institutions in the five countries have adopted and are using standardized biosafety risk assessment and risk management mechanisms developed by the project.

- Targeted communicators, opinion-makers and the general public have increased science-based awareness and understanding of biosafety.
- Networks to promote inter-country and inter-institutional cooperation on biosafety and the environment are established among the five participating countries.

16. *Assumptions:* Project design assumes that partner governments will sustain their support for the project throughout its implementation and beyond, given the potential economic and environmental costs associated with not acting to secure full compliance with the Cartagena Protocol. Further, the multi-country approach, leveraging economies of scale and of technical expertise is expected to promote the evolution of mechanisms and models for country and inter-institutional collaboration on biosafety and biotechnology which can achieve more rapid impact on the quality of planning and decision-making in a fast-evolving situation.

17. *Risks:* Key risks and mitigation measures are shown below:

Risk to GEO/PDO	Mitigation Measures	Rating
<p><i>Modification of Cartagena Protocol:</i></p> <p>Liability and Redress Agreement to be reviewed in 2007. Cartagena Protocol will have five-year review in 2008.</p>	<p>In the event of problems implementing the Project according to agreed work plans, due to changes in international/national agreements, CIAT in consultation with the PMC and World Bank/GEF, would develop alternatives, depending on the status of the CP. Even in the worst-case (without-CP) scenario, building country capacity for risk assessment, management, communication and cost-benefit analysis remains vitally important and would proceed.</p>	<i>Moderate</i>
<p><i>Focus and coherence:</i></p> <p>Participation of multiple countries with differing interests/capacity to implement Cartagena Protocol, and participation of multiple entities within each country, could complicate implementation.</p>	<p>Initial selection of entities will be based on expertise, complementarities and work record as entry points for each country to guarantee project commitment and execution.</p> <p>Governance arrangements include a Project Management Committee with representatives of partner countries to foster common approaches and to ensure that participating entities focus on project objectives and outputs.</p>	<i>Moderate</i>
<p><i>Project sequencing:</i></p> <p>Deficient or slower-paced performance of project partners, may affect sequencing of project activities and financing.</p>	<p>CIAT, in consultation with the PMC and World Bank/GEF, would develop alternative action plan for recouping country performance, pace of project execution.</p> <p>Funds will flow to CIAT, not individual countries in the first instance, permitting control over the flow of funds vis a vis performance.</p>	<i>Moderate</i>
<p><i>Changed commitment to project objectives:</i></p> <p>Electoral change in a partner country resulting in biotechnology rejection</p>	<p>CIAT, in consultation with the PMC and World Bank/GEF, would develop strategy consistent with</p>	<i>Moderate</i>

might shift broad support away from the project.	project activities and objectives, to educate new administration in project goals and methodologies.	
<i>Costa Rica has not ratified the Cartagena Protocol:</i> Continued lack of ratification of the CP by Costa Rica at the onset of project implementation, may force its withdrawal from the project.	CIAT in consultation with PMC and World Bank/GEF, will reformulate the work plan and re-distribute deliverables among the partners.	Moderate
Overall Risk Rating		Moderate

2. COUNTRY OWNERSHIP

a) COUNTRY ELIGIBILITY

Table 2: Project Participating Countries: Status re Cartagena Protocol

Country	Signing	Accession	Ratification	Entry into Force
Brazil	--	24 Nov. 2003	--	22 Feb. 2004
Colombia	24 May 2000	--	20 May 2003	11 Sep. 2003
Costa Rica	24 May 2000	--	--	--
Mexico	24 May 2000	--	27 Aug. 2002	11 Sep. 2003
Peru	24 May 2000	--	14 April 2004	13 July 2004

Table 3: GEF Eligibility: Participating Countries

Country	Parties of the Cartagena Protocol	Convention on Biological Diversity	Eligibility for GEF funding categories
Brazil	Entry into force	Entry into force, Ratified on 28 February, 1994	Eligible for CBD & CP funding
Colombia	Entry into force	Entry into force, Ratified on 28 November 1994	Eligible for CBD & CP funding
Costa Rica	Not yet ratified	Entry into force, Ratified on 26 August 1994	Eligible for NBF development and National BCH establishment only
Mexico	Entry into force	Entry into force, Ratified on 11 March 1993	Eligible for CBD & CP funding
Peru	Entry into force	Entry into force, Ratified on 7 June 1993	Eligible for NBF development, CBD & CP funding

CP – Cartagena Protocol; CBD – Convention on Biological Diversity; BCH – Biosafety Clearing House

18. All five countries had already developed and implemented a national biosafety legal framework prior to the Cartagena Protocol and all have either ratified the CBD or are in process of ratification (Costa Rica) (see Tables 1 and 2 above).

b) COUNTRY DRIVENNESS

19. Criteria for individual country selection included high levels of biodiversity of important crops and wild relatives and geographic distribution of wild/weedy relatives of economically important crops; status of development/implementation of biosafety policy including active GEF-funded projects and World Bank projects in agriculture and rural development; complementary research strengths and expertise related to implementing the Cartagena Protocol; and potential future role in regional biosafety efforts/strategies (Mexico for North America, Costa Rica for Central America, Colombia and Peru for the Andean region, and Brazil for the Southern Cone). The selected countries accept their role in providing a regional biosafety capacity platform and understand that by acting in consortium, they can achieve compliance with the CP - and the benefits of that compliance - more rapidly. The countries and their GEF biosafety Focal Points have indicated ownership of the project by pooling funds for co-financing during preparation and implementation, and by sending Letters of Endorsement.

3. PROGRAM AND POLICY CONFORMITY

a) FIT TO GEF OPERATIONAL PROGRAM AND STRATEGIC PRIORITY

20. The proposed project fits within the GEF focal area on Biodiversity and the GEF Operational Program (OP) 13 on Conservation and Sustainable use of Biological Diversity Important to Agriculture. The project would improve country capacity to manage the safe and sustainable use of transgenic crops and derivatives of agricultural importance (key crops in their region of origin), and to conserve newly-created genetic resources, thereby improving the quality and health of the global environment. Further, due to the cross-cutting nature of the biosafety issue, the project also fits under OP1 Arid and Semi-arid Zones, OP2 Coastal, Marine and Freshwater Ecosystems, OP3 Forest Ecosystems, and OP4 Mountain Ecosystems.

21. The project is also consistent with the GEF Biodiversity Strategic Priority no. 3 on Capacity-Building for Implementation of the Cartagena Protocol on Biosafety in supporting the development and/or strengthening of the national biosafety clearing house (BCH), biosafety knowledge generation and validation, training and capacity building, and promoting public awareness and a stronger biosafety policy environment. CP Article 22 asks that parties cooperate in capacity building with an emphasis on scientific and technical training in the proper, safe management of biotechnology, in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. Indeed, the basis for financial assistance to countries through the GEF is to build capacity to implement the CP.³

b) SUSTAINABILITY (INCLUDING FINANCIAL SUSTAINABILITY)

22. *Institutional Sustainability:* The planned international consortium of national partners collaborating with reputable, national institutions, International Agricultural Research Centers

³ The project will also support, towards the end of its implementation, Strategic Priority 4 Generation and Dissemination of Best Practices for addressing current and emerging biodiversity issues, having identified and adapted innovative approaches and tools for risk assessment, databases for knowledge-sharing on biosafety, and in producing science-based materials for training and communication purposes.

(IARC) and Advanced Research Institutions (ARI) is a realistic and workable mechanism to build biosafety capacity in the region. The consortium will be expected to establish database integration and sharing, and set standards and protocols to be adopted and enforced through collaboration. The development and strengthening of the biosafety-database (web-enabled), shared among partners and others, is part of the strategy to improve sustainability of the project's activities and outcomes beyond its lifetime. Establishing networks to promote inter-institutional and inter-country collaboration on biosafety and the environment are designed specifically to boost institutional sustainability of the project beyond its life. Progress on network-building will be monitored throughout project execution. Institutional sustainability is the expected outcome of the project's multi-country strategy and structure, which will use the technical experience and complementary expertise of country Centers of Excellence. Sustainability is also bolstered by embedding the project in existing ministerial and institutional structures in each country and existing operational units in CIAT as regional coordinator, the latter enhanced by recruitment of a manager and a monitoring/evaluation (M&E) professional.

