



REQUEST FOR CEO ENDORSEMENT/APPROVAL

PROJECT TYPE: Medium-sized Project

THE GEF TRUST FUND

Submission Date: Jan/ --- /2010

PART I: PROJECT INFORMATION

GEFSEC PROJECT ID: 3630

GEF AGENCY PROJECT ID:

COUNTRY(IES) : Guatemala

PROJECT TITLE: Development of mechanisms to strengthen the implementation of the Cartagena Protocol in Guatemala

GEF AGENCY(IES) : UNEP, (select), (select)

OTHER EXECUTING PARTNER(S) : OTECBIO

GEF FOCAL AREA(S) : Biodiversity

GEF-4 STRATEGIC PROGRAM(S) : BD-SP6-Biosafety (see preparation guidelines section on exactly what to write)

NAME OF PARENT PROGRAM/UMBRELLA PROJECT: BIOSAFETY PROGRAM

Expected Calendar (mm/dd/yy)	
Milestones	Dates
Work Program (for FSPs only)	
Agency Approval date	01/01/2010
Implementation Start	03/01/2010
Mid-term Evaluation (if planned)	03/01/2012
Project Closing Date	03/01/2014

A. PROJECT FRAMEWORK (Expand table as necessary)

Project Objective: To assist Guatemala to put in place a well articulated, effective and transparent national biosafety system through the development of the necessary policies, regulatory and technical instruments, and local capabilities in order to meet national development needs								
Project Components	Inv, TA, or STA ²	Expected Outcomes	Expected Outputs	GEF Financing ¹		Co-Financing ¹		Total (\$) c=a+ b
				(\$ a)	%	(\$ b)	%	
1. Strengthening the legal, regulatory and policy framework on biosafety, to make it fully consistent with the CPB and national goals for sustainable development	TA	<p>Outcome 1.1: A comprehensive, coordinated, and inter-institutional policy framework for biosafety is approved and adopted.</p> <p>Outcome 1.2: The transboundary movement, transit, handling and use of Living Modified Organisms (LMOs) are regulated, consistent with the CPB</p> <p>Outcome 1.3: A National Biosafety System is proposed and adopted, along with a coordination, continuity and sustainability strategy</p> <p>Outcome 1.4: Biosafety policies are integrated into national programs, plans and strategies for sustainable</p>	<p>1.1.1 National policy on biosafety and biotechnology, in line with sectoral policies, national regulations, and National Competent Authorities (NCA) roles defined by the CPB.</p> <p>1.1.2 Implementation plan</p> <p>1.2.1 Biosafety regulations for: risk assessment and management, environmental release, illicit and unintentional transboundary movements of LMOs, transit, penalties, research, contained use, food safety and environmental safety, and others.</p> <p>1.3.1 An administrative system with clear procedures for handling requests and clearly defined mandates, responsibilities and communication channels for different NCAs</p> <p>1.3.2 Permanent and Ad Hoc scientific advisory biosafety structures</p> <p>1.3.3 A continuity and sustainability strategy for the</p>	129,750	60	90,800	40	220,550

		development.	system 1.4.1 Official adoption and implementation of Biosafety policies in different NCAs					
2. Implementing the technical foundations of a functional national biosafety risk assessment and risk management system	TA	Outcome 2.1: The institutional and administrative framework is reinforced and articulated to allow for effective handling of requests and coordinated decisions Outcome 2.2: The science base for the evaluation of potential risks and benefits of LMO use in Guatemala is strengthened for use in biosafety risk assessment and management Outcome 2.3: Biosafety measures are applied in accordance with international guidance, national criteria and to the extent necessary and feasible to prevent possible adverse effects of LMOs	2.1.1 Inter-institutional coordinated and harmonized technical documents, guides, criteria and administrative formats for LMO applications 2.1.2 Filing system created to handle mock request documentation. 2.1.3 Validated risk assessment and evaluation methodologies. 2.1.4 Institutional agreements and coordination mechanisms for decision-making on internal use of LMOs and cross-sectoral collaboration 2.2.2 Science based guidelines, scientific protocols, and data collection plans to inform biosafety risk assessment and management decisions 2.3.1 Guidelines and plans for effective and science based national biosafety measures	65,072	42	89,000	58	154,072
3. Creating the necessary institutional capacity and human resources for effective decision making and regulatory compliance in biosafety	TA	Outcome 3.1: Institutions are more proficient in risk /benefit analysis, and more knowledgeable of monitoring and enforcement requirements. Outcome 3.2: Technological capacity is sufficient for in-house analysis of LMOs. Outcome 3.3: Capacity for the safe development and use of modern biotechnology is strengthened in Guatemala.	3.1.1 Training Program for the use, management and regulation of biotechnology. 3.1.2 Decision-makers introduced to biosafety risk assessment principles 3.1.3 Technical staff trained in carrying out risk assessments and defining risk management measures, including follow-up and enforcement of decisions 3.2.1 State-of-the-art technology, training and laboratory equipment for LMO testing 3.3.1 Relevant scientific research and information to inform biosafety decisions regarding the local biodiversity, environment and human health	233,980	47	263,337	53	497,317
4. Gaining experience in	TA	Outcome 4.1: Information availability	4.1.1 Public sensitization strategy and campaigns	62,942	38	100,540	62	163,482

generating and managing biosafety information and public sensitization strategies and public awareness		in biosafety is increased and contributes to public sensitization and participation processes. Outcome 4.2: Collaboration with all NCAs is achieved for the management of biosafety information and for greater transparency in biosafety decisions and management.	4.1.2 Biosafety informative material in printed and digital formats, made available to the public 4.2.1 Permanent mechanisms for accessing and sharing biosafety information in NCAs 4.2.2 NCA Sensitization Plan for regulatory compliance. 4.2.3 Enhanced national biosafety website 4.2.4 New biosafety and biodiversity information available to the general public and decision makers					
5. M&E				63,620	100			61,864
6. Project management, coordination support				61,000	30	140,555	70	201,555
Total Project Costs				A 616,364	47	B 684,232	53	1,300,596

¹ List the \$ by project components. The percentage is the share of GEF and Co-financing respectively of the total amount for the component.

² TA = Technical Assistance; STA = Scientific & Technical Analysis.

B. SOURCES OF CONFIRMED CO-FINANCING FOR THE PROJECT (expand the table line items as necessary)

<i>Name of Co-financier (source)</i>	<i>Classification</i>	<i>Type</i>	<i>Project</i>	<i>%*</i>
CONAP	Exec. Agency	In-kind	97,744	14
CONAP	Exec. Agency	In Cash	131,000	19
SENACYT	Nat'l Gov't	In Cash	32,000	5
SENACYT	Nat'l Gov't	In-kind	45,000	6
MAGA	Nat'l Gov't	In-kind	25,000	4
MARN	Nat'l Gov't	In-kind	17,988	3
UVG	University	In-kind	35,500	5
ICTA	Nat'l Gov't	In-kind	150,000	22
Fac Farmacia	University	In-kind	100,000	15
FAUSAC	University	In-kind	50,000	7
Total Co-financing			B 684,232	100%

* Percentage of each co-financier's contribution at CEO endorsement to total co-financing.

C. FINANCING PLAN SUMMARY FOR THE PROJECT (\$)

	<i>Project Preparation a</i>	<i>Project b</i>	<i>Total c = a + b</i>	<i>Agency Fee</i>	<i>For comparison: GEF and Co-financing at PIF (amounts including PPG costs)</i>
GEF financing	20,000	A 616,364	636,364	61,636	636,364
Co-financing	5,100	B 684,232	689,332		495,120
Total	25,100	1,300,596	1,325,696	61,636	1,131,484

Please note that the co-financing pledge for the project has increased significantly with respect to the PIF.

D. GEF RESOURCES REQUESTED BY AGENCY(IES) , FOCAL AREA(S) AND COUNTRY(IES)¹

GEF Agency	Focal Area	Country Name/ Global	(in \$)		
			Project (a)	Agency Fee (b) ²	Total c=a+b
Total GEF Resources					

¹ No need to provide information for this table if it is a single focal area, single country and single GEF Agency project.

² Relates to the project and any previous project preparation funding that have been provided and for which no Agency fee has been requested from Trustee.

E. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:

Component	Estimated person weeks	GEF amount(\$)	Co-financing (\$)	Project total (\$)
Local consultants*	682	154,240	72,000	226,240
International consultants*	38	63,000	0	63,000
Total	720	217,240	72,000	289,240

* Details to be provided in Annex C.

F. PROJECT MANAGEMENT BUDGET/COST

Cost Items	Total Estimated person weeks	GEF amount (\$)	Co-financing (\$)	Project total (\$)
Local consultants*	416	61,000	59,000	120,000
International consultants* (+)				
Office facilities, equipment, vehicles and communications*			24,675	24,675
Travel*				
Others				
Staff time (managmt support)			56,880	56,880
Total		61,000	140,555	201,555

* Details to be provided in Annex C.

M & E budget: US\$ 61,864 Integrates international consultant costs (fees and travel) for the Mid-Term and Terminal Evaluations that are not cited here.

G. DOES THE PROJECT INCLUDE A "NON-GRANT" INSTRUMENT? yes no

(If non-grant instruments are used, provide in Annex E an indicative calendar of expected reflows to your agency and to the GEF Trust Fund).

H. DESCRIBE THE BUDGETED M & E PLAN: Project monitoring will be the responsibility of the OTECBIO as the National Executing Agency, and will require periodic delivery of technical and financial reports to UNEP. The progress of project activities and financial expenditures that reflect and support project activities will be monitored in accordance with UNEP's internal guidelines for project supervision, monitoring and evaluation. For further detail, please refer to section 6 and appendix 7 of the project document (attached as annex1).

In addition to requisites such as the use of the GEF Tracking Tool for biosafety, periodic reporting to UNEP, the yearly Project Implementation Review process, and the incorporation of mid-term and end-of-term external evaluations, there are three additional and specific M&E activities that have been built into the project. These are: National Biosafety System validation and testing, Training Program evaluations, and Adaptive Management. These have been incorporated into the project's design and budget in the interest of testing the effectiveness of the project's proposed interventions and measure its performance, not only in terms of activities and execution, but also in terms of qualitative results. The project's Steering Committee also plays a key oversight function, to oversee project activities and ensure the project is on track to meet its objectives (see section 6). All costs associated with project M&E are laid out in Appendix 7 of the

project document, where specific and measurable targets are also specified for complying with the project's logframe. Total M&E costs are estimated at \$ 61,864.

PART II: PROJECT JUSTIFICATION: In addition to the following questions, please ensure that the project design incorporates key GEF operational principles, including sustainability of global environmental benefits, institutional continuity and replicability, keeping in mind that these principles will be monitored rigorously in the annual Project Implementation Review and other Review stages.

A. STATE THE ISSUE, HOW THE PROJECT SEEKS TO ADDRESS IT, AND THE EXPECTED GLOBAL ENVIRONMENTAL BENEFITS TO BE DELIVERED: There have been no substantial changes the overall project design or with respect to section A of the PIF, the text of which is copied (and updated) below. Additional information is nonetheless provided in sections 2.1, 2.2, 3.1, 3.2 and Appendices of the project document (attached as annex 1).

Guatemala began to set the bases for its biosafety framework through the UNEP-GEF Project for the Development of a draft National Biosafety Framework (NBF) in 2002, and continued with the UNEP-GEF Biosafety Clearing House (BCH) project in 2007, to address specific BCH-related needs. One of the major outcomes of the Guatemala NBF project was the preparation of a proposal for a national biosafety law, which was submitted and presented by the Environmental and Natural Resources Commission to the Guatemalan Congress, and the subsequent ratification of the Cartagena Protocol for Biosafety (CPB) in 2004. Despite these milestones, full compliance with the country's obligations as a Party has yet to be attained, as several barriers remain that need to be overcome. These include: a weak capacity and technical knowledge for assessing the risks and benefits associated with biotechnology products, and for making management decisions and enforcing them; only partial understanding of the tasks and responsibilities entailed in the full application of the CPB by the NCAs; poor technological infrastructure for ensuring compliance, especially in transboundary movements and monitoring; a high level of public misinformation on, and opposition to, living modified organisms (LMOs); lack of effective means for strengthening public awareness on the safe use of LMOs; difficulties in achieving a balanced representation and participation of the different sectors of society in instances dealing with LMOs, and a poor science-base for decision making.

The components proposed in the current MSP aim to address gaps in capacity or barriers already identified during development of the NBF. By building on previous outcomes, they will focus on priority needs relating to public awareness, expanding the regulatory framework, strengthening institutional mechanisms and structures already in place, putting into practice risk assessment and risk management practices, training (including the establishment of long-term programmes), monitoring and enforcement, and ensuring sustainability of results and full integration of relevant authorities. The establishment of a workable and cost effective biosafety system, through which each intentional transboundary movement or domestic use of LMO can be properly processed and the safe use of biotechnology can be promoted, will contribute to the conservation and sustainable use of biodiversity and reduce potential risks to wild relatives and agro-biodiversity in Guatemala, thus helping to achieve the global environmental goals of the CBD and CPB. Guatemala has national biodiversity of global importance, as it has been identified as one of the richest points of the planet in terms of biological diversity, in other words, it is considered a "megadiverse" region. With regard to flora, it currently occupies third place for abundance of flora by unit area, which includes 7,754 species of reported plants, with 40% of these endemic to Mesoamerica. With respect to fauna, 62 species are endemic, with 2,027 registries of invertebrate's species found in Guatemala. At the level of genetic diversity, Guatemala is center of origin, diversification and domestication of several of the most important global crop species, many of which are already available as Genetically Modified varieties or could be in the near future. Importantly, 24% of all bean species, 43% of pumpkin species and 52% of all maize races known in Mesoamerica can be found in Guatemala, while certain cassava varieties are unique world-wide. This biodiversity is already considered to be highly threatened, by negative forces such as invasive exotic species and human intervention, thereby justifying the need to install effective protection and vigilance mechanisms, including those concerning the use of LMOs.

The current MSP will therefore strengthen the institutional capacity of the National Council of Protected Areas, given its role as both CPB and BCH Focal Points, as well as other relevant competent authorities, to manage biosafety in a manner coherent with the objectives and procedures of the CPB. The installation of biosafety management within several institutions in the form of joint programmes, plans and campaigns, together with a better understanding of the issues at

stake and the functionings of the CPB, as well as the strengthening of decision-making structures and bases, will not only be key for ensuring the sustainability of the capacity being built, but also for making the decisions and safeguards taken in biosafety more effective, transparent, coordinated and technically-sound. For this the national biosafety policy, combined with new biosafety regulations, will be the main foundations on which institutional efforts will be based and sustained, as will the Training Program for the use, management and regulation of biotechnology, and the consolidation of various institutional agreements, such as that to increase capacity-building through cross-sectorial collaborations. These efforts will also be complemented by seeking to build capacity through an adaptive and learning-by-doing approach, whereby case-by-case experience and progressively opening an increasing number of biosafety domains will serve to strengthen biosafety management and CPB compliance in a step-by-step manner.

The leadership role of the National Council of Protected Areas (CONAP), which will be politically supported by the Ministry of Environment and Natural Resources and channeled through the Technical Office for Biodiversity (OTEBIO), will be a key success factor behind the overall strengthening of the biosafety system, and in laying down the foundations for sustaining biosafety activities and functions over time. Component 1 will require a strong degree of coordination, support and consensus-seeking amongst government authorities, while Components 2 and 3 will imply more in-house work, joint tasks with the Ministry of Agriculture and close contacts with the scientific community. Finally, Component 4, which will benefit directly from the coordination initiated through Component 1, will rely strongly on the impetus and level of mutually supportive integration achieved by the Ministry of Environment and Natural Resources with other Ministries and sectors of society, with respect to how biosafety is viewed and managed in the country, and therefore informed and promoted to the wider public and stakeholders. As a multisectorial instance, the National Commission in Biotechnology (CNCB), comprising several national bodies, public (including CONAP), private and also academic and investigative institutions, all bound by the work on biotechnology and its safe use, will also play an important role. This consolidated committee is expected to offer a platform for the coordination and political follow-up that is needed to ensure the continuity, integration and sustainability of actions initiated under this project.

