GLOBAL ENVIRONMENT FACILITY
INVESTING IN OUR PLANET

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January 14, 2010

Dear Council Member,

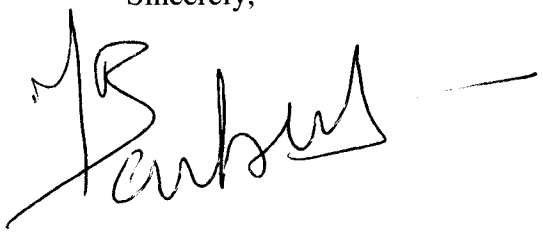
I am writing to notify you that we have today posted on the GEF's website at www.TheGEF.org, a medium-sized project proposal from UNEP entitled ***Costa Rica: Implementation of the National Biosafety Framework*** *under the Global: Biosafety Program*, to be funded under the GEF Trust Fund (GEFTF).

The project's objective is to protect biodiversity by fulfilling Costa Rica's obligations as a Party to the Cartagena Protocol on Biosafety (CPB), and implementing the country's National Biosafety Framework for the safe management of Living Modified Organisms (LMOs).

The project proposal is being posted for your review. We would welcome any comments you may wish to provide by January 29, 2010, in accordance with the new procedures approved by the Council. You may send your comments to gcoordination@TheGEF.org.

If you do not have access to the Web, you may request the local field office of the World Bank or UNDP to download the document for you. Alternatively, you may request a copy of the document from the Secretariat. If you make such a request, please confirm for us your current mailing address.

Sincerely,



cc: Country Operational Focal Point, GEF Agencies, STAP, Trustee

Request for CEO endorsement/Approval

Project Type: Medium-sized Project
The GEF Trust Fund

Submission Date: November 30, 2009

PART I: PROJECT INFORMATION

GEFSEC Project ID: 3629
GEF agency Project ID:
Country(ies): Costa Rica
Project Title: Implementation of the National Biosafety Framework of Costa Rica
GEF Agency(ies): UNEP, (select), (select)
Other Executing partner(s): The National Technical Commission for Biosafety (CTNBio)
GEF Focal Area(s): Biodiversity, (select), (select),
GEF-4 Strategic program(S): BD-SP6
Name of parent program/umbrella project: BIOSAFETY PROGRAM

Expected Calendar	
Milestones	**Dates**
Work Program (for FSP)	(actual)
GEF Agency Approval	January 2010
Implementation Start	March 2010
Mid-term Review (if planned)	September 2011
Project Closing Date	March 2013

A: PROJECT FRAMEWORK (Expand table as necessary) *A fully comprehensive Logframe (Results Framework) is provided in Appendix 4 of the UNEP ProDoc.*