23. *Financial Sustainability:* Avenues for fortifying financial sustainability continue to be explored during preparation and will be defined and quantified during further project preparation and implementation. The regional operational model is expected to create medium-term economies of scale in implementing the CP. Involvement of international agencies in the project is a potential opportunity for garnering their longer-term financial support; exploratory discussions have been held with several agencies including bilateral donors, e.g., USAID. The consortium approach also improves the fund-raising prospects of a group of countries versus a single country and reduces intra-regional competition and duplication of effort. In addition, the project provides a base from where LAC regional biosafety capacity can be strengthened. Constructing active fund raising capacity in the partner countries, as well as effective partnerships with other stakeholders and donors, are expected to boost financial sustainability. All avenues for leveraging additional, longer-term financing are being explored by CIAT, working with country representatives.

c) REPLICABILITY

24. Developing and strengthening the capacity of Centers of Excellence in the partner countries is expected to improve regional biosafety knowledge and evaluative processes in the sub-regions, based on their agro-ecological and social needs. Further, the consortium will have, by end-project, established and tested knowledge-sharing mechanisms for replicating country experiences. Methodologies and tools developed by the project will be designed for easy transfer and trained technical personnel are available within the region to conduct training and transmit core messages. Training plans are under preparation and will be available at appraisal and incorporated in the Operational Manual. The multi-country approach also provides a better foundation for replicating similar biosafety operations in other countries of the LAC region. The lessons learnt under this project both during project preparation and implementation would be used in other proposed World Bank-supported multi-country projects for biosafety (e.g., current proposed GEF project for West Africa and those in the pipeline for other regions in Africa and Asia/Oceania). Within LAC, evaluation of project outcomes at the mid-term review and at the end of project for all components will form the basis for a replication strategy. It incorporates lessons learned and an agenda for reaching other countries outside the immediate project. The project will seek opportunities for similar, follow-on operations or structured learning events in

other countries in the region, promoting standardized, best practice methodologies across the region for biosafety risk assessment and management, cost-benefit analysis and science-based biosafety public information campaigns.

d) STAKEHOLDER INVOLVEMENT

25. Given the ramifications of compliance with the CP, biosafety capacity-building per se, and the controversy surrounding GMO crops, the stakeholder universe is broad and this is reflected in the reach of the project's knowledge generation and dissemination objectives and functions. The immediate target audience for this project is the national agricultural innovation system (NAIS), competent authorities and civil society (including environmental interests, farmer groups, producer organizations and community organizations) in the participating countries, with the international organizations as regional facilitators. Stakeholder engagement is seen as an evolving, continuous and adaptable process, responsive to immediate and longer-term circumstances.

26. Project development was initiated through a dialogue on national biosafety issues between the relevant country ministries and/or their agencies, and CIAT. This dialogue revealed that, despite biosafety legal codes, technical capacity to implement the CP was weak and variable in and between countries. This launched a CIAT-coordinated consultative process involving, among other activities, a series of courses on biosafety for national biosafety committee members, and in-country capacity analyses to define major bottlenecks, the most glaring of which was found to be the lack of science-based assessment methodologies and processes. Countries also expressed concern about the trans-boundary movement of GMO and their need to have confidence in neighboring countries, which led to a series of meetings in-country between representatives of ministries of agriculture, social protection and health, and decisions about who would be the project country focal points. While the courses conducted by CIAT included civil society representatives with divergent views concerning GMO/biosafety, the general discussion leading to project preparation focused more on responding to the needs expressed by country authorities with responsibility for planning, decision-making and management of the biotechnology/biosafety spectrum.

There has been intense consultation with many involved parties as part of project preparation. These include discussions with national research institutes from each country, government biosafety agencies, ministries responsible for natural resources, agriculture, production in each country, as well as international and regional agricultural institutes. As project preparation advances, consultations will be continued and amplified to include a broader spectrum of stakeholders, including NGOs and farmers groups. Some of these consultations have begun, and will be concluded prior to appraisal. These will be duly documented in the Project Document.

27. In terms of design, the project will focus on the key elements for successful stakeholder engagement which tend to fall by the wayside in the rush to participate in the discourse. The project will ensure that stakeholder involvement, broadly defined, is improved by promoting the twin ideas of technical excellence and quality of information in biosafety risk assessment and management. Much of the information publicly available now has no scientific basis, which has tended to confuse perceptions of biosafety and biotechnology, and increase the element of controversy.

e) MONITORING AND EVALUATION

28. The framework for the monitoring and evaluation (M&E) of outcomes and results will be fully developed by the Project Appraisal date. This framework takes into account that a well-designed system is critical to ensure timely and successful implementation of the Project, and to enhance its impact for the beneficiaries by the systematic and periodic analysis of lessons learned, and their effective dissemination. Project monitoring and evaluation would be the responsibility of CIAT. Performance indicators have been established for the Project and its components, and are presented in the Results Framework in Annex B. The M&E system is based on a cascade of goals, purposes, results, and activities where higher-order activity, that is, components, become the purpose of the lower order, that is, the subcomponents. This approach will ensure the tracking of all activities to the developmental objective of the Project. The PMC will assist in keeping the national interests within the framework of implementation progress. The Project design includes baseline determinations and performance (milestones) indicators to monitor the implementation of the plan. Such monitoring will consist of an internal evaluation at the component level, and one at the Project level. The monitoring will be based on periodic reports.

29. By using a management information system (MIS) and the financial management system, Project activities will be kept on track and potential problems identified and appropriately addressed. CIAT will design the MIS for M&E, reporting formats for each component and national office according to the target annual performance objectives and monitoring indicators shown in Annex B. The quarterly reports will cover the progress in implementation, and milestones in the use of project funds and impact. Quarterly technical and financial reports will be consolidated by CIAT into bi-annual progress reports to be submitted to the Bank within two months of the end of each six-month reporting period. These bi-annual reports will also include an implementation plan and activity program for the subsequent six months of the reporting period. A midterm review will assess the overall progress of the Project. The lessons learned and recommendations for any needed improvements would be used in restructuring or realigning the Project plans. Post-project impact assessments will be conducted to improve quantitative assessment of the Project outcome.

4. FINANCIAL MODALITY AND COST EFFECTIVENESS

Table 4: Project Co-Financing (US\$'000)

Source of Financing	Classification	Type	Amount	Status
CIAT	Private	In-kind	1,415.0	Agreed
Brazil	Government	In-kind	4,655.0	Agreed
Mexico	Government	In-kind	1,750.0	Agreed
Colombia	Government	In-kind	1,245.2	Agreed
Costa Rica	Government	In-kind	1,500.0	Agreed
Peru	Government	In-kind	180.0	Agreed
TOTAL:			10,745.2	

30. The proposed GEF Project is part of a larger program totaling US\$15.7 million. This includes requested financing of US\$5.0 million from GEF, approximately US\$9.3 million from the five participating Governments, and US\$1.4 million from CIAT. As shown in the Incremental Cost Analysis (Annex A), GEF support of US\$5.0 million is expected to leverage additional financing of US\$10.75 million comprising: (a) biosafety capacity-building in knowledge generation for biosafety risk assessment and management (Component 1) of US\$8.86 million; (b) strengthening biosafety decision-making capacity (Component 2), of US\$0.97 million; and (c) building public awareness on biosafety for communicators, opinion-makers and the general public (Component 3), of US\$0.92 million.

31. The cost-effectiveness of the multi-country approach to capacity-building was one of the main criteria supporting the proposed project design. In a without-project scenario, the rapidly expanding adoption of transgenic crops without systematic risk and impact assessment, safety management and tracking/monitoring systems entails significant risks and costs for countries. This is particularly true because the countries in the project are among the world's richest in biodiversity and with national strategies and aspirations for expanding agricultural production and trade. Similarly, a scenario involving five separate country projects has serious implications in terms of scale, cost and time inefficiencies, lost opportunities for collaboration and exploitation of comparative advantage and complementary skills, and potentially weak sustainability. The third scenario – using one country as regional demonstrator – would require major, long-term investment to reach International Standards (IS) and multi-disciplinary technical capacity, an unacceptable option given the rapidly evolving biosafety situation. A formal economic analysis is under consideration in terms of methodology and assumptions and will be completed by Appraisal.

5. INSTITUTIONAL COORDINATION AND SUPPORT

f) CORE COMMITMENTS AND LINKAGES

32. This multi-country project will complement and build on the experiences of the ongoing GEF-funded biosafety project in Colombia, and the development of country Biosafety Clearing House (BCH) facilities. Outside the LAC region, the GEF biosafety operation in India has provided significant lessons, while experiences of the Team preparing the new GEF-supported biosafety operation in West Africa, have been instructive (see PAD, Annex 1). The project responds to participating governments' strategic context as expressed in Country Assistance Strategy (CAS) pillars, national agricultural policies and the biosafety context, synthesized below by country.

33. *Brazil:* Brazil has the highest biodiversity of any country on earth and is already facing the ecological consequences of continuous expansion of the agricultural frontier. Brazil revised its first national biosafety law (Law 8.974/95 of 1995), substituting Law 11.105/05 approved in March 2005, which differs from the initial framework by separating biosafety risk analysis and technical capacity responsibilities of the National Biosafety Committee (CTNBio) from the political and socio-economic decisions now taken by a commission of nine Ministers of State involved in GMO approval and commercial release. The new law is expected to reduce ideological disputes, and facilitate the deployment of LMO/GMO technology following approval for environmental release and for human/animal consumption, with proper environmental and health safeguards.