The scope and specific activities of the MSP were defined through a PPG, during which a proper stocktaking exercise was undertaken, as the first step in the project design. It covered those areas defined in the GEF *Strategy for Financing Biosafety* and was characterised by stakeholder involvement and consensus-seeking to ensure high social support for the project. Final project design hence is responsive to real country needs and priorities; it sets specific targets and indicators for the achievement of desired outcomes, on the basis of the base-line information obtained during the stock-taking assessment, together with a concerted discussion (with the CNCB, amongst other stakeholders) of Guatemala's current state of affairs in biosafety, expectations for improvement and resource mobilization, and goals for CPB compliance. Ensuring stakeholder buy-in during project design was a key factor for ensuring country-ownership and effective project implementation, the results of which are evident from the co-financing pledges agreed by various institutions.

B. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH NATIONAL AND/OR REGIONAL PRIORITIES/PLANS :

Section B of the PIF is inserted below; though there have been no substantive changes, this section is further developed under section 3.6 of the project document.

Guatemala has been a Party to the CBD since 1995 and to the CPB since 2004 (Legislative decree 23-2004). In addition, there are other political instruments relevant to biosafety. The National Policy on Food and Nutritional Safety provides a coordinated strategic framework to guarantee the availability and access, in a sustainable and culturally appropriate way, to healthy and nutritional food. This policy states in one of its items that Guatemala needs to regulate the import of genetically modified products. The Framework Policy on Environment Management aims among other things to prevent and minimize the impacts and risks to human beings and the environment resulting from production processes, while the National Strategy for the Preservation and Sustainable use of Biodiversity and the Action Plan of Guatemala seeks the reduction of threats to biodiversity and includes, in its scope, the protection, use and valuation of genetic resources, and the need to support population food safety through the preservation and availability of such genetic material. The creation of a solid biosafety framework is therefore fully concordant with these policies, with the country's conservation priorities and with the fulfillment of Objective VII of the Millennium Development Goals of Guatemala, which aim to guarantee the sustainability of the environment, by achieving development without jeopardizing nature.

C. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH GEF STRATEGIES AND STRATEGIC PROGRAMS: This section remains as section C of the PIF:

The current proposal concords fully with GEF's *Strategy for Financing Biosafety* (Doc GEF/C.30/8/Rev.1) approved in December 2006, and responds directly to Biodiversity Strategic Objective 3 (SO3), Strategic Programme 6 (Building Capacity for the Implementation of the Cartagena Protocol on Biosafety) of the new *Focal Area Strategies and Strategic Programming for GEF-4* (Doc GEF/C.31/10) approved in July 2007. It is also fully aligned with the key elements of a national biosafety framework, required for the implementation of the CPB and emphasized in the *Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol* agreed at COP-MOP-3 of the CPB. The main areas of work, in this case, fall within the "Key elements requiring concrete action" (section 3) and the "National Level" implementation issues (section 5.1) described in the *Updated Action Plan*.

D. JUSTIFY THE TYPE OF FINANCING SUPPORT PROVIDED WITH THE GEF RESOURCES. Biosafety is an important priority worldwide, but not in a developing country where health, education, and infrastructure needs, among others, are more pressing than conservation of biodiversity. A grant is the only way the government can be stimulated to make biosafety a priority, as it would be unwilling to acquire a loan to finance biosafety needs.

E. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES: Please refer to section 2.7 of the project document; an outline is provided by section D of the PIF below:

CONAP through the OTEBIO has worked with UNEP and with the financial support of GEF on the project "Building Capacity for Effective Participation in the BCH", which focuses on the practical training of key stakeholders and competent authorities, the creation of an enabling environment for Guatemala to meet its BCH obligations under the CPB, through the provision of computer hardware and software for institutional access and use of the BCH, and the support of further capacity building through the development and dissemination of an interactive computer-based training package. The objectives of the current MSP will give continuity to those of the BCH project, which has recently concluded, and ensure cost-efficiency based on lessons learnt. Both projects were and will be executed by the OTECBIO, which acts as both CPB and BCH Focal Points.

As a multisectorial instance, the National Commission in Biotechnology (CNCB) has been developing initiatives that can contribute to the fulfillment of the objectives of the CPB, specially in the research area. These initiatives will complement this project and will generate important synergies, especially at the level of political commitments and institutional coordination. The National Council of Science and Technology (CONCYT) has also opened an area with government financing, for the research and development of genetically modified organisms (flora & fauna), and their potential use in Guatemala. These stakeholders will be important partners for both project execution and the achievement of project goals, for which their collaboration and involvement will be ensured prior to project initiation.

F. DISCUSS THE VALUE-ADDED OF GEF INVOLVEMENT IN THE PROJECT DEMONSTRATED THROUGH INCREMENTAL REASONING: In addition to section F of the PIF copied below, further information is provided in section 3.7 and Appendix 3 of the project document with regard to incremental reasoning.

The GEF involvement adds value to this project by augmenting the extent to which the CPB would be implemented in Guatemala, the possibility of achieving transversal results in a fixed timeframe across several institutions, and the effectiveness of structures and processes created for the purpose of biosafety. Without GEF involvement, national implementation of the CPB would be much slower, due to low institutional capacity, lack of an approved national legal framework uncertainties with regard to CPB interpretation, and Guatemala would be unlikely to engage fully in CPB activities, including COP/MOPs, or make full use of its Party status. The achievement of results in the desired time-span, the involvement of several competent institutions and the commitment to common financing of components would also be affected in the absence of GEF support, as a GEF-funded MSP will provide greater opportunity for institutional coordination, integration and results-based planning and follow-through. In the absence of a project, biosafety activities would likely be implemented sectorially (by each NCA), or under the coordination of the CONAP but without the prior commitment of many institutions, and would therefore have a much lower impact. Similarly, the effectiveness of participatory initiatives, as well as the reliability of decision-making processes and structures, would be lessened

without GEF support. Although there would still be institutional efforts to open spaces for public participation and to operate formal instances for technical and political decisions in biosafety, these measures would not achieve their desired long-term effects without the means to carry out training activities and campaigns to raise public awareness, as well as increase the availability of and public access to biosafety information. The concomitance of the GEF project activities would allow these instances and mechanisms to be more effective, and hence sustainable, by contributing to the improvement of biosafety management in Guatemala on the basis of participatory and technically-sound processes.

G. INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS, THAT MIGHT PREVENT THE PROJECT OBJECTIVE(S) FROM BEING ACHIEVED AND OUTLINE RISK MANAGEMENT MEASURES: The risks outlined in section G of the PIF (below) have been further elaborated in section 3.5 of the project document

The NBF project showed that biosafety in Guatemala needs to be brought down from the government level to the level of stakeholders, as affected parties especially in the productive sector (agriculture, fisheries, forestry, industry, manufacturers, commerce, etc) are often little aware of the regulations, procedures and responsibilities entailed in the safe use of biotechnology. Therefore, risks to the project include pressures faced by productive sectors to incorporate biotechnology products in an unregulated manner, given that the grain commerce in Guatemala is based on the import of seeds and grains, of unknown LMOs contents, currently lacking border or regulatory controls. Hence the emphasis placed on completing the regulatory framework, together with ensuring public participation, awareness raising, education and sensitization, and project design with the involvement of key stakeholders through consultation processes. These measures should ensure greater commitment and understanding of project goals during its execution, and greater outreach capacity, and eventually, greater compliance with biosafety regulations as well as monitoring and enforcement strategies. The lack of reliable information on LMOs in Guatemala also poses a threat to project objectives, as it is permissive for the disinformation network that currently prevails. To mitigate this information deficiency, the project seeks to build partnerships and institutional agreements for the provision of official, impartial and up-to-date information on biosafety that can be made public, and to ensure that it is managed in the correct manner. Duplication of efforts and overlap of functions between NCAs, as well as pressure by opposition groups on public and private institutions to incorporate biotechnology in their institutional management and/or mandates, are also possible drawbacks that could derive in political decisions that could slant project objectives and lead to parallel or even opposing initiatives. The establishment of a multi-sectorial steering committee to guide project progress and to understand sectorial positions from the onset of the project will help to counteract this possibility.

H. EXPLAIN HOW COST-EFFECTIVENESS IS REFLECTED IN THE PROJECT DESIGN: Section H of the PIF (below) and section 7.3 of the project document describe the cost-effectiveness of the project design.