Project Objective: ***Protect biodiversity by fulfilling Costa Rica's obligations as a Party to the Cartagena Protocol on Biosafety (CPB) and implementing the country's National Biosafety Framework for the safe management of Living Modified Organisms (LMOs***).								
Project Components	**Inv, TA, or STA****	**Expected Outcomes**	**Expected Outputs**	**GEF Financing***		**Co-financing***		**Total ($)**
				($)	**%**	**($)**	**%**	
1. Putting in place a national biosafety regulation and promoting a biosafety policy in accordance with the CPB.	TA	**Outcome 1.1.** A comprehensive regulatory framework for biosafety is in place, providing the architecture of an integrated administrative and management system. **Outcome 1.2.** New policy in biosafety and its action plan is translates into ongoing NCA involvement in CPB implementation. **Outcome 1.3.** Legal and sectorial capacity is built for considering cases of liability and redress (L&R) and implementing a co-existence regime.	1.1.1 Biosafety regulation (/technical norms) for LMOs use in food, feed and processing, 1.1.2 Biosafety regulation (/technical norms) for LMOs in transboundary movements (transit, identification, etc) 1.2.1 National Policy and Action Plan (submitted) 1.2.2 National Reports to the CPB, prepared involving with at least 2 NCAs 1.2.3 National position paper for COP/MOP-5 1.2.4 Units and personnel in charge of biosafety are identified 1.3.1 List of agricultural companies and farmers known to use LMOs in the country, or that are potentially affected by LMO use. 1.3.2 Survey analysis on sectorial knowledge regarding coexistence and L&R 1.3.3 Draft guidelines for LMO users on liability and redress (L&R) 1.3.4 Draft guidelines for LMO users on agricultural coexistence 1.3.5 Regulatory proposal for L&R 1.3.6 Workshops and informative materials on coexistence, with takes into account CPB decisions related 1.3.7 Position documents on L&R for COP/MOP-5 and COP/MOP-6	179,365	51	175,000	49	354,365
2. Making operational and administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms.	TA	**Outcome 2.1** NCAs needs are addressed so that administrative capacities are in place to handle requests, make informed decisions, and communicate decisions to applicants and the BCH. **Outcome 2.2.** Decisions on LMOs are based on risk assessments, timely, transparent and coordinated, and avoid duplicity or unnecessary	2.1.1 Permanent administrative structures in all NCAs for handling LMOs requests and notifications 2.1.2 Forms and formats for LMOs requests and notifications 2.1.3 Biosafety measures and standards established for each sector 2.1.4 BCH informed of national decisions, new procedures and standards 2.1.5 Information available upon request on procedures, requirements, standards and ongoing processes 2.1.6 Financial mechanisms to support the administrative system 2.1.7 Simplified procedures for LMOs authorization	111,394	48	120,000	52	231,394

		bureaucracy.	2.2.1 Coordinated and consolidated LMOs evaluation and decision-making mechanisms 2.2.2 LMOs requests processed efficiently 2.2.3 Biosafety decision-makers and advisory structures appointed 2.2.4 Periodic administrative evaluation of LMOs sectorial authorization processes 2.2.5 Procedures for review of decisions					
3. Building technical capacity in NCAs and related institutions for comprehensive biosafety management.	TA	**Outcome 3.1** Capacity to monitor and ensure regulatory compliance is increased. **Outcome 3.2** Sufficient technical and human capacities are put in place for risk assessment and management for decision-making, considering both traditional and novel LMOs. **Outcome 3.3** Transboundary movements of LMOs will occur in accordance with the CPB, and in a manner that is understood and accepted by the private sector (exporters /importers)	3.1.1 NCA-specific lists of personnel to be trained 3.1.2 Mechanisms to encourage the integration of civil observers into official monitoring and inspection plans 3.1.3 Official auditors and civil observers selected and trained 3.1.4 Annual inspection Plan for authorized LMOs is approved. 3.2.1 NCA-specific lists of personnel to be trained 3.2.2 Collaboration agreements for design and implementation of training activities 3.2.3 NCA professionals trained in specific areas of biosafety such as risk assessment and management of LMOs 3.2.4 Decision-makers briefed on the basics of biosafety and ongoing progress of the CPB 3.2.5 Leaflet for risk-benefit analysis and LMO management is available for decision making process. 3.3.1 NCA-specific quarantine and customs personnel selected and trained 3.3.2 Approved forms for identifying LMOs subject to transboundary movements	182,394	46	212,130	54	394,524
4. Improved communication, education, public perception and participation in biosafety of all relevant stakeholders.	TA	**Outcome 4.1** Public awareness regarding the safe use of LMOs in Costa Rica is augmented through a formal educational strategy **Outcome 4.2** Public information sharing is promoted through greater access to biosafety information. (BCH)	4.1.1 Draft Education Strategy on LMOs and biosafety (TEACH: Training and Education in AgrobioteCHnology) and its Action Plan for carrying out long-term formal and informal educational actions for dissemination of biosafety 4.1.2 Cooperation agreements between NCAs, biotechnology industry, international organizations and/or other governments agencies 4.1.3 Improved knowledge and understanding of Ministry of Education advisors regarding safe use of biotechnology. 4.2.1 Internal tracking system for LMO requests 4.2.2 Informative dissemination material	108,677	46	126,000	54	234,677