34. More broadly, as delineated in the 2003 CAS, the economic and social context in Brazil mandates a strategy for growth based on equity and sustainability, supported by improved productivity, stronger institutions, and a focus on key environmental focal points including sustainable use and conservation of the rainforest biome. Innovation supporting the welfare of all Brazilians, but especially the poorest, is targeted. Government's Multi-year Plan 2004-2007 known as "Brazil for Everyone" calls, *inter alia*, for greater harmony between development and the environment, and for managing natural resources as a critical element in reducing poverty, since natural resources constitute up to 80% of the assets of the poor especially in the North and Northeast regions of the country, and the preservation and controlled use of the natural resource base is linked directly to equity and sustainability. An important element of government's current agricultural strategy is to provide incentives for the development and adoption of the latest technology to expand production and exports.

35. *Mexico:* Mexico's current National Development Plan tacitly acknowledges that recent economic growth has in large part been predicated on "mining" natural resources and, in the absence of a coherent approach to environmental protection, has contributed significantly to environmental degradation. Water, forestry, biodiversity and air quality have been depleted to foster growth, which "green" national accounting estimates costs Mexico some 10% of GDP annually. It is becoming a binding constraint on the country's external competitiveness, ability to access new markets and attract foreign investment, among others. As a member of the WTO, OECD and NAFTA, Mexico is now compelled to upgrade environmental standards and compliance mechanisms due to the negative global externalities from degrading production.

36. Mexico has a complex position in the international biosafety panorama. It is the only member of NAFTA to have ratified the Cartagena Protocol and is bound by its provisions. Further, Mexico is the Center of Origin and Diversity (COD) of maize, the principal staple food of Mesoamerica. Large asymmetries with its NAFTA partners and the need to meet its commercial agreements, put Mexico in a difficult situation with respect to biodiversity conservation; government faces implementation challenges in regard to both its trade and biosafety obligations. Mexico's new law (May 2005) on Biosafety and Genetically Modified Organisms, regulates through the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), Environment and Natural resources (SEMARNAT) and Health (SALUD), all activities related to LMO. These mandates are legally-binding with respect to permits for release of LMO into the environment. Mexico's national focal point is the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms (CIBIOGEM), integrating the Ministries of Agriculture, Health, Environment, Finance, Commerce and Education, and the National Council for Science and Technology. CIBIOGEM's creation greatly expanded the inclusiveness of the biosafety debate in Mexico.

37. *Colombia:* Government's current agricultural strategy rests on preparing the sector to take on the challenges of regional/global trade agreements by: improving producer support mechanisms; restructuring the sector to increase productivity to international standards; promoting the creation of new, technology-based sectors and strengthening the science, technology and innovation components of agricultural production; and, responding to global demand while guaranteeing the maintenance, protection and sustainable development of existing ecosystems/biodiversity and the broader environment. Government's peace agenda, as reflected

in the CAS, has been the driving force behind recent national development plans and implies forging ahead with the established reform program in, among others, the environmental and social sectors, with focused support for rural development and natural resources management. Government's strategy calls for mainstreaming environment in key sectors of the economy.

38. Government has demonstrated commitment to biosafety issues, as a lead country in formulating and signing the Cartagena Protocol, by implementing institutional, legal, environmental and public information measures since 1991, including under the 1998 law on Biosafety and Genetically Modified Organisms (LBOGM), creating a National Technical Advisory Biosafety Committee, and corresponding regulations for the introduction, production, release and trading in agriculture and livestock GMO. The Ministry of Agriculture, through the Colombian Agricultural Institute (ICA) authorizes the use, manipulation, export and import of LMO for agriculture, fishery, commercial forestry and agro-industry. When the LMO is for environmental use, responsibility is with the Ministry of Environment and Territorial Development, and in the case of food and health, with the Ministry of Social Protection. This law also specifies the legally-binding mandates with respect to permits for releasing LMO into the environment.

39. *Costa Rica*: Exploring the nexus between agriculture and the environment has become a core challenge for Costa Rica. The CAS pillars support Government's strategic emphasis on strengthening trade and competitiveness, the economic diversification agenda and continuing the country's pioneering leadership on environmental management. The Ministries of Agriculture and Environment are strongly committed to finding solutions to stimulate productive, sustainable agriculture which reduces poverty among smallholders and incorporates conservation practices fully integrated into rural landscapes. Government is demonstrably committed to preserving biodiversity through progressive environmental policies. The country is a global leader on the environmental and has developed markets for global and local environmental services, contributing to rural development, fostering conservation of biodiversity, preservation of forest eco-systems on private land, and the production and sale of environmentally friendly products.

40. Costa Rica established in 1990 a National Technical Commission on Biosafety under the Phytosanitary Protection Law 7664 and its regulations, administered by the Ministry of Agriculture and Livestock. The authorized plantation of GMO crops in Costa Rica is permitted only for seed production; crops per se, have not yet been released for commercial production or for the production of human/animal food. However, Costa Rica has invested significant resources in GMO development and accumulated substantial knowledge on their management, sees itself as a leader in the region and sees GMO technology as having major potential economic, social and environmental benefits.

41. *Peru*: Some 35% of the total workforce is in agriculture. Although in aggregate, agricultural production per capita has declined, a few important products stood out, e.g., rice output increased 8% per year in the 1980s and 1990s, while poultry and egg production grew at similar rates. The Ministry of Agriculture has interpreted these positive results as indicative more generally, of what could be done with better incentives and modern agricultural technologies. The Peru CAS supports government's programs and institutional reforms for renewing growth and reducing poverty, while strengthening emphasis on partnerships with IDB

and the Andean Development Corporation to advance its strategic pillars which include increased competitiveness with greater social equity.

42. In biosafety specifically, the Peruvian Government's National Strategy for Biodiversity (approved September 2001) requires that biosafety considerations be factored into all related policies, planning and sector programs, and stipulates the development of mechanisms to regulate the manipulation of genetic resources, promoting biotechnology as an important tool for both the development and control of living modified organisms (LMO). Further, legislation currently before the Peruvian Congress explicitly justifies support to biotechnological innovation on grounds of national food security; global export competitiveness; prudent utilization of Peru's mega-biodiversity, moving away from extensive agriculture/de-forestation to higher-value, intensive agriculture; increasing nutritional value and health properties of food crops and other plant materials; and industrial, pharmaceutical and soil recuperation applications.

g) CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IAS, AND IAS AND EXAS, IF APPROPRIATE.

43. The proposed project would establish and/or consolidate existing collaboration and consultation between relevant authorities in the partner countries, including alliances between the centers of excellence and between the project and potential additional donors being actively sought by CIAT for this project (e.g., USAID). The task team had consultations with UNDP and UNEP whose experiences and lessons in the region have been incorporated in the design of the proposed project. Further consultations on the substance and objectives of the project would continue to be established with UNEP and UNDP. Opportunities for synergies between project activities and similar, complementary activities of these agencies will be explored further during preparation, appraisal and implementation. At the country level, collaborating agencies formally include: EMBRAPA (National Agricultural Research Corporation, Ministry of Agriculture, Brazil); Ministry of Agriculture, Colombia; University of Costa Rica (CIBCM); Ministry of Environment, Mexico (CONABIO); and Ministry of Environment, Peru (CONAM). The implications of biotechnology and biosafety cross sectors and boundaries; no single ministry/entity can be solely responsible for decision-making on biosafety issues. Further, capacity development must be sustainable. The most efficient institutional framework, and the one likely to be achieved more rapidly, entails upgrading the skills and knowledge of existing technical and other personnel through training and information sharing among prominent, specialist entities and proactive communication of findings to the broader sphere of interests.

C) PROJECT IMPLEMENTATION ARRANGEMENTS

44. The project would be implemented over three years, with the grant partner and implementing agency being the Colombia-based International Center for Tropical Agriculture (CIAT), a globally-recognized institution with experience managing multiple projects, working in an integrated manner through a consortium of partner countries and their respective "Centers of Excellence" (CE), building institutional alliances to leverage complementary skills in evaluating and managing transgenic crops and their products. Each CE will engage other national, competent entities in GMO technology, as needed. The consortium approach provides an opportunity to increase biosafety knowledge and exchange information and experiences

among countries at different levels of engagement with transgenic crops while providing a forum to share knowledge generated by the various project activities.