The project is cost-effective in its design, as it aims to achieve catalytic influences through building institutional capacity for various facets of environmental management. Policy changes and greater integration and coordination amongst governmental institutions, to reflect the transversal nature of biosafety and its relationship with commercial and productive issues in favour of a more sustainable development, will be the main drivers of change. Focusing the project on managerial tasks and needs will hence benefit other areas of biodiversity protection, and empower CONAP and other competent authorities through the experience gained. The projects also builds on progress made during previous UNEP-GEF projects, and targets those areas of the current NBF that are known to present the greatest deficiency, that are most important for full CPB implementation and compliance, and that will achieve the greatest long-term impacts. This targeted approach will be further refined through an initial stock-taking assessment, in order to tailor the project's final design as cost-effectively as possible to specific needs. By focusing on regulatory elements, compliance and technical capacity-building across several institutions, the project will establish legal mandates and internal structures for the sustainable management of the national biosafety framework, in an effective and coordinated manner, involving low-cost activities that will be characterised by consensus-seeking. Participation, transparency and information-related initiatives will also be combined with extensive stakeholder involvement to ensure high social support for the project and to increase the cost-effectiveness of each activity. The cost-effectiveness of proposed project activities was considered during the project preparation phase, as part of the consultation exercises of the PPG. The means to ensure the sustainability of the capacity being built was also examined during project preparation, through inter-Ministerial discussions and consultations with the CNCB, and then built into project design.

PART III: INSTITUTIONAL COORDINATION AND SUPPORT

A. INSTITUTIONAL ARRANGEMENT: UNEP is the only GEF agency involved and will provide project oversight from ROLAC (Regional Office for Latin America and the Caribbean) based in Panama City.

B. PROJECT IMPLEMENTATION ARRANGEMENT: The National Council for Protected Areas (CONAP), as Executing Agency for this project and also CPB focal point, will delegate project operations to the Technical Office of Biodiversity (OTECBIO) where prior UNEP/GEF projects for biosafety have been carried out. The implementation arrangements are described in section 4 of the project document, and further explained together with decision structures in appendix 10.

PART IV: EXPLAIN THE ALIGNMENT OF PROJECT DESIGN WITH THE ORIGINAL PIF:

The project design relates closely to the original PIF, but some filtering was necessary. The original project framework contained 4 technical components, which have been maintained in the project design. Under component 5, the costs of M&E have now been added, while project management costs are specified under component 6. Outcomes and outputs, however, have been rearranged among components to better fit with project objectives and implementation strategy. Several outcomes have been consolidated, and some have become outputs. Similarly, several outputs were consolidated and some became activities. The original PIF contained 21 outcomes (some of which were repetitive) and 32 outputs. The project's final results framework contains 12 and 24 outputs, thus simplifying, clarifying and making more achievable what was originally proposed in the PIF. This fine tuning took part within the process of project drafting and design. A slight adjustment with regards to the how the funds are distributed among the project's components was also made, with variations in the proportion of GEF funding against co-funding but without modifying the overall request to the GEF Trust Fund. As the PIF indicated, M&E costs were to be extracted from the 4 technical components (as an estimate of M&E costs was not available at the time), thus resulting in a decrease in individual component budgets. Lastly, the total co-financing pledge has significantly augmented from USD 490,020 in the PIF to USD 684,232 in the current CEO Endorsement Request.

PART V: AGENCY(IES) CERTIFICATION

This request has been prepared in accordance with GEF policies and procedures and meets the GEF criteria for CEO Endorsement.

Agency Coordinator, Agency name	Signature	Date (Month, day, year)	Project Contact Person	Telephone	Email Address
Maryam Niamir-Fuller Director DGEF UNEP GEF Agency Coordinator maryam.niamir- fuller@unep.org Tel. 011-254-762-4166			Tea Garcia-Huidobro DGEF - UNEP Regional Office for Latin America and the Caribbean (ROLAC) Panama City, Panama	+507 305 3169	tea.garciahuidobro@ unep.org

ANNEX A: PROJECT RESULTS FRAMEWORK

Appendix 4 of the project document (Logical Framework) was been inserted here for ease of reference.

Results /Logical Framework

Intervention Logic

Project GOAL	To facilitate Guatemala’s compliance with and the implementation of the Cartagena Protocol through the establishment of a national biosafety system
Project OBJECTIVE	To assist Guatemala to put in place a well articulated, effective and transparent national biosafety system through the development of the necessary policies, regulatory and technical instruments, and local capabilities in order to meet national development needs. (Project impact to be measured through GEF-4 SO3 Tracking Tool (Appendix 15))

Component 1: Strengthening the legal, regulatory and policy framework on biosafety, to make it fully consistent with the CPB and national goals for sustainable development

Outcomes and Outputs	Objectively Verifiable Indicators			Sources of verification	Risks and assumptions	
	Indicators	Baseline	Midterm Target			End of project Target
Outcome 1.1: A comprehensive, coordinated, and inter-institutional policy framework for biosafety is approved and adopted.	National Biosafety Policy presented, approved and in implementation	No inter-institutional or national biosafety policy or coordinated biosafety system exists. Biosafety is not seen as a development issue linked with the opportunities of biotechnology.	Policy is presented and approved by at least five NCAs	Policy is approved by at least eight NCAs and at least three have developed implementation strategies	Written Policy Official approvals Implementation plans Project progress reports Project M&E reports	Stakeholder decision makers recognize the relevance of a National Biosafety Policy and agree to participate in and adopt the results of the project
	Number of NCA and stakeholder agreements or official commitments backing participation in and adoption of the Policy	Technical personnel participating in biosafety processes lack the authority to approve policies or regulations. Stakeholder decision makers don’t usually back or participate in Biosafety efforts	By PY1 at least 4 NCAs have officially backed the Policy. By PY2 at least 6 NCAs have officially backed the Policy.	Policy adoption commitments from at least eight NCAs	Inter-institutional agreements. Letters of support	There is personnel and policy continuity through the 2012 presidential election. Technical delegates to the process have full backing from their superiors.
	Number of NCAs and stakeholders providing co-financing and personnel for policy implementation	Biosafety is unofficially assigned to full time personnel as a task additional to their job description. Only one NCA (MAGA) currently assigns personnel and budget to biosafety	At least three NCAs provide co-financing for Policy implementation.	At least five NCAs provide co-financing for Policy implementation.	Official personnel appointments. ANC organigrams, post descriptions and budget documents Project progress reports. Project M&E reports.	Stakeholders are financially able to provide co-financing.

Outputs for Outcome 1.1:

- 1.1.1 National policy on biosafety and biotechnology, in line with sectoral policies, national regulations, and National Competent Authorities (NCA) roles defined by the CPB.
- 1.1.2 Implementation plan

Outcomes and Outputs	Objectively Verifiable Indicators			Sources of verification	Risks and assumptions	
	Indicators	Baseline	Midterm Target			End of project Target
Outcome 1.2: The transboundary movement, transit,	Coordinated and consulted biosafety regulations are proposed and adopted	NCA regulation of biosafety is independent, uncoordinated,	The type of legal strategy to use is defined. The different regulations	At least three regulatory instruments are approved and adopted.	Official regulation approval documents. Proposed regulation.	The steering committee and subcommittees agree do supervise

handling and use of Living Modified Organisms (LMOs) are regulated, consistent with the CPB		insufficient or non-existent. There is no science-based biosafety regulation that all stakeholders agree upon and feel can be well implemented.	needed are listed and prioritized. Supporting technical instruments are listed and prioritized. At least three regulatory instruments have been drafted	The majority of prioritized regulatory instruments have been drafted and proposed	Steering committee records. Project progress reports.	drafting of legal instruments. There is agreement to prioritize the proposed regulatory instruments
---	--	--	---	---	--	--

Outputs for Outcome 1.2:
1.2.1 Biosafety regulations for: risk assessment and management, environmental release, illicit and unintentional transboundary movements of LMOs, transit, penalties, research, contained use, food safety and environmental safety, and others.