			by sector 4.2.3 Mechanisms for public participation prior to granting LMOs authorizations is augmented 4.2.4 Biosafety guidelines, protocols, and updated data on national biotechnology and LMOs use (especially in the agricultural sector) are on the National Biosafety Webpage and/or BCH 4.2.5 Media tools and other informal education initiatives reproduced and expanded for other sectors					
5. M&E costs				66,000				66,000
6. Project management (Only considers Project Personnel)				71,043	35	129,102	65	200,145
Total Project Costs				718,873		762,232		1,481,105

* List the $ by project components. The percentage is the share of GEF and Co-financing respectively to the total amount for the component. ** TA = Technical Assistance; STA = Scientific & technical analysis.

B. Sources of confirmed Co-financing for the project. (Expand the table line items as necessary)

Name of co-financier (source)	Classification	Type	Amount ($)	%*
Ministries involved in the project execution	Nat'l Gov't	In-kind	762,232	100
	(select)	(select)		
Total Co-financing			762,232	100

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

C. Financing Plan Summary for the project ($)

	Project Preparation a	***Project b***	***Total c = a + b***	***Agency Fee***	***For comparison:*** *GEF and Co-financing at PIF*
GEF financing	8,400	A 718,873	727,273	71,887	718,873
Co-financing	9,320	B 762,232	771,552		750,102
Total	17,720	1,481,105	1,498,825	71,887	1,468,975

D. GEF Resources Requested by Focal Area(s), Agency(ies) or Country(ies)

GEF Agency	Focal Area	Country Name/ Global	(in $)		
			Project	Agency Fee	Total
UNEP	Biodiversity	Costa Rica	718,873	71,887	790,760
Total GEF Resources			718,873	71,887	790,760

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

E. Consultants working for technical assistance components:

Component	***Estimated person weeks***	***GEF amount($)***	***Co-financing ($)***	***Project total ($)***
Local consultants*	358	140,500		140,500
International consultants*	10	21,000		21,000
Total	368	161,500		161,500

* Provide detailed information regarding the consultants in annex C.

F. Project management Budget/cost

Cost Items	***Total Estimated person weeks***	***GEF amount ($)***	***Co-financing ($)***	***Project total ($)***
Local consultants*	156	71,043		71,043
International consultants* (+)	4	15,400		15,400
Office facilities, equipment, vehicles and communications*				
Travel* (++)		27, 100		27,100
Others: ** **Technical personnel**			129,102	129,102
Total		**113,543**	**129,102**	**242,645**

* Details to be provided in Annex C. ** For Others, it has to clearly specify what type of expenses here in a footnote:

Note 1: This budget includes part of M&E costs: (+) External evaluators fees for Mid-Term Review /Evaluation and Terminal Evaluation (M&E). (++) Up to 3 regional meetings with national and regional UNEP-GEF project coordinators (estimate: US$ 22,500) and international travel for Mid-Term Review /Evaluation and Terminal Evaluation (US$ 4,600).
Note 2: Co-financing contributions to project management cited here only include staff costs (technical personnel). Operational costs (such as office facilities, equipment, etc) have been integrated into the co-financing of the project's technical components, a breakdown of which can be seen in Appendix 2 of the UNEP ProDoc.

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:

The budget for monitoring and evaluation plan has been designed in such a way as to be coherent and congruent with the requirements stipulated by the GEF, and to establish real and objective means for evaluating the indicators set for the project, at mid- and end-of-term. It will involve the Project Manager, the CTNBio and UNEP as the parties responsible for M&E. For further details, please refer to Section 6 and Appendix 7 (Costed M&E Plan) in the attached UNEP ProDoc.