45. The project will be supervised by a Project Management Committee (PMC) comprising key representatives of CIAT and the designated National Coordinators (NC) of each partner country. The PMC will have an approval role in the flow of funds and reporting to the donor, and will oversee the execution of thematic areas under Component 1. The PMC will also have an approval role in operational planning, administration, budget, annual plans and monitoring project progress. Within CIAT, day to day project implementation will be the responsibility of the existing Projects Office responsible for servicing all projects and donors, supported by the Directors of Finances and Administration. For the project, these arrangements will be supplemented by hiring three incremental professionals (full-time manager, M&E specialist and staff assistant). The project will also be supported by established CIAT technical and administrative professionals, responsible for day to day technical and administrative operations. CIAT will monitor progress, prepare planning materials, provide administrative support, handle budget preparation, auditing of financial statements and allocate project funds through the PMC, according to approved work plans. Responsibility for national-level execution in partner countries will reside with the National Coordinators under Letters of Understanding with their respective institutions. Implementation arrangements are presented in greater detail in Annex 6 of the PAD.

ANNEX A: INCREMENTAL COST ANALYSIS

Overview

The project's **global environmental objective** is to support implementation of the Cartagena Protocol (CP) on biosafety by improving the institutional capacity of agriculture and environmental ministries as well as specific, biosafety-related agencies in the five participating countries, to implement their national biosafety regulations in compliance with the CP.

This will be achieved through the following components:

- 1. Strengthening technical capacity in knowledge generation for biosafety risk assessment and management** including: 1.1 Strengthening of technical capacity for environmental risk assessment and management; and 1.2 Strengthening of technical capacity for socioeconomic impact assessment.
- 2. Strengthening biosafety decision-making capacity**
- 3. Increasing public awareness on biosafety for communicators, opinion-makers and the general public**

These components will: (a) improve the countries' decision-making in line with international obligations; (b) lead to more responsible use of products of biotechnology in agriculture, while maintaining high and consistent standards of environmental protection in centers of biodiversity; and (c) improve regional decision-making, policy making and biodiversity protection in the project countries.

The principal expected outcomes of the project are therefore: (a) Clearly-defined institutional mechanisms for administering biosafety including defined responsibilities in biosafety within each national institution/agency and designated biosafety technical specialists and personnel; (b) Sustainable biosafety frameworks and project-established methodologies as indicated by annual budgets allocated to targeted biosafety-related institutions and agencies; (c) Functioning mechanisms established to promote

inter-institutional and inter-country collaboration on biosafety and the environment, among the five participating countries; (d) Standardized risk assessment, risk mitigation, cost-benefit assessment and emergency response methodologies and mechanisms used by project targeted institutions and agencies, and participating countries, to manage the use, handling and transfer of GMO; and (e) Greater awareness and understanding of biosafety on the part of communicators, opinion-makers and the general public, using science-based information generated by the project.

The GEF Alternative would achieve these objectives and outcomes at an incremental cost of US\$15.745 million of which US\$5.0 million is being requested from the GEF.

Context and Broad Development Goals

The project is a grant-based, full-sized GEF operation in five Latin American countries. Brazil, Colombia, Costa Rica, Mexico and Peru have been selected based on criteria related to the scale of their use of Genetically Modified Organisms (GMOs), the level of their development of biosafety policy and their importance in terms of biodiversity. The project would ensure that these countries will be able to implement the basic objectives of the Cartagena Protocol, including the assessment, management and monitoring of the potential risks posed by transgenic crops including risks to the conservation and sustainable use of biodiversity and risks to human health. It would thus provide significant global environmental benefits in terms of conservation of globally significant biodiversity.

The project builds on other biosafety activities managed by the Bank and under execution in India and Colombia and would provide sustainable benefits in terms of biosafety that could also be replicated in further countries in the region, particularly under the guidance of the International Center for Tropical Agriculture (CIAT) – the proposed recipient of the grant and also the implementing agency. This is particularly significant as Latin America – and these countries in particular – have adopted the use of Genetically Modified Organisms at a faster rate than any other region in the world and, also, as Latin America – and these countries in particular – are the centre of origin of many important agricultural crops and harbor many race/weedy/wild relatives of these, the conservation of which is important for future crop-breeding.

Despite the significance of the five project countries and the region in terms of biodiversity, the Latin America and Caribbean region generally has received relatively little attention regarding biosafety in comparison to the Africa and Asia regions. In addition, recent developments in international agreements on biosafety, increasing use of GMOs in these countries and increasing global movement of GMOs also make such a project all the more important. This project is therefore a priority for the region.

Baseline scenario

The baseline scenario for the five countries sees very little going towards capacity building and no coordinated efforts in the region. Without this project, the countries will undertake the necessary steps at a much slower rate and with little regional coordination and consequently greatly reduced efficiency and effectiveness. In particular, CIAT would not have funding to put towards organizing regional biosafety initiatives and there would be no integrated approach to take advantage of the potential synergies of coordination. It is also very unlikely that best-practice guidelines would be developed or that future replication within countries or within the region would occur.

The baseline scenario therefore sees the countries in the region very slowly developing their own methods without taking advantage of the economies of scale and without maximizing the potential biodiversity conservation benefits that could be achieved through such activities.

Costs of the Baseline Scenario.

The costs of the baseline activities for each country are given below, disaggregated by activities that contribute to each component of the project.

Component 1: Strengthening technical capacity in knowledge generation for biosafety risk assessment and management

In the absence of this project, CIAT would invest US\$3.66 million for: mapping distribution of crops; gene flow analysis and monitoring; crop management for minimizing transgene flow; evaluating and minimizing effects on non-target organisms; socio-economic impact assessment of LMOs in the tropics; and cost-benefit analysis for LMOs in centers of crop-diversity.

CIAT would also invest US\$0.09 million for coordination of international projects that enable promotion and supervision of activities both in-country and across countries.

The Mexican government is currently spending US\$5.6 million on strengthening biosafety technical capacity in Mexico.

The Brazilian government is currently spending US\$6.46 million on strengthening biosafety technical capacity in Brazil.

The Colombian government is currently spending US\$4.0 million on strengthening biosafety technical capacity in Colombia.

International organizations are spending about US\$0.12 million in workshops regarding biosafety in Peru.

In Costa Rica, the Ministry of Agriculture financed an amount of US\$0.03 million to strength technical capacity on environmental biosafety in order to review a National Biosafety Framework for based on the Cartagena Protocol on Biosafety.

Academic institutions strengthen technical capacity in Costa Rica by providing matching funds to financed research projects related to environmental biosafety for mapping distribution of weedy and wild rice species and gene flow analysis. This funding is approximately US\$2.41million over the life of the project. In addition, academic institutions have invested approximately US\$0.1 million as investments in socio-economic studies that relate to the baseline for the GEF-WB project.

The total amount of baseline funding going towards this component is therefore **US\$ 22.47 million.**

Component 2: Strengthening biosafety decision-making capacity

In the absence of this project, CIAT would invest US\$0.70 million for: training on environmental risk assessment for competent authorities and practitioners; and training on socio-economic and cost-benefit assessment for competent authorities and practitioners.

The Mexican government is currently spending US\$0.22 million on strengthening decision-making capacity in Mexico.

The Brazilian government is currently spending US\$0.11 million on strengthening decision-making capacity in Brazil.

There are currently no baseline activities occurring or planned regarding strengthening decision-making capacity in Colombia.

The Peruvian government is currently spending US\$0.22 million on strengthening decision-making capacity in Peru.

Costa Rica's National Executive Agency (NEA): National Committee of Biosafety has spent US\$0.195 million preparing, evaluating and reviewing a National Biosafety Framework for Costa Rica based on the Cartagena Protocol on Biosafety for strengthening decision-making capacity in Costa Rica. Furthermore, an investment of US\$0.045 from the Ministry of Agriculture has been spent on capacity building in decision-making of competent authorities.

The total amount of baseline funding that would contribute to the objectives of this component is therefore **US\$1.49 million**.

Component 3: Increasing public awareness on biosafety for communicators, opinion makers and the general public

There are currently no baseline activities occurring or planned regarding increasing public awareness on biosafety in Mexico.

The Brazilian government is currently spending US\$0.02 million on increasing public awareness on biosafety in Brazil.

There are currently no baseline activities occurring or planned regarding increasing public awareness on biosafety in Colombia.

There are currently no baseline activities occurring or planned regarding increasing public awareness on biosafety in Peru.

An amount of US\$0.5 million is being co-financed by the University of Costa Rica for increasing public awareness on biosafety.

The total amount of baseline funding that would contribute to the objectives of this component is therefore **US\$ 0.7 million.**

The total cost of the Baseline scenario for the entire project would therefore be US\$24.66 million. GEF.