Outcome 1.3: A National Biosafety System is proposed and adopted, along with a coordination, continuity and sustainability strategy	Definition of individual stake-holder responsibilities and inter-institutional communication strategies for biosafety decision making	There is overlap between biosafety legal mandates and no official channels that permit a functional or coordinated national biosafety system. This has so far paralyzed decision-making. Technical personnel responsible for biosafety in different NCA and stakeholder institutions are not in communication with one another.	By PY1 a list of critical aspects for communication and coordination mechanisms has been defined. By PY2 individual and joint responsibilities have been assigned, clarified and submitted for approval by authorities in terms of spheres of influence, communication channels and LMO approval routes	Clear individual and joint responsibilities and communication routes for risk assessment, risk management and risk communication.	Stakeholder technical profiles and list of responsibilities and roles. Communication and /or inter-institutional coordination maps or documents. Individual stakeholder official role and communication channel approval documents. Project progress and M&E reports.	Stakeholder authorities agree to abide by coordinated roles, instruments, and communication strategies.
	Definition of the National Coordination Committee on Biosafety (NCCB) (or its equivalent) role, scope, operations and tasks, and creation of advisory (support) structures	NCCB operates sporadically and lacks an official mandate or role. There is no scientific advisory structure for biosafety risk assessment or to propose management measures.	By PY2 the technical profile, role, scope, operation and tasks for the NCCB (or its equivalent) have been defined. Permanent or Ad hoc scientific advisory structure (entity) defined.	NCCB (or its equivalent) operates regularly, consistently, and financially independent from the Project	Official Policy and implementation plan describing technical profiles, role, scope, operation, tasks and structure of NCCB or equivalent Resolution or decree creating NCCB	The NCCB (or its equivalent) is recognized as an integral part of the national biosafety system. There is continuity in the NCCB institutional delegates

Outcomes and Outputs	Objectively Verifiable Indicators				Sources of verification	Risks and assumptions
	Indicators	Baseline	Midterm Target	End of project Target		
Outcome 1.3 (Cont.)	Strategy for continuity and sustainability of the National Biosafety System	Only one NCA (MAGA) currently assigns personnel and budget to biosafety.	A strategy for continuity and sustainability of the National Biosafety System is presented as part of the National Biosafety Policy	Policy implementation commitments and agreements include continuity and sustainability aspects of the National Biosafety System and NCAs include them in their Policy implementation strategies	Continuity and Sustainability strategy document. Official approval documents and Policy implementation strategies.	Policy and National Biosafety system are adopted before the end of the project

Outputs for Outcome 1.3:						
1.3.1 An administrative system with clear procedures for handling requests and clearly defined mandates, responsibilities and communication channels for different NCAs						
1.3.2 Permanent and Ad Hoc scientific advisory biosafety structures						
1.3.3 A continuity and sustainability strategy for the system						

Outcome 1.4: Biosafety policies are integrated into national programs, plans and strategies for sustainable development.	National and stakeholder policies, programs and strategies contain specific indications over modern biotechnology and biosafety	Only one NCA (SENACYT) includes biosafety in its policies. Other NCAs have not defined official positions or policies regarding biosafety	At least three NCAs have defined which biosafety aspects are necessary to include in defined policies, programs or strategies.	At least five NCAs have incorporated biosafety aspects into their policies, programs or strategies.	Stakeholder official Policy, program or strategy documents.	Policies, programs or strategies are due or able to be revised or prepared during the duration of the project.
--	---	---	--	---	---	--

Outputs for Outcome 1.4:						
1.4.1 Official adoption and implementation of Biosafety policies in different NCAs						

Component 2: Implementing the technical foundations of a functional national biosafety risk assessment and risk management system

Outcomes and Outputs	Indicators	Objectively Verifiable Indicators			Sources of verification	Risks and assumptions
		Baseline	Midterm Target	End of project Target		
Outcome 2.1: The institutional and administrative framework is reinforced and articulated to allow for effective handling of requests and coordinated decisions	Number of agreed upon and approved technical and administrative documents, instruments, guidelines or criteria	Only one NCA has handled an LMO request. Other NCAs with legal biosafety obligations have no validated procedures and no process routes or communication channels for biosafety decision making.	By PY2 joint technical or administrative instruments for risk assessment and decision making are developed and approved by at least 3 NCAs.	Joint technical or administrative instruments for risk management are developed and approved	NCA internal guidelines or approval documents. Project progress reports. Project M&E reports	Stakeholders agree to develop joint and coordinated risk assessment and management methodologies
	At least 1 mock decision on the release or national use of an LMO is jointly taken by NCAs.	There are no inter-institutional or joint technical or administrative instruments for risk assessment or management.	By PY3, a mock LMO request is put together and includes validation plans for communication channels, process routes and instruments for risk assessment and decision making	Process routes, communication channels and instruments are improved, validated and adopted as a result of the mock approval request.	Mock approval request results. Workshop minutes and working documents. Validation plans. NCA internal guidelines or approval documents. Project progress and M&E reports.	NCAs agree to validate instruments, process routes, and communication channels through a mock approval approach

Outputs for Outcome 2.1:						
2.1.1 Inter-institutional coordinated and harmonized technical documents, guides, criteria and administrative formats for LMO applications						
2.1.2 Filing system created to handle mock request documentation.						
2.1.3 Validated risk assessment and evaluation methodologies.						
2.1.4 Institutional agreements and coordination mechanisms for decision-making on internal use of LMOs and cross-sectoral collaboration						

Outcome 2.2: The science base for the evaluation of potential risks and benefits of LMO use in Guatemala is strengthened for use in biosafety risk assessment and	Risk assessment methodologies (instruments, guidelines, and criteria) are validated by the scientific community.	Only one NCA has carried out risk assessment. Scientific community is rarely consulted on biosafety management issues.	Risk assessment methodologies are presented and discussed with the scientific community, and their feedback is incorporated.	Risk assessment instruments, guidelines, and criteria are utilized in a mock approval request, and methodologies are validated by the scientific community	Mock approval request results. Workshop minutes and working documents. Draft, revised and final versions of methodologies.	Stakeholders agree to validate risk assessment and management methodologies, and to review mock approval request results.
---	--	--	--	--	--	---

management					Project progress and M&E reports.	
	Number of risk monitoring scientific guidelines or data collection plans (Such as LMO detection, monitoring of the use of LMO's in the country, evaluating LMO impacts on biodiversity, etc)	There are no coordinated or locally agreed upon scientific guidelines or data collection plans to inform risk monitoring and feedback biosafety decisions	By PY2, there is agreement between stakeholders on which scientific protocols, guidelines and data collection plans to draft.	A least 80% of scientific protocols, guidelines and data collection plans presented for validation are approved by Scientific subcommittee	Scientific protocols, guidelines and data collection plan proposals	Stakeholders agree that Scientific protocols, guidelines and data collection plans are necessary and adopt the resulting recommendations
Outcomes and Outputs	Objectively Verifiable Indicators				Sources of verification	Risks and assumptions
	Indicators	Baseline	Midterm Target	End of project Target		
2.2 (cont.)	Implementation strategy and costs are determined for scientific protocol and data collection plan	Local capabilities and budgets have not been analyzed in order to promote feasible and cost-effective scientific protocols or data collection plans	----	An implementation strategy and cost estimate is proposed for data collection plans deemed necessary	Implementation strategies and cost estimate documents	It is possible to estimate local budgets in order to draft locally feasible scientific protocols, guidelines and data collection plans
Outputs for Outcome 2.2:						
2.2.2 Science based guidelines, scientific protocols, and data collection plans to inform biosafety risk assessment and management decisions						
Outcome 2.3: Biosafety measures are applied in accordance with international guidance, national criteria and to the extent necessary and feasible to prevent possible adverse effects of LMOs	Number of inter-institutional and institutional National Biosafety Plans and measures for monitoring and control of LMOs presented and approved.	There are no coordinated or locally agreed upon National Biosafety Monitoring Plans and measures to tackle issues such as border inspections and border inspector training, emergency responses upon accidental or illicit release, or field site inspections.	National Biosafety Monitoring Plans and measures to be drafted are agreed upon.	National Biosafety Monitoring Plans and measures are consulted with stakeholders and approved by NCA authorities.	Proposals for National Biosafety Monitoring Plans and measures. Stakeholder consultation workshops. Inter-NCA communications. NCA internal approval documents.	Stakeholders agree that National Biosafety Plans and measures are necessary and adopt the resulting recommendations
	An implementation strategy and costs are determined for National Biosafety Plans	Local capabilities and budgets have not been analyzed in order to promote feasible and cost-effective biosafety monitoring and control measures	-----	An implementation strategy and cost estimate is proposed for National Biosafety Plans and measures deemed necessary	Implementation strategies and cost estimate documents	It is possible to estimate local budgets in order to draft locally feasible National Biosafety Plans and measures
Outputs for Outcome 2.3:						
2.3.1 Guidelines and plans for effective and science based national biosafety measures						