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:

Costa Rica seeks to improve its performance in biosafety through the current Medium-Sized GEF Project (MSP). As set forth in the initial Project Identification Form (PIF), the overall goal of the current proposal is to implement Costa Rica's National Biosafety Framework and to fulfill the country's obligations as a Party to the Cartagena Protocol on Biosafety (CPB), in order to contribute to an adequate level of protection in the use of products of modern biotechnology and reduce the potential impact of Living Modified Organisms (LMOs) on biodiversity and human health.

The project is strongly focused on operational issues, and on building technical capacity and levelling this capacity among the different National Competent Authorities (NCAs), as defined by the CPB. Costa Rica first began working towards this goal through the UNEP-GEF Project "Development of a National Biosafety Framework" (NBF), as a result of which a draft biosafety law was prepared, as well as other regulatory proposals and tools, and the ratification of the CPB was attained. As a result of this important initial effort, both the Biotechnology Program of the Ministry of Agriculture and Livestock, and the National Technical Commission for Biosafety were consolidated as the main coordination mechanisms in biosafety. The active participation of various public and private institutions interested in establishing a national regulatory framework for LMOs was also achieved and lead to a consensus law proposal. Overall, the NBF project helped to: (i) Develop protocols and basic guidelines for risk assessment and risk management, including monitoring and assessment; (ii) Improve biosafety regulations and review the administrative system, for science-based decision-making; (iii) Improve and develop mechanisms for the exchange of information at the national level; (iv) Preview potential benefits of LMOs and socioeconomic issues; (v) Preliminarily update procedures and mechanisms for the management of confidential information and intellectual property rights in decision making processes and legislation generation; and (vi) Prepare strategies for promoting and improving public perception of biosafety, and for raising public awareness, education and public participation in biosafety matters. These important first steps were not only an opportunity to examine gaps, strengths and weaknesses, but also offered NCAs a broader vision of the responsibilities and functions that needed to be fulfilled in order to complete and implement a comprehensive biosafety framework.

Cost Rica then decided to continue its biosafety capacity-building efforts by presenting, through the International Centre for Tropical Agriculture (CIAT) and together with another 3 countries in the region, two multi-country GEF projects with the World Bank (WB), which address technical capacities relating to the CPB and are at inception stage. These multi-country projects ("Biosafety in Centers of Biodiversity: Building Technical Capacity in Latin America for Safe Deployment of Transgenic Crops", and "Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety") will involve the

University of Costa Rica as the main national partner, and the Ministry of Agriculture and Livestock (MAG) as a focal point.

In addition, Costa Rica has finalized the establishment of its Biosafety Clearing House mechanism through the UNEP-GEF project “Building Capacity for effective participation in the Biosafety Clearing House” (BCH). As a next step, Costa Rica wishes to carry out a national UNEP-GEF project for the completion and implementation of its national biosafety framework, with emphasis on biosafety coordination and management needs, in order to provide a solid institutional base on which to consolidate the following components of Costa Rica's biosafety system:

1. A national biosafety framework comprising regulations and a biosafety policy, in accordance with the CPB
2. An operational, administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms
3. Increased technical capacity in NCAs and related institutions for comprehensive biosafety management
4. Improved communication, public perception and participation in biosafety of all relevant stakeholders

In Costa Rica, LMOs have so far been introduced in the agricultural sector, on an experimental scale or for the purpose of seed production, but their continued use, up-scaling and possible commercial production for food and feed purposes are putting the country’s biosafety system to test. Costa Rica is catalogued as a mega-diverse country, and is home to many wild species related to agricultural varieties. As an agriculturally strong country and a user of living organism technology, the potential impacts of novel LMOs on the local environment and their relationship with global warming issues need to be dealt with carefully, especially if these LMOs aim to solve problems relating to bio-fuels, lowering contaminant levels, sustainable use of energy, plastic and garbage degradation, water purification, and agricultural production under extreme weather conditions, or are intended as bio-factories and merchandises. For these reasons, strengthening biosafety management within Costa Rica still represents a challenge and an ongoing effort.