GEF Alternative scenario

The alternative scenario would see the Colombian-based CIAT, as both grant partner and implementing agency, coordinating the activities of the five countries to create a competent pool of regional biosafety technical personnel and practitioners and to develop standardized, comprehensive biosafety databases and methodologies for biosafety management and socio-economic cost-benefit analysis. This approach would be innovative and cost-effective in that it would integrate and standardize countries' technical/analytical biosafety capacity at a regional level. The activities developed would be specifically created as models for replication to apply to further crops and countries in order to ensure the project could be scaled up to contribute to providing comprehensive biosafety improvements throughout the region. The project includes specific actions for dissemination of information in order to lead to this replication.

This would achieve a greater understanding of biotechnology and biosafety within the countries involved and better informed decision-making. This would also lead to replication in other countries and the global environmental consequences would be improved biodiversity conservation in hotspots in Latin America – and particularly improved conservation of rare/weedy/wild relatives of agriculturally important crops – and improved human health through increasing safe development of agriculture both for providing increased nutrition and avoiding possible negative consequences of growing Genetically Modified Organisms.

The GEF involvement would provide crucial incremental financing to maximize the global biodiversity conservation benefits of the project and to ensure that this would form a model for replication throughout the region.

Costs of the GEF alternative

The following presents the disaggregated costs that would be paid by the various institutions to fund the four components of the GEF alternative scenario.

Component 1: Strengthening technical capacity in knowledge generation for biosafety risk assessment and management

The GEF would contribute US\$4.043 million to strengthen technical capacity for environmental risk assessment and management and socio-economic cost/benefit assessment.

CIAT would contribute US\$1.315 million to strengthen technical capacity for environmental risk assessment and management and socio-economic cost/benefit assessment.

Mexico would contribute US\$1.75 million towards: assessment and monitoring of potential effects on non-crop (non-target) organisms; adaptation of methods and tools for socio-economic impact assessment of LMOs in centers of crop diversity; and development of analytical skills for analysis of potential benefits.

Brazil would contribute US\$3.1 million towards: assessment and monitoring of gene flow, assessment and monitoring of potential effects on non crop (non target) organisms; adaptation of methods and tools for socio economic impact assessment of LMOs in centers of crop diversity; and development of analytical skills for analysis of potential benefits.

Colombia would contribute US\$1.10 million towards compilation and generation of baseline data for tracking and monitoring gene introgression persistence of novel traits in crop biosafety in cassava and potato; generation and use of GIS reference databases for mapping distribution of crops; adaptation and regional standardization of methodologies for evaluating effects on non target organisms; and development of analytical skills for potential benefits and costs of LMOs in centers of crop diversity.

Peru will contribute US\$0.10 million towards assessment and monitoring of potential effects on non-crop (non target) organisms.

Costa Rica will contribute US\$ 1.35 million towards adaptation and regional standardization of methodologies for large scale monitoring of gene flow; development of analytical skills for analysis of potential risks and benefits of LMOS, adaptation of methods and tools for socio-economic impact assessment of LMOs and evaluation of effects on non-target organisms.

The total additional cost of the GEF Alternative scenario for this component would therefore be **US\$12.9 million with US\$4.04 million.**

Component 2: Strengthening biosafety decision-making capacity

The GEF would contribute US\$0.56 million to build biosafety capacity for decision-making entities (competent authorities) and for practitioners (i.e. public and private research community), through participatory scientific and technical training on risk assessment, risk management and risk communication.

CIAT would contribute US\$0.05 million towards training on environmental risk assessment and socioeconomic impact assessment for competent authorities and practitioners.

Brazil would contribute US\$0.84 million towards training on environmental risk assessment and socioeconomic impact assessment for competent authorities and practitioners.

Colombia would contribute US\$0.035 million towards training on environmental risk assessment and socioeconomic impact assessment for competent authorities and practitioners.

Peru would contribute US\$0.04 million towards training on environmental risk assessment and socioeconomic impact assessment for competent authorities and practitioners.

Costa Rica will contribute US\$ 0.15 million towards training on environmental risk assessment and socioeconomic impact assessment for competent authorities and practitioners.

The total additional cost of the GEF Alternative scenario for this component would therefore be **US\$ 1.53 million.**

Component 3: Increasing public awareness on biosafety for communicators, opinion makers and the general public

The GEF would contribute US\$0.39 million to finance communication specialists to develop communication strategy/plans, develop and test information materials on biosafety, and information campaigns to insert science-based messages into the public debate/discourse at multiple levels.

CIAT would contribute US\$0.05 million towards development of information packages, and compilation of science-based information on biosafety for dissemination to general public.

Brazil would contribute US\$0.72 million towards development of information packages, and compilation of science-based information on biosafety for dissemination to general public.

Colombia would contribute US\$0.11 million towards compilation of science-based information on biosafety for dissemination.

Peru would contribute US\$ 0.04 million towards compilation of science-based information on biosafety for dissemination.

The total cost of the GEF Alternative scenario for this component would therefore be **US\$1.31 million.**

The total cost of the GEF Alternative scenario for the entire project would therefore be US\$15.745 million of which US\$5.0 million is being requested from the GEF.

Incremental Costs

The incremental cost – the additional cost above the baseline scenario (US\$24.66 million) – is US\$ 15.745 million. This would be financed partly by a US\$ 5 million GEF grant and partly by US\$10.745 million co-financing to work towards providing global environmental benefits. These global environmental benefits would be sustainable and would be scaled up through replication in further areas of biosafety within the five countries and throughout the region, thus producing significant additional

benefits. The matrix below summarizes the baseline and incremental expenditures during the five-year project period:

Attachment 1: Incremental Cost Matrix

Cost Category	US\$ Million	Domestic Benefit	Global Benefit
Component 1: Strengthening Technical Capacity in Knowledge Generation for Biosafety Risk Assessment and Management			
Baseline	US\$22.47	Existing capacity is weak and, due to lack of institutional capacity and government commitment, technical capacity within the countries will grow slowly and with reduced efficiency and effectiveness. Domestic benefits will be limited.	Lack of government commitment and heavy dependence on scientific consultative committees means that institutional and technical capacity within the countries is small. Without this project, the situation is unlikely to change significantly and technical capacity will continue to grow only slowly and in an uncoordinated manner. Furthermore, it will not be oriented towards achieving global benefits. Global benefits will therefore be very small.
With GEF Alternative	US\$35.37	Demonstrated compliance with international commitments under the Cartagena Protocol will enable increased trade and growth of the agricultural sector.	Technical capacity will be strengthened efficiently and effectively through regional integration and coordination for carrying out risk assessment and socio-economic cost-benefit assessment. The GEF, and other, incremental financing will finance the activities that relate to achieving global environmental benefits and will particularly be used to orient aspects of the risk assessment and cost-benefit analysis to take account of globally significant biodiversity. Having an emphasis on standardization and producing replicable models and disseminating these, the consequences will include sustained improvements in the ability of the countries and the region to ensure conservation of globally significant biodiversity.
Incremental	US\$12.9		
Comp 2: Strengthening Biosafety Decision-making Capacity			
Baseline	US\$1.49	Decision-making capacity within the countries will continue to be weak and only grow slowly and in an uncoordinated manner. Domestic benefits will be limited.	Decision-making capacity within the countries will continue to be weak and only grow slowly and in an uncoordinated manner. In particular, it will not be oriented towards achieving global benefits. Global benefits will therefore be very small.
With GEF Alternative	US\$3.02	Demonstrated compliance with international commitments under the Cartagena Protocol will	Decision-making capacity of competent authorities will be strengthened efficiently and effectively through providing training in risk assessment, risk management, risk communication and socio-economic cost-benefit

		enable increased trade and growth of the agricultural sector.	assessment. The GEF, and other, incremental financing will finance the activities that relate to achieving global environmental benefits and will particularly be used to orient aspects of the risk assessment and cost-benefit analysis to take account of globally significant biodiversity. The training given here and lessons learned will be made available through CIAT to the entire region and the results will therefore be sustained improvements in the ability of the countries and the region to ensure conservation of globally significant biodiversity.
Incremental	US\$1.53		
Comp 3: Public Awareness on Biosafety for Communicators, Opinion Makers and the General Public			
Baseline	US\$0.7	Public awareness within the countries will continue to be influenced by partial and inaccurate information. Domestic benefits of this will be limited.	Public awareness within the countries will continue to be influenced by partial and inaccurate information. Accurate information regarding links to biodiversity will be particularly hard to obtain and global environmental benefits of this will therefore be limited.
With GEF	US\$2.01	Increased understanding will contribute to increased consumer confidence and improve trade and growth in the agricultural sector.	Raising public awareness is a key area where global environmental benefits can be realized through orienting information towards including coverage of global biodiversity issues. Accordingly, GEF incremental financing will finance activities towards developing public awareness of the issues relating to biosafety and biodiversity conservation including in information campaigns, public debates, press-briefings, publications and other media.. This will be efficiently achieved through taking advantage of economies of scale able to be achieved by using the CIAT to organize this centrally. The information and other lessons learned generated here will be made available through CIAT to the entire region and the results will therefore be sustained improvements in the ability of the countries and the region to ensure conservation of globally significant biodiversity.
Incremental	US\$1.31		
	Total Baseline: US\$24.66 million		
	Total GEF Alternative: US\$40.405 million		
	Total Incremental Costs: US\$15.745 million of which US\$5.0 million is requested from the GEF		