Component 3: Creating the necessary institutional capacity and human resources for effective decision making and regulatory compliance in biosafety						
Outcomes and Outputs	Objectively Verifiable Indicators				Sources of	Risks and assumptions

	Indicators	Baseline	Midterm Target	End of project Target	verification	
Outcome 3.1: Institutions are more proficient in risk /benefit analysis, and more knowledgeable of monitoring and enforcement requirements.	Number of institutions and personnel participating in training program (workshops) and obtaining positive results. Number of workshops, evaluations and case studies	Personnel in key posts are untrained in most aspects of biosafety and knowledge levels vary significantly. Isolated courses and workshops have taken place, yet key personnel still feel unprepared to make biosafety decisions	By PY1 at least 20 key personnel from at least 7 NCA and stakeholder institutions participate successfully in the first two workshops (70% pass rate). By PY2 at least 20 key personnel from at least 7 NCA and stakeholder institutions complete the next three workshops successfully (75% pass rate).	At least five training guides and five on-line training modules are developed and evaluated by workshop participants. At least 10 new personnel receive and pass the virtual workshop series (75% pass rate).	Workshop enrollment and completion documents, and test results. Virtual workshop enrollment and completion documents, and test results. Participant module evaluations Project progress and M&E reports.	Key personnel obtain work time and permission to attend workshops. The necessary international Spanish-speaking experts are recruited to develop and teach workshops.
	Information sources on international biosafety training opportunities	Local experts and key personnel express a desire for more formal and long term biosafety training opportunities, which are not available locally	The local BCH website contains periodically updated information on external biosafety training opportunities. Biosafety training is inserted into the national program for Human Resource training in Biotechnology	At least two people are trained abroad on biosafety subjects relevant to this project.	Local BCH website. Officially approved SENACYT HR training in Biotechnology Program. Minutes of Biotechnology commission meetings. Acceptance letters and proof of enrollment or completion from biosafety training programs abroad	Local personnel are accepted in training programs abroad. Biotechnology commission integrates biosafety into HR training in biotechnology program and provides co-financing for training abroad.

Outputs for Outcome 3.1:

- 3.1.1 Training Program for the use, management and regulation of biotechnology.
- 3.1.2 Decision-makers introduced to biosafety risk assessment principles
- 3.1.3 Technical staff trained in carrying out risk assessments and defining risk management measures

Outcomes and Outputs	Objectively Verifiable Indicators				Sources of verification	Risks and assumptions
	Indicators	Baseline	Midterm Target	End of project Target		
Outcome 3.2: Technological capacity is sufficient for in-house analysis of LMOs.	Number of institutions who provide space, personnel and co financing for laboratory facilities, and receive equipment and training in LMO detection	Only one stakeholder has dedicated laboratory equipment for LMO detection; independent verification of results is not possible. Personnel are not trained in sampling and LMO testing techniques.	By PY1 five partner institutions have been identified and produced a list of required equipment and personnel to be trained. By PY2 institutional agreements have been signed and at least three partners have been	Five institutions have officially agreed and demonstrated the necessary space, personnel and co financing, in order to be equipped and trained. Five institutions have received and installed equipment.	List of partner institutions. Equipment and personnel lists provided by institutions. Budgetary data for specific institutions. Signed institutional agreements.	The relevant institutions agree to participate and assign personnel and resources for training in use of equipment and detection techniques

			equipped, after co financing has been demonstrated to warrant equipment purchase.	Personnel (at least 1 person) from five institutions is trained in use of equipment and relevant LMO detection techniques	On site visits. Training workshop reports and participants lists. Project progress and M&E reports.	
Number of validated and implemented scientific protocols for LMO detection	There are no locally approved or official scientific protocols or quality standards for sampling of LMOs or their detection	By PY1 analytical protocols to be validated or implemented, and LMO to be tested, are identified.	Assigned personnel implement the necessary techniques to operate new equipment and validate scientific protocols through successful detection of at least 1 LMO.	Laboratory reports. Documented suggestions for improvement of scientific protocols. Analysis results. Project progress and M&E reports	LMO material is obtained for detection technique validation and implementation. Participating institutions assign personnel and resources to protocol validation	

Outputs for Outcome 3.2:

3.2.1 State-of-the-art technology, training and laboratory equipment for LMO testing

Outcome 3.3: Capacity for the safe development and use of modern biotechnology is strengthened in Guatemala.	Approval of LMO Special Research Program	Research regarding LMOs and biosafety is directed exclusively by individual research interests	A research topic priority list in the form of the Special LMO Research Program	Special LMO Research Program is officially approved by the National Science and Technology Council (CONCYT)	Special LMO Research Program document, CONCYT records and minutes	SENACYT agrees to participate and provide co-financing
	Number of research calls	There is no specific local financing mechanism for LMO and biosafety research. Biosafety and LMOs are not keywords for local granting agencies, preventing project identification	At least 1 agency commits to the financing of LMO and Biosafety research	At least two specific calls for LMO and Biosafety research projects take place	Local granting agencies letters. Local granting agencies publication of annual research calls	Cooperation and co financing from local granting agencies is obtained
	Number of grants assigned to biosafety related subjects		Biosafety and LMOs are integrated as possible keywords into granting agency nomenclature	At least eight LMO and biosafety research projects are approved and financed	Research project approval documents. Internal granting agencies records	Local scientists propose enough high quality LMO and biosafety research projects

Outputs for Outcome 3.3:

3.3.1 Relevant scientific research and information to inform biosafety decisions regarding the local biodiversity, environment and human health

Component 4: Gaining experience in generating and managing biosafety information and public sensitization strategies and public awareness

Outcomes and Outputs	Objectively Verifiable Indicators				Sources of verification	Risks and assumptions
	Indicators	Baseline	Midterm Target	End of project Target		
Outcome 4.1: Information availability in biosafety is increased and contributes to public sensitization and participation processes.	Preparation and approval of a Biotechnology and Biosafety Sensitization Strategy, and number of dissemination events to initiate its implementation	There is no coordinated or inter institutional education and sensitization strategy for biosafety or biotechnology	Biotechnology and Biosafety Sensitization Strategy is drafted, together with an implementation plan, is discussed with relevant stakeholders and approved by SENACYT and Steering Committee	4 dissemination events carried out for the general public and specialized sectors with at least 40% assistance if based on invitations. Risk communication strategies and guidelines adopted by NCAs. Lessons learned collected and recommendations emitted for optimizing	Biotechnology and Biosafety Sensitization Strategy document and implementation plan. SENACYT Biotechnology Commission minutes. Event invitation lists. Event agendas and participants lists. Evaluation (lessons learnt) from strategy	SENACYT agrees to participate and provide co-financing

			Strategy implementation.	implementation. NCA internal approval documents and official communications. Project progress and M&E reports	
Number of physical and virtual informative resources produced and distributed	There are few biosafety educational resources. Information is not easily accessible or centralized for easy public access, nor easily understood by the general public.	Necessary information is collected, revised and edited to inform the general public on at least 3 key areas of biosafety agreed between NCAs (eg. what is an LMO and how modern biotechnology is used in Guatemala).	Information is produced in printed and digital form, considering different user levels and different languages, and distributed to at least 5 dissemination centers (eg. universities, public libraries, etc).	NCA communications. Printed biosafety information guides. Distribution letters and invoices. Local BCH website	

Outputs for Outcome 4.1:

4.1.1 Public sensitization strategy and campaigns

4.1.2 Biosafety informative material in printed and digital formats, made available to the public

Outcomes and Outputs	Objectively Verifiable Indicators				Sources of verification	Risks and assumptions
	Indicators	Baseline	Midterm Target	End of project Target		
<p>Outcome 4.2: Collaboration with all NCAs is achieved for the management of biosafety information and for greater transparency in biosafety decisions and management.</p>	Number of inter institutional agreements on biosafety information management and equipped NCAs	3 NCAs have been equipped in order to comply with BCH requirements but NCAs don't report regularly to the BCH website (central portal).	By PY1 at least three agreements with non-equipped NCAs are signed, to manage BCH information and internal tracking needs. By PY2 at least five new NCAs have been equipped for information management.	All newly and formerly equipped NCAs report to the BCH Focal Point on their maintenance and regular use of the BCH equipment for its intended purpose. At least 3 institutional agreements to harmonize criteria for handling confidential information submitted with LMO approval requests.	Equipment purchase and delivery invoices. NCA and project inventories. Semesterly reports to the BCH Focal Point. Signed agreements. Internal NCA guidelines for BCH collaboration.	Stakeholders recognize the importance of biosafety information exchange
	Guidelines are revised for BCH access and use; Number of registries (% increase) and a management plan agreed and initiated for the local BCH site.	The local BCH website only has four registries to this date. There is currently no management plan for the local BCH site.	By PY1 BCH access and user guidelines are revised. By PY1 a management plan for the local BCH is drafted and adopted by 1 NCA. By PY2 every equipped NCA has fed at least one new registry to the local BCH website, as part of the implementation of the	Personnel from at least 6 NCAs has become familiar with BCH procedures through user training. Local BCH registries increase by 100% with respect to PY2. The local BCH management plan is revised and adopted for	Local BCH website registries. Training workshop report. BCH procedure surveys and tests. Revised guidelines document. Management plans (2010-2013 and 2014-2018). Project progress and	NCAs have relevant information to report to the local BCH website. CONAP is able to finance the local BCH management indefinitely.

		management plan.	a further five years.	M&E reports.	
New information modules on the local BCH website are designed as tools to support decision making.	Information available on the BCH website is not used to inform biosafety decisions or as reference material.	Local biodiversity information module created, with fields for data on native species (eg. distribution, ecological and biological characteristics, etc).	Biodiversity information module populated and validated as a tool by at least 3 NCAs and 3 sectoral experts. Educational science based biosafety decision making modules created and validated as a tool by at least 3 NCAs and 3 sectoral experts.	Initial data base. Local BCH website. BCH procedure surveys and tests. Minutes of meetings. Project progress and M&E reports.	National Biosafety Policy declares the local BCH website an official and trustworthy source of biosafety information.

Outputs for Outcome 4.2:

- 4.2.1 Permanent mechanisms for accessing and sharing biosafety information in NCAs
- 4.2.2 NCA Sensitization Plan for regulatory compliance.
- 4.2.3 Enhanced national biosafety website
- 4.2.4 New biosafety and biodiversity information available to the general public and decision makers

ANNEX B: RESPONSES TO PROJECT REVIEWS (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF) The responses to the comments of UNEP's Project Review Committee, made prior to submission of the project package to the GEF, are provided here.

(a) Project Title: Development of Mechanisms to strengthen the implementation of the Cartagena Protocol in Guatemala

(b) Project Type: MSP

(c) Focal Area: Biodiversity

(d) Reviewers: Stephen Twomlow, Geordie Colville, Alex Owusu-Biney, Adamou Bouhari, Alexander Juras.

(e) PRC Rapporteur: Eric Mugo

Review Criteria & Responses

i. Overall compliance with UNEP and GEF policies, criteria and financial rules

- Overall compliant, check allocation for component 5, suggest M & E component is separated to meet 10% management cost. All the project management allocated to project manager, are there no other expected costs?

Component 5 has now been separated to show the respective amounts for: (i) M&E (Component 5); and (ii) Project management, coordination and support (Component 6). Though there are other expected project management costs, the 10% quota is not enough to cover the Project Coordinator's salary. Therefore, much of those costs, such as running costs, will be covered through co-financing and others have been absorbed within the administration of the technical components.

- Ensure figure consistency across the project document and CEO endorsement request. The figures have been checked and consistency verified across all documents.

- Reconcile Table A & B minor differences in CEO endorsement request. No need for data in Table D as the project is a single implementing agency project.

Tables A and B of the CEO Endorsement request had a USD 1 difference with regards to co-financing; this has now been corrected.

- Outcome 3.3 - Biotech research not covered, could rephrase as safe use of modern biotechnology.

Outcome 3.3 (in both the CEO Endorsmt + ProDoc Appendix 4) has been corrected to read "safe development and use of modern biotechnology" in line with PRC's suggestion.

- No co-financing for consultancy even for local consultants?

Aside from co-financing for management consultants, the national executing agency will co-finance a full-time technical staff under a consultant contract to manage the BCH website.

Though true that cash co-financing provided for activities such as workshops for the national biosafety and biotechnology sensitization plan, LMO research priority plan, and scientific subcommittee activities could instead be used to cover consultancy costs, this type of expenditure is administratively difficult in the government sector. Therefore, rather than provide cash co-financing for direct contracting of consultants, the preferred option has been to put cash funding towards workshop activities, international experts' airfare and board and printing costs for the various events. This explains the dearth of co-funded consultancies.

- Will be useful in the narrative to bring out Monitoring and enforcement in both documents as it is implicitly mentioned though a critical component for regulatory compliance

Both documents now make clear statements on the inclusion of monitoring and enforcement within the scope of the project, given that these are pivotal aspects linked to biosafety regulatory compliance and post-approval follow-up.

- Para 2 of the project document – Regulatory procedures need not be friendly but adequate to facilitate decision making

As requested, the text has been changed to read: "... and users can count on biosafety regulations and procedures to be user-friendly, clear and efficient, and most of all, achievable and adequate for decision-making."

- Para 10 of the project document – Ratifying the protocol means Party status rather rephrase to show meeting obligations as party

The sentence has been re-phrased, as suggested.

- Para 8 of the project document – Since first law was not passed why emphasis on Regulation for RA and not regulatory measures for biosafety cf. output 1.2.1

Output 1.2.1 has been corrected and clarified. The regulations listed refer to all the areas still to be regulated, including risk assessment and risk management among them.

ii. Institutional arrangements and project decision making bodies

- Adequate

iii. Project description and intervention logic consistency with the log frame

- Another look at institutional and policy context para 35 – first BS activity EA and not MSP

The start of paragraph 35 has been changed to read "The first biosafety Enabling Activity...."

- Review components 2 & 3 to bring out the expected Monitoring and Enforcement roles.

Monitoring and enforcement have been highlighted throughout the ProDoc, and are specifically stated in components 2 & 3, though specific roles have not yet been ascribed to individual institutions.

- Review para 101 – SOPs as a tool for Environmental Safeguards, no issues raised on social safeguards. Need further update. [Need for standard text for all BS prodoc].

Further text has been developed, stating that no adverse environmental or social impacts are foreseen with this project.

iv. Adequacy of selected outcome indicators

- Adequate

v. M&E evaluation plan and budget conformity with GEF policies and project needs

- Adequate

vi. Adequacy of risk analysis and risk mitigation measures

- Tabular presentation of the risks and mitigation measures for each should be used.

Section 3.5 of the ProDoc has been changed to present project risks and their corresponding mitigation measures in a table format.

vii. Analysis of potential negative impacts in another focal area (negative environmental impact) and need for social safeguards (GEF fiduciary requirements); gender considerations and other stakeholder participation issues, as relevant

- Adequate

viii. Adequacy of budget

- Might be useful to take another look at the allocation for equipment and component on Public engagement (Component 4).

With regards to equipment, please see the response to comment (d) below. With regards to Comp. 4 and the reasoning for what is proposed therein: Based on lessons learnt from Enabling Activity (NBF Development project), sensitization activities in this project are more targeted. This means that: (a) much effort is going into attaining the acceptance of regulations and integration of the biosafety policy

into national plans, and thus, this type of political awareness raising has been included under Component 1; (b) activities for raising public awareness and promoting public participation in general will be focused at Govt and key sectors such as agricultural producers and scientists, as the project cannot expect to reach the general population in an effective manner in such a short time and with such a small budget.