A primary task that is pending in relation to completing its biosafety framework is the establishment of a biosafety policy, as well as specific regulations, particularly for LMOs used for Food, Feed or for Processing (FFPs), in accordance with the CPB. Having the ability to eventually deal with cases of liability and redress is also of interest to Costa Rica, as is the operation of an agricultural co-existence regime (for the coexistence of LMOs, organic and traditional production systems), as well as an LMOs identification and certification scheme for ensuring transparency and regulatory compliance of LMOs products that are subject to transboundary movements. In this area of work, cross-sectorial regulations, norms and standards as well as in-country coordination will need to be enhanced so that other Ministries (in addition to the MAG) are integrated into the processes of evaluation, authorization and inspection of FFPs and other LMOs, and the agricultural, livestock, industrial, import/export and bioremediation sectors are sensitized regarding the need to comply with biosafety regulations and standards. In addition, biosafety regulations will need to be harmonized with other regulations so that commercial and social aspects can be considered in accordance with the CPB.

Importantly, putting in place an harmonized legal and policy framework to guide NCAs will not only allow Costa Rica to complete and give continuity to prior efforts, but will also create the necessary institutional framework for transparent, sustained and coordinated biosafety action, such that continued and targeted capacity-building may be carried out through long-term biosafety training programs, information management strategies may be adopted, an administrative system that will support biosafety decision-making may be set up, and tools and inputs generated through other GEF-funded initiatives may be reviewed, fine-tuned, formalized, make official and fully integrated into the biosafety system in a coherent fashion. An administrative system that operates through specific and permanent mandates in NCAs, has clear procedures and formats for dealing with LMOs requests and notifications, and efficiently supports LMOs evaluation and decision-making processes will also be set up through this project. For this, adequate structures and mechanisms need to be put in place, including decision-making and advisory bodies, together with sufficient capacity and tools, to allow internal NCA processes to match each other as well as concur with CPB dispositions.

Costa Rica aims to have the biosafety operations running smoothly, to be able to keep track of all LMOs requests, with appropriate procedures for each, and be able to communicate decisions effectively and provide public information upon request. Information is recognized as an important basis for a technically-sound and transparent biosafety system, so that efforts will be made to create and maintain mechanisms for accessing, processing, presenting and analyzing technical information and statistics on national LMOs uses (requests, decisions, locations, etc) in all NCAs. For this, the efforts initiated through the UNEP-GEF BCH project, as well as data obtained from international sources and the WB-GEF multi-country projects (especially national environmental data) will be of great relevance, while information-gathering and -management will be established as formal NCA requirements so that BCH compliance is promoted as a means of administrative accountability. Continuous BCH management as part of the biosafety system, as well as periodic BCH training, will be incorporated into the project on a targeted needs basis, in order to maintain a homogenous standard in the country's BCH participation.

The main capacity-building focus of the current project is in relation to the management and operational needs of NCAs, where technical capacity still needs to be installed. Only by levelling such capacity in all NCAs will the combination of LMOs evaluations, consultations, management decisions, inspections and follow-up effectively contribute to safeguarding the environment as well as human and animal health.

Capacity for LMOs management needs to be built by strengthening the human network, as well as the scientific, technical and information base with which LMOs are managed. A significant part of this capacity will be based on the outputs generated by the WB-GEF projects, yet the institutional fabric on which to rest these outputs will be provided by the current project. Much will be gained from the sub-regional harmonization, access to scientific data, and use of international protocols for risk assessment of 5 key crops that the WB-GEF projects will articulate, as these will provide the bases for designing, planning and initiating training programs through the current project, aimed at NCA decision-makers and technical staff. Likewise for the risk communication strategies to be deployed by the WB-GEF MSP, and the experience to be gained with the application of socioeconomic considerations, all of which will form the basis of the technical norms, guidelines, standards and protocols to be developed for other types of LMOs, or formalized and internally accredited through the current project, and of the biosafety communication strategy that is to be adopted and revised.