**ANNEX B: Results Framework and Monitoring
LATIN AMERICA: Regional Capacity-Building in Biosafety**

Global Environmental Objective	Project Outcome Indicators	Use of Project Outcome Information
<p>GEO:</p> <p>Strengthened capacity in the five participating countries to implement the Cartagena Protocol (CP) on biosafety.</p>	<ul style="list-style-type: none"> • By EOP, all targeted institutions in the five countries have adopted and are using standardized biosafety risk assessment and risk management mechanisms developed by the project. • By EOP, targeted communicators, opinion-makers and the general public have increased science-based awareness and understanding of biosafety. • By EOP, networks to promote inter-institutional and inter-country cooperation on biosafety and the environment are established among the five participating countries. 	<ul style="list-style-type: none"> • Y4: Evaluate the project strategy for strengthening country capacity to implement the CP. • Y4: Evaluate effectiveness of project Training Plan for authorities and practitioners. • Y4: Analyze experience with network building to assess potential for cross-country collaboration, and sustainability of the project strategy. • Y4: Assess project techniques for promoting science-based awareness of biosafety among the general public.
Intermediate Outcomes	Intermediate Outcome Indicators	Use of Intermediate Outcome Monitoring
<p>Outcome One :</p> <p>Standardized biosafety risk assessment and management methodologies established.</p>	<p>Outcome One :</p> <ul style="list-style-type: none"> • End Y2: # studies completed on environmental risk-benefit assessment and management, and on socio-economic impact assessment in five countries. • End Y2: Standardized methodology available for socio-economic cost/benefit assessment across countries. • Y3-4: # databases established for tracking and monitoring gene flow, and for mapping distribution of crop/landrace populations. • Y3: Crop management strategies and operational guidelines to minimize transgene flow and potential effects on non-target organisms, five selected crops. • Y4: Technical, science-based toolkits (one per crop) on risk/benefit assessment and management, prepared and distributed by the five target countries 	<p>Outcome One :</p> <p>Y2-Y3: Plan and initiate systematic use of study results.</p> <p>Y3: Measure progress in formulating standardized methodologies for biosafety risk assessment and management and make needed adjustments.</p> <p>Y3: Assess progress in establishing databases for tracking and monitoring gene flow, and mapping distribution of crop/landrace populations.</p> <p>Y3: Input to project Mid-Term Review</p> <p>Y4: Gauge capacity of Montreal BCH to service biosafety information demands stemming from project activities.</p> <p>Y4-Y5: Input to project Implementation Completion Report.</p>

	<ul style="list-style-type: none"> Y4: 60% project-generated knowledge (studies, methodologies) downloaded to depositories and websites, country Biosafety Clearing House (BCH), Regional (CIAT) and Montreal BCH. 	
<p>Outcome Two:</p> <p>Biosafety planning and decision-making capacity strengthened</p>	<p>Outcome Two :</p> <ul style="list-style-type: none"> Y1: Project Training Plans and course materials developed for five countries. Y2-3: Targeted authorities and experts trained by experts in biosafety and environmental risk assessment and management. Y2-3: Targeted authorities and experts trained by experts in biosafety socio-economic cost-benefit assessment. Y4: 10-30 % decline in processing time for biosafety decisions by targeted authorities and experts, baseline vs. end-project, in five countries. Y4: Toolkits adopted and being used by targeted authorities and experts. 	<p>Outcome Two :</p> <p>Y3: Measure effectiveness of project Training Plan and need for adjustments.</p> <p>Y3: Input to Mid-Term Review</p> <p>Y3: Assess extent to which targeted authorities and experts are using standardized cost-benefit analysis for maize and cotton.</p> <p>Y4: Assess extent to which targeted authorities and experts are using standardized risk assessment and management techniques.</p> <p>Y4-Y5: Input to project Implementation Completion Report</p>
<p>Outcome Three:</p> <p>Enhanced awareness of biosafety by communicators, opinion makers and the general public</p>	<p>Outcome Three:</p> <ul style="list-style-type: none"> Y1: Knowledge dissemination plan developed and available. Y3-Y4: # of information briefings using science-based knowledge generated by the project. Y3: 1 video and companion booklet produced on biosafety risk assessment and management, and cost-benefit methodologies - in accessible language. Y1 (baseline), Y4 (end-project): 2 surveys completed to measure changes in public perceptions of biosafety, using tested survey methodologies. 	<p>Outcome Three:</p> <p>Y2: Determine schedule for and launch, dissemination activities.</p> <p>Y3: Input to project Mid-Term Review</p> <p>Y3-Y4: Gauge rate and coverage of information dissemination in each country and adjust program if needed.</p> <p>Y4: Gauge effectiveness of public awareness campaign.</p> <p>Y4-Y5: Input to project Implementation Completion Report</p>

Proposed Arrangements for Results Monitoring

Project Outcome Indicators	Baseline	Target Values				Data Collection and Reporting		
		YR1	YR2	YR3	YR4	Frequency and Reports	Data Collection Instruments	Responsibility for Data Collection
Global Environmental Objective								
<p>1. All targeted institutions in the five countries have adopted and are using standardized biosafety risk assessment and risk management mechanisms developed by the project.</p> <p>2. Targeted communicators, opinion-makers and the general public have increased science-based awareness and understanding of biosafety.</p> <p>3. Networks to promote inter-institutional and inter-country cooperation on biosafety and the environment are established among the five participating countries.</p>	<p>Uneven quality of national biosafety systems and institutional capacity b/w the five countries.</p> <p>Weak risk assessment & management, & cost-benefit analysis, & poorly-informed public discourse.</p> <p>Biosafety Centers of Excellence exist in all project countries.</p> <p>All countries, except Peru, already have field releases under national systems.</p> <p>All five countries have biosafety frameworks in place</p>	<p>Implementation arrangements (national and inter-country) in place and target institutions briefed/ready.</p> <p>Prepare all operational plans.</p> <p>Initiate all component activities (C1, C2 and C3).</p>	<p>Implement Work Program described below.</p> <p>Initiate discussions and activities on biosafety risk issues with international collaborators.</p>	<p>Implement the Work Program described below.</p> <p>Mid-Term Review (1st half of CY)</p>	<p>Implement Work Program described below.</p> <p>End-Project evaluation.</p>	<p>Quarterly, Annual and Mid-Term progress reports.</p> <p>Y3: Mid-term Review Report</p> <p>End Y4: Implementation Completion Report</p> <p>End Y4: Final Report by CIAT with country and institutional contributions & input.</p>	<p>Management Information System (MIS) with time-bound country input.</p> <p>M&E Reports.</p> <p>Mid-Term Review activities</p> <p>WB supervision reports (ISR)</p> <p>Databases, maps, publications, websites, manuals.</p> <p>Ex-post analysis and reporting</p>	<p>National Coordinators (NCs)</p> <p>Regional Component Coordinators (RCCs)</p> <p>CIAT Projects Office</p> <p>WB Task Team Leader</p>

Intermediate Outcome Indicators								
Component 1:								
1. # studies completed on environmental risk-benefit assessment and management, and on socio-economic impact assessment in five countries.	Data methods, strategies and skills exist in Centers of Excellence, but not organized or standardized.	Data methodologies and strategies compiled and reviewed based on existing knowledge adapted to LAC conditions.	Selected, adapted methodologies and strategies tested and dissemination process initiated.	Best practice methodologies introduced and consolidated within target biosafety institutions and agencies.	Standardized methodologies and strategies validated, published and promoted.	Quarterly, annual and Mid-Term progress reports Mid-term Report (from Mid-Term Review activities)	Progress reports – quarterly, annual and mid-term. M&E Reports	National Coordinators (NCs) Regional Component Coordinators (RCCs)
2. Standardized methodology available for socio-economic cost-benefit assessment across countries.	Laws and regulations for biosafety exist but institutional capacity to execute is uneven.			All planned databases established, accessible and operational for the five project crops, in all five countries.		Implementation Completion Report (Final Year)	WB supervision reports (ISR)	CIAT Projects Office WB Task Team Leader
3. # databases established for tracking and monitoring gene flow, and for mapping distribution of crop/landrace populations.	GMO application processing is slow in all five countries and lacking in science-based, uniform criteria, methodologies for approval or rejection.					End-Project report by CIAT with country and institutional inputs on experiences, lessons and sustainability	Databases, maps, publications, websites, manuals and courses.	
4. Crop management strategies and operational guidelines to minimize transgene flow and potential effects on non-target organisms, five selected crops.							Ex-post analysis and reporting	
5. Technical, science based toolkits (one per crop) on risk/benefit assessment and management, prepared/distributed by the five target countries.								