This accounts for the un-ambitious but realistic scope of Component 4; as such, text has been added to the PRoDoc and Appendices to better describe the target audiences of sensitization activities, and the above reasoning in general.

ix. Adequacy of consideration and integration of PAG recommendations

– Adequate

x. Adequacy of responses to STAP or other previous reviews

– N/A

xi. Adequacy of project sustainability measures

– Adequate

xii. Other comments

a. Reconcile Appendix 10 with narrative, some repetitive detail can be omitted

This has been done, as requested; only the schematic figure is shown in Appendix 10, while the explanatory text remains in section 4 of the ProDoc.

b. Appendix 12 absent

This Appendix was sent together with the rest, but in Office 2007 format, and may not have been readable due to software incompatibility. It has now been submitted as an Office 2003-compatible file.

c. Look at para 92 - sustainability structure should be part of the Biosafety System. A sentence could be added on provisions for sustainability through the policy and the regulatory regime proposed.

It is indeed recognized that the sustainability of the project pivots around achieving the sustainability of the biosafety system that the project is seeking to initiate. Although some reference was made to the importance of mainstreaming biosafety into the country's policy and regulatory frameworks, this has now been emphasized further in the ProDoc.

d. Another look at the final procurement plan – allocation for only PCR standard or Real Time PCR? May be useful to restrict to 2 or 3 PCRs unless no other equipment or accessories are expected. No other equipment purchase for LMO Detection apart from PCR?

PRC Real Time would be ideal but is too costly. The preferred option was to have several labs equipped with PCR that would allow for cross-referencing and verifications, rather than a single lab equipped with the state-of-the-art technology. Immuno-detection is presented as an alternative to detection by PCR, and immunology equipment and reagents will be purchased as well. A full (detailed) list will be provided in the final procurement plan, to be agreed at the project's inception workshop.

PRC Decision: Cleared for submission once all the issues raised in the review comments above have been addressed and a comprehensive response to each comment provided.

PRC Chairperson: Alexander Juras

ANNEX C: CONSULTANTS TO BE HIRED FOR THE PROJECT USING GEF RESOURCES

Position titles	\$/ person week	Estimated person weeks	Tasks to be performed	Dollar amount
For Project Management				
<p>The section shows how project management costs are covered including co-financing. Project management requires two full-time staff (Project Manager and Admin Assistant) and also involves co-financing support in the form of technical staff from 2 key institutions, as detailed below. This additional project management support totals US\$ 56,880. For further detail, please refer to Appendix 1 (2nd spreadsheet “budget by outcome and activity”) and Appendix 2 (co-financing).</p> <p>(*) Project manager will be funded by GEF for 132 weeks, then by co-financing for the remaining 76 weeks of the project, resulting in a GEF contribution of \$61,000 and co-financing of \$35,000</p>				
Local				
Project Manager (*)	462 (includes co-financing)	208 (includes co-financing)	Overall responsibility for project operations. For full TORs: please refer to appendix 11 of project document	96,000 (*)
Administrative Assistant	Co-financing (considered at 116 dollars/week)	208	Full-time support to the Project Manager	24,000
Staff time: Support from OTECBIO Director and Advisor	Co-financing (considered at USD 496 /week)	58	CONAP (OTECBIO) continuous administrative and logistical support for project, additional to project coordinator, project administrative assistant, and workshop, training and committee meetings	28,800
Staff time: Support from OTECBIO Project Official	Co-financing (considered at USD 372 /week)	29		10,800
Staff time: Support from OTECBIO and SENACYT Administration	Co-financing (considered at USD 149 /week)	43.5		6,480
Staff time: Support from SENACYT Technical Director	Co-financing (considered at USD 514 /week)	7	SENACYT administrative and logistical support for special project activities, additional to workshop, training and committee meetings	3,600
Staff time: Support from SENACYT Biotechnology Commission Advisor	Co-financing (considered at USD 496 /week)	14.5		7,200
Justification for travel:				
To be determined: Project Manager travel to regional meetings to be convened by UNEP, for training and to promote coordination, exchanges and mutual support between biosafety projects in the region				
International				
International consultants will be required for M&E activities (mid-term review/evaluation and terminal evaluation) and have been costed in the M&E plan budget, to include estimative fees and travel costs (ticket and per diem).				
For Technical Assistance				
Local				
National Policy coordinator	346	104	Coordinate drafting of National Biosafety Policy, drafting of regulations, proposal of National Biosafety System, and Policy Task Force meetings	36,000
Legal consultants	256	78	Draft regulations	20,000

Lobbyist	419.5	22	Lobby governmental agencies after administration change for project and result adoption	9,230
Technical instrument consultants	250	72	Draft administrative and technical instruments and tools	18,000
Training program coordinator	346	112	Coordinate training program workshops, contact and guarantee international experts of teaching, consolidate program material in short course	36,000
Research priority setting consultant	416	12	Coordinate workshops and write LMO research priority program	5,000
Sensitization Plan consultant	416	24	Coordinate workshops, write Biotechnology and Biosafety Sensitization strategy, and implement biosafety aspects of the strategy	10,000
New BCH module consultant	416	24	Create and program new BCH modules	10,000
Biosafety short course programmer	416	24	Create and program virtual biosafety short course	10,000
BCH permanent staff	Co-financing (considered at USD 346 /week)	208	Staff in charge of BCH website maintenance and coordination	72,000
International				
Expert for Policy, technical instrument, and regulatory instrument writing	1750	2	Guide and inform Policy, technical instrument, and regulatory instrument writing	3,500
Experts for technical instruments, scientific protocols and data collection plan writing	1750	6	Guide and inform technical instrument, scientific protocols, and data collection plan drafting	10,500
Experts for Training Program	1750	24	Train participants on biosafety, risk assessment, risk management, monitoring, risk communication, etc.	42,000
Experts in Laboratory techniques and LMO detection	1750	4	Train participants in LMO detection methods using GEF financed equipment	7,000

OVERALL SUMMARY:

<i>Technical assistance</i>		Estimated person weeks		Dollar amount
Local Technical Assistance consultants (GEF)	3278	472		154,240
Local Technical Assistance consultants (Co-financing)	346	208		72,000
International technical consultants (GEF)	1750	36		63,000

<i>Project Management</i>		Estimated person weeks		Dollar amount
Local Project Management consultant (GEF)		132		61,000
Local project management support - technical and admin staff (Co-financing)	variable	152		56,880
Local Project Management consultants (Co-financing) (+)		284		59,000

(+) Includes administrative assistant (above, 208 weeks) and 76 weeks of project manager

ANNEX D: STATUS OF IMPLEMENTATION OF PROJECT PREPARATION ACTIVITIES AND THE USE OF FUNDS

A. EXPLAIN IF THE PPG OBJECTIVE HAS BEEN ACHIEVED THROUGH THE PPG ACTIVITIES UNDERTAKEN.

The PPG was effective in achieving its objectives, in that it allowed a participatory process and a stock taking exercise to provide relevant inputs and feedback to the project design. Participating stakeholders included all those listed as cofinanciers of the project, and other interested actors. Project preparation included consultations and outreach to different NCAs through workshops, meetings, and interviews. The project has been drafted successfully and fine tuned to the country's current situation and biosafety needs. All programed PPG activities have been completed.

B. DESCRIBE FINDINGS THAT MIGHT AFFECT THE PROJECT DESIGN OR ANY CONCERNS ON PROJECT IMPLEMENTATION, IF ANY: N/A

C. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES AND THEIR IMPLEMENTATION STATUS IN THE TABLE BELOW:

<i>Project Preparation Activities Approved</i>	<i>Implementation Status</i>	<i>GEF Amount (\$)</i>				<i>Co-financing (\$)</i>
		<i>Amount Approved</i>	<i>Amount Spent To date</i>	<i>Amount Committed</i>	<i>Uncommitted Amount*</i>	
Proj prep. planning	Completed					500
Stock taking	Completed	8,625	8,625			1,730
Task Groups	Completed	4,125	4,125			640
Project components	Completed	7,250	7,250			1,730
MSP proposal	Completed					500
Total		20,000	20,000			5,100

* Any uncommitted amounts should be returned to the GEF Trust Fund. This is not a physical transfer of money, but achieved through reporting and netting out from disbursement request to Trustee. Please indicate expected date of refund transaction to Trustee.

ANNEX E: CALENDAR OF EXPECTED REFLAWS

Provide a calendar of expected reflows to the GEF Trust Fund or to your Agency (and/or revolving fund that will be set up) N/A