However, an important aspect that will only be addressed in the present project is the institutional needs in relation to setting up a LMOs risk management and monitoring system that comprises LMOs detection methods for purposes of control, identification and certification; plans and procedures for carrying out effective and coordinated inspection activities in various sectors of LMOs use; establishment of biosafety measures and standards for different productive sectors; and the definition of emergency response procedures, in case of accidental release of LMOs. The risk management and monitoring system also contemplates a novel modality for civilian participation to complement the role of official auditors, as detailed below. Another important aspect is the establishment of long-term training programs to tackle emerging biosafety challenges. Such training needs will be addressed by devising, together with NCAs and in collaboration with members of the scientific and international communities, training modules and programs regarding novel types of LMOs and new biosafety developments, taking into account national biosafety information and know-how, and possible collaborating entities.

New technical developments in biosafety of interest to Costa Rica include: LMOs with novel traits and/or stacked genes; LMOs detection standards and identity certification; the implementation of an agricultural coexistence system to permit co-production of LMOs, traditional and organic crops; effective and methodic consideration of socio-economic factors in decision-making; and exploring the operations of a liability and redress regime for eventual cases of damage from inappropriate LMOs use. Ultimately, these issues influence the country's ability to uphold the objectives of the CPB and are considered key operational issues in relation to the implementation of Costa Rica's biosafety framework. NCA training therefore needs to be adaptive, reflective of state-of-the-art developments and responsive to risk management concerns. The aim is therefore to increase the technical capacity of NCAs and other institutions, so that they may keep up with the evolution of biosafety and the CPB, and be able to identify and cater for particular needs with regards to LMOs risk assessment,

identification, detection, certification, coexistence, and liability. For this, the experience acquired through the prior and current GEF projects, together with opportune collaborations with external agents, will all be of primordial importance.

Given that improving the technical knowledge of NCA staff will not suffice to enable effective and sustainable LMOs management in all sectors of LMOs use, both awareness-raising and educational initiatives will be implemented, as a compliment to the NCA training programs and as a follow-up from the initiatives executed through the WB-GEF MSP. Thus, this project aims to increase and sustain the awareness of decision-makers, educators and communicators, and sectors such as agricultural producers, food and feed processors, regarding novel biosafety issues and the manner in which they are being integrated into the country's biosafety framework. These topics will go beyond those addressed by the WB-GEF projects and will include liability and redress, transboundary requirements including identification, coexistence issues, detection and certification of LMOs, among others. The dissemination of biosafety norms and standards, and of the need for agricultural coexistence measures, will be of particular interest to the private sector, especially farmers, seed producers and exporters, and will include the use of the BCH and the national web page to provide updated information on LMOs use, biosafety and/or biotechnology in Costa Rica, as well as necessary guidelines and protocols. Stakeholder involvement in this respect will be facilitated once biosafety dissemination has initiated under the WB-GEF projects.

An innovative aspect that will not be addressed by the WB-GEF projects, however, will be the drafting of an education strategy for biotechnology (TEACH strategy: Training and Education in AgrobioteCHnology). This TEACH strategy, which will target both formal and informal means of education, is to be defined in conjunction with other NCAs -namely, Ministry of Education (MEP), the Ministry of Science and Technology (MICIT) and Universities (CONARE)- and will involve the biotechnology industry and the aforementioned international organizations concerned with biosafety. Its purpose is to raise the level of awareness and acceptance of biotechnology, and consequently of biosafety, especially in the agricultural and industrial sectors. In the area of public participation, a novel mechanism for the creation of "civil observers" is to be set up, in order to complement existing auditing and inspection mechanisms and take advantage of tendencies observed among civilians interested in environmental protection. The formal recognition and training of such "civil observers" and their integration as part of NCA vigilance mechanisms will not only serve to expand the country's capacity to monitor biosafety through a combination of formal and informal means, but will also motivate and sustain public participation in advocating for the safe use of biotechnology applications in Costa Rica.

The proposed project therefore seeks to allow Costa Rica to complete efforts initiated through prior initiatives, so as to have in place complete legal, policy and administrative frameworks, and sufficient technical capacities to fully implement the CPB and achieve an efficient and sustainable internal biosafety system. The project's 4 components coincide with the requirements for CPB implementation identified in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol adopted at COP-MOP-3 of the CPB, as well as with decisions of COP-MOP-4, and respond to the manner in which Costa Rica began the development of its NBF. The implementation arrangements have also been built around integration, so that the project will be executed with the full involvement as well as co-financing from key institutions such as the Ministry of Environment and Energy, the Ministry of Health, the State Phytosanitary Service, and the National Service for Animal Health of the MAG, in addition to collaborations with the MEP, the MICIT, CONARE, industry, and international organizations (IICA). Together, these partnerships will help to ensure sustainability, durability and relevance of the capacities being built.

Further details on the outputs, activities and timeframe of each component can be found in Section 3 and Appendix 4 of the UNEP ProDoc (attached), which was elaborated on the basis of a stock-taking assessment and an ample consultation exercise to ensure the project's design was responsive to real country needs. A full description of the country's biosafety baseline, and in particular of the threats, root causes and biosafety barriers to be addressed through the current proposal, are provided in Section 2 of the ProDoc. A guiding factor in this analysis was the level of CPB compliance attained by Costa Rica since its ratification. Likewise, complementarity with other GEF-funded initiatives was a prominent consideration in the project's logic.

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

Costa Rica is well known for its clear environment policies, and its active participation in various international environmental agreements. As one of many steps taken in favor of environmental protection, the Government of Costa Rica ratified the Convention on Biological Diversity in August 1994 and the Cartagena Protocol on Biosafety in February 2007. The CPB was published in November 2006 and is now Law Nº 8537. The 2006-2010 Presidential Government Plan of Dr. Oscar Arias Sanchez also reminds of this ongoing commitment, in the chapter on environmental sustainability policies, while the State of the Nation 2008 report (*Agriculture: Recent trends and environmental implications. One year of climatic and environmental crisis*) indicates an urgent need to establish LMOs risk assessment and management measures in Tropical conditions.

Costa Rica has also elaborated a National Strategy in Biodiversity Conservation and Sustainability[1], comprising 13 strategic objectives of which the tenth relates to capacity building for the prevention of socioeconomic and environmental risks derived from the use of LMOs produced through biotechnological means with biosafety capacity building projects. Building capacity in biosafety is therefore a specific line of action of this Strategy (http://www.cbd.int/doc/world/cr/cr-nbsap-01-p1-es.pdf).

In June 2003, Costa Rica started the UNEP-GEF Project for NBF development, through which the need for a national policy for biosafety and modern biotechnology was defined, and a draft biosafety law was developed but not adopted. In November 2006, Costa Rica completed the project, having already taken the necessary steps to ratify the CPB and obtain the substantive support and participation of the Biotechnology Program of the MAG, and of the National Technical Commission for Biosafety. Moreover, Costa Rica is part of the hemispheric task force in biotechnology and biosafety, created by IICA-CATIE-OIRSA, and has historically been an active leader in biosafety in Central America.

C. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH GEF STRATEGIES AND STRATEGIC PROGRAMS:

The current proposal is fully alligned with the key elements emphasized in the *Updated Action Plan for Building Capacities for the Effective Implementation of the CPB*, adopted at COP/MOP-3, and with Strategic Programme-6 (of SO-3) of the Biodiversity Focal Area Strategy, recently approved as part of GEF's *Focal Area Strategies and Strategic Programing for GEF