6. 60% project generated knowledge (studies, method's.) downloaded to depositories/websites, in country, regional (CIAT) and Montreal BCHs.								
Component 2:								
<p>1. Project Training Plans and course materials developed for five countries.</p> <p>2. Targeted authorities and experts trained by experts in biosafety and environmental risk assessment and management.</p> <p>3. Targeted authorities and experts trained by experts in biosafety socio-economic cost-benefit assessment.</p> <p>4. 10-30% decline in processing time for biosafety decisions by targeted authorities and experts, baseline vs. end-project, 5 countries.</p> <p>5. Toolkit adopted and being used by targeted authorities and experts.</p>	<p>Uneven decision-making capacity in major biosafety institutions and agencies in all five countries, for the safe handling, transfer and use of the targeted transgenic crops</p> <p>Senior authorities and technical specialists responsible for GMO processing and decision-making lack organized, modern knowledge and databases to execute their responsibilities.</p>	<p>Evaluate existing materials and develop Training Plan</p> <p>Solicit and select professional trainers to assist seminar/course development and delivery</p>	<p>Initiate implementation of Training Plan including toolkit development, initiation of annual training seminars and courses, and practice efforts to promote enrollment of key biosafety authorities and practitioners.</p>	<p>Implement all elements of the Training Plan</p>	<p>Evaluate Training Plan including through systematic feedback from participants</p>	<p>Quarterly, annual and Mid-Term progress reports.</p> <p>Mid-Term Review Report</p> <p>End-project Implementation Completion Report (ICR)</p> <p>End-Project report by CIAT with country and institutional inputs on experiences, lessons and sustainability</p>	<p>Progress reports (quarterly, annual and mid-term)</p> <p>M&E Reports</p> <p>WB supervision reports (ISR)</p> <p>Publications;</p> <p>Website placement of information and data;</p> <p>Manuals;</p> <p>Training materials; (course books, CDs and audio-visuals).</p>	<p>National Coordinators (NC)</p> <p>Regional Component Coordinators (RCC)</p> <p>CIAT Projects Office</p> <p>World Bank Task Team Leader</p>
Component 3:								

<p>1. Knowledge dissemination plan developed and available</p> <p>2. # information briefings using science based knowledge generated by the project.</p> <p>3. 1 video and companion booklet on biosafety risk assessment and management, and cost-ben. methodologies in accessible language.</p> <p>2. 2 surveys completed (Y1 baseline, Y4 final) measuring changes in public perceptions of biosafety, using available, tested survey methods.</p>	<p>Weak, science-deficient information base for communicators, opinion-makers and general public, all five countries.</p> <p>Poor quality media coverage of biosafety issues promoting distorted public discourse.</p> <p>Available information unsuitable for targeted audiences.</p> <p>Need for science-based information in non-technical, accessible language.</p>	<p>Develop Communications Plan using appropriate professionals and standardized, available methodologies</p> <p>Exploit available inventories of materials and methods.</p> <p>Initiate Baseline Survey of public attitudes and perceptions to biosafety.</p> <p>Collate and input survey results.</p> <p>Design video and booklet with assistance of communications professionals.</p>	<p>Develop and test information dissemination tools, methods and materials.</p> <p>Initiate dissemination as project results emerge and are incorporated in messages and materials.</p> <p>Develop new materials in non-technical language and initiate test promotion and dissemination.</p> <p>Initiate deposit of project-generated knowledge to country BCHs, Montreal BCH, and establish BCH websites.</p>	<p>Prepare video and booklet based on project-generated information, with professional assistance.</p> <p>Initiate press briefings with national science writers & journalists, & other opinion-makers.</p>	<p>Conduct follow-up survey of public attitudes and perceptions re biosafety and biotechnology</p> <p>Evaluate impact on target groups of project communications strategy & materials</p> <p>Collate and disseminate feedback to competent authorities and practitioners.</p>	<p>Quarterly, annual and Mid-Term progress reports.</p> <p>Mid-Term Review Report</p> <p>End-project Implementation Completion Report (ICR)</p> <p>End-Project report by CIAT with country and institutional inputs on experiences, lessons and sustainability.</p>	<p>Progress reports (quarterly, annual and mid-term)</p> <p>M&E Reports</p> <p>WB supervision reports (ISR)</p> <p>Publications</p> <p>Website placement of information and data</p> <p>Manuals</p> <p>Training materials (course books, CDs and audio-visuals).</p>	<p>National Coordinators (NC)</p> <p>Regional component coordinators (RCC)</p> <p>CIAT Projects Office</p> <p>World Bank Task Team Leader</p>
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ANNEX C: RESPONSE TO PROJECT REVIEWS

- a) Convention Secretariat comments and IA/ExA response

No comments have been received by Convention Secretariat that need response.

b) STAP expert review and IA/ExA response:

STAP Roster Review

Reviewer: Dr. Ariel Alvarez Morales (Research Specialist, Center for Research and Advanced Studies, Department of Genetic Engineering, Guanajuato Campus, Mexico - March 6, 2006)

The document presented describes a proposed, free-standing, biosafety capacity-building operation in five Latin American countries, grant-funded by a full-sized GEF contribution of US\$5.0 million channelled through the Colombia-based, International Center for Tropical Agriculture (CIAT), and with an estimated total budget of US\$12.9 million.

“The global objective is to contribute to the ability of Mexico, Brazil, Colombia, Peru and Costa Rica to implement the Convention on Biological Diversity (CBD) and the Cartagena Protocol (CP) on biosafety to reduce the environmental risks of modern biotechnology, ensuring an adequate level of protection in the area of transfer, handling and use of transgenic crops in centers of crop biodiversity.”

The proposed project is regional in scope, and pretends to generate standardized, science-based mechanisms and methodologies for biosafety risk, cost and benefit assessment, and project them in organized, accessible form - as an integral part of project activities - to competent authorities, biosafety practitioners, organized civil society and the general public.

COMMENTS

It is mentioned in the document that “In 2004, Latin America grew 30% (23 million hectares) of the total global area of transgenic crops, second only to the United States (48 million ha). This rapid growth is the logical outcome of the manifest delivery of economic benefits for the agricultural economy of the region, by the initial products of biotechnology”. However, this statement fails to recognize that it is only Argentina, not an adherent to the CP, the sole contributor to this significant percentage of transgenic crop adoption in the area.

Nevertheless, this fact indicates that the rest of Latin America has lagged behind considerably, and this is, at least in part, due to the lack of an efficient biosafety framework in the rest of the countries capable of addressing the issues required to responsibly commercialize GMOs. In this respect, no doubt the five countries involved in the present proposal could benefit significantly by implementing a sound mechanism to efficiently address the responsibilities derived from their national legal systems as well as the responsibilities acquired with the international community.

RESPONSE (IA & EA): In 2005, the total area of transgenic crops grown in Latin America and the Caribbean (LAC) accounted for 28.8 million hectares (32% of the total from 6 countries relative to the global area of 90 million ha). Of the 28.8 million ha in LAC, 17.1 million ha were in Argentina (59%), 9.4 million ha in Brazil (33%), 1.8 million ha in Paraguay, 0.3 million ha in Uruguay, 0.1 million ha in Mexico, and about 0.05 million ha in Colombia and Honduras (Clive James. ISAAA Brief Report 34 Global Status of Commercialized Biotech/GM Crops: 2005). Therefore transgenic crop production includes not only Argentina but also CP compliant countries. A retrospective analysis of the increase in number of countries and the area of GM crops grown from 2000 to 2005, indicate that while in 2000 LAC grew 10 million ha just in Argentina (23% of the global area), by 2005 LAC region grew 32% of the global area (9% increase) in 7 countries, while Brazil was the third principal adopter after US and Argentina, followed by Canada and China. The increase in adoption of transgenic crops (mainly soybeans) in Brazil did not follow a step-wise mechanism due to the lack of an efficient biosafety framework resulting in a rapid non-authorized introduction as a response to pressure from farmer groups which then triggered the authorization process. This project aims to facilitate the establishment of an

efficient biosafety framework in the participating countries by strengthening the technical capacity for a science-based decision process in order to implement the already existing legal framework in these countries and allowing them to comply with International Treaty commitments in particular the implementation of the Cartagena Protocol.

It is also necessary to recognize that mega diverse countries face unique and difficult problems when addressing potential environmental risks. This again is the case of the five countries presenting the proposal.

In support of this proposal it is necessary to acknowledge that there is unquestionable capacity, quality and professionalism involved in the participating institutions, both in terms of infrastructure and human resources. The proposal seems sound and well balanced between the countries and between the proposed activities. However, I have two major concerns about the projection of the results obtained in terms of the future sustainability of a practical and efficient biosafety framework in the countries involved.

MAJOR CONCERNS

It is repeatedly mentioned in the proposal that the project will finance training in environmental risk assessment, risk management and risk communication for competent authorities. Who are they going to train? In most of these countries the different Ministries or Secretaries rely heavily on consultative committees for reviewing requests to release GMOs, and provide an opinion that most often is the result of a scientific exercise that includes risk assessment, without anyone being a professional risk assessor, although some of them may have an in-depth knowledge about risk assessment.

Nevertheless, the scientists that are members of such consultative committees can only devote a small fraction of their time to these activities and very often they are unable to participate as often as would be required. To have a regulatory system that is based on scientific data, as this is the fundamental base of a risk assessment, without a capable group of professional full-time risk assessors and risk managers does not seem congruent.

The training of academics, field technicians, laboratory technicians, etc., is important, however, these people would not be involved in the most important aspects that the CP demands. Among other activities:

Reviewing risk assessment data presented as part of request for trans-boundary movement or field releases of LMOs.

Reviewing or proposing risk management measures.

Writing scientifically sound decision documents.

Providing accurate information to the BCH in compliance to the CP

Furthermore, the professional risk assessors and risk managers from the different government entities- such as agriculture, environment and health- should be the persons responsible for maintaining the links and communication between the corresponding entities in the five countries involved in the proposal.

I do not see in the proposal any reference to this issue. I do not know how many full-time professional risk assessors are there in each country, or how many full-time government professionals will be trained to fulfil this role.

Are there enough of these people in the appropriate offices within governments to ensure continuity and an efficient and prompt response to the demands of the CP? If not, is there a commitment of the governments to provide or open new positions for these people? How many? When?

Without the involvement and decisive commitment of the government entities involved I cannot see how this project can achieve their main goals. One can see in the table describing the “Status of Biosafety in participating Countries” that in some cases work in this area began as early as 1988, with Peru being the late entry in 1995. So the experience these countries have in Biosafety ranges from around 17 to 10 years. Why they have not put in place yet an efficient system to regulate GMOs?

I am convinced one of the major problems has been the lack of government commitment and the heavy dependence on scientific consultative committees to do the work government officials should be doing on a full-time base, with the cooperation of the scientific consultative committees. If this situation is not resolved to begin with, there is not going to be enough capacity building, database support or scientific data obtained if there is not an adequate end-user.

RESPONSE (IA & EA): *The project fosters regional collaboration between diverse country participants and finances training for biosafety practitioners and competent authorities, standardization and sustainability of methodologies and mechanisms being the primary objective (Annex 4 of the PAD). In the description of **Component 2: Strengthening biosafety decision-making capacity:** it is indicated that the project will build biosafety capacity for decision-making entities (competent authorities) and for practitioners (i.e. public and private research community), through participatory scientific and technical training on risk assessment, risk management and risk communication, using the knowledge generated by biosafety practitioners in this project from **Component 1: Strengthening technical capacity in knowledge generation for biosafety risk assessment and management**) in a collaborative effort across the five countries.. The Core participants include the implementing bodies of national biosafety frameworks (i.e. national biosafety committees) and the biotechnology R&D community (i.e. transgenic crop developers, plant breeders, and other relevant agricultural science professionals, especially those working in public sector research). The project seeks to establish efficient mechanisms of communication and cooperation between those providing the technical assistance (generating biosafety information) and those responsible for the decision making process, instead of just concentrating on training of the National authorities as other initiatives has done with very limited impact. Because of lack of resources the National competent authorities are incapable of conducting the proper technical assessment themselves in a proper manner. The project proposes to strengthen the capacity that already exist in the countries and benefit from multi-country collaboration to facilitate science-based analysis and decision-making. The commitment of the Governments of each participating project country is clear since in all cases, the National competent authority for the biosafety decision process is involved in addition to the main National Technical Institutions used as a reference for the science based process (Table 6.1 from the PAD), and as indicated by the corresponding country GEF Focal Point endorsement letters.*

Another point that seems important to me, and that to a certain extent is a consequence of the problem mentioned above is that, in these countries biosafety authorities are usually reactive, and very seldom proactive. The fact that this proposal wants to focus only on plant LMOs is worrying:

“Although the CP Protocol sets a framework for the biosafety aspects of all living organisms resulting from modern biotechnology, the most important field of application in the near-medium term is the biosafety of agricultural crops modified by modern biotechnology.....Human resource development, database development, baseline information about crops (especially in mega-diversity areas) and expertise in methodologies for risk assessment are cited explicitly by the CP as priority areas for development”

I need to disagree with the idea that agricultural crops modified by modern biotechnology are the most important in the near-medium term. These are the present! And the near and medium term challenges will be crops producing pharmaceuticals, transgenic fish, and transgenic arthropods. Therefore I see the need to include these areas in the training program proposed rather than waiting to have the first proposals for

release of these types of LMOs on the desk of the regulator and then starting to think about how to address these issues.

RESPONSE: *The project Global Objective is to support implementation of the Cartagena Protocol (CP) on biosafety, reducing the environmental risks of modern biotechnology, with positive impact on global biodiversity. Plants producing pharmaceuticals are outside the scope of the CP, which are regulated by other International Treaties, thus will not be addressed by this project. In the case of transgenic animals although recognized as important in the LAC countries, currently are still under early experimental phases with no clear evidence of commercialization in the near future. The legal framework regulating these organisms is not present or is in a preliminary stage in the participating countries. In contrast, all 5 participating countries already have a legal framework for regulating transgenic plants, have some experience in their implementation and because of that, have been able to identify the main bottlenecks to fulfill this task. Due to broader adoption of such transgenic crops, these countries have increased pressures to comply with the CP where technically sound and safe trans-boundary movement of crop plants will be the main asset. Although the broad scope of transgenic organisms and the need of their proper regulation is recognized, the dilution of the limited resources requested in the project beyond plants will compromise the quality, impact and sustainability of the deliverables outputs.*

RECOMMENDATIONS

R.1. The project, as presented, can be of great value to the involved countries and to the whole region, and such efforts should be given high priority in terms of finance. I believe the project should be financed but the project should seriously consider as a priority the training of personnel from the different government entities involved to produce professional risk evaluators/risk managers, and the governments should clearly state their commitment to this effort by providing appropriate personnel or to make available the minimum number of required positions.

R.2. Further, training should not be constrained to plant issues but should open up to include animals and plants producing pharmaceuticals.

c) GEF Secretariat's comments at Work Program Submission and World Bank responses:

Program Designation and Conformity:

Please clarify what are the outputs under components 3 regarding the national BCHs.

World Bank response:

Since the UNDP/GEF funded project is establishing national BCH mechanisms, the project would avoid any activities that duplicate the effort. To seek synergies, the proposed project would provide capacity building activities, in particular under Component 1. Information generated through the activities under Component 1 will be fed into the Montreal BCH and to the national BCHs. Component 1 has been updated to reflect this output.

Program Designation and Conformity:

Specifics are not described. Please correct.

World Bank response:

Institutional and financial sustainability have been reviewed and further strengthened (see Section 3. b).

Replicability:

Specific measures are not included. Please provide.

World Bank response:

Replicability section has been updated (see Section 3. b).

Stakeholder Involvement:

Please describe stakeholders involvement in this proposal and in further project development and implementation.

World Bank response:

There has been intense consultation with many involved parties as part of project preparation. These include discussions with national research institutes from each country, government biosafety agencies, ministries responsible for natural resources, agriculture, production in each country, as well as international and regional agricultural institutes. As project preparation advances, consultations will be continued and amplified to include a broader spectrum of stakeholders, including NGOs and farmers groups. Some of these consultations have begun, and will be concluded prior to appraisal. These will be duly documented in the Project Document. This participatory approach is reflected in section 3.d of the project document.

Monitoring and Evaluation:

Please provide indicative cost of M&E.

World Bank response:

The M&E activities have been mainstreamed in the project in the components. The total cost of M&E activities in addition to the project management is projected to be \$300,000, which will be finalized during project appraisal.

Core Commitments and Linkages:

Please explain what are the coordination activities foreseen with other IAs working in the participating countries.

World Bank response:

The task team had consultations with UNDP and UNEP whose experiences and lessons in the region have been incorporated in the design of the proposed project. Further consultations on the substance and objectives of the project would continue to be established with UNEP and UNDP. Opportunities for synergies between project activities and similar, complementary activities of these agencies will be explored further during preparation, appraisal and implementation (see Section 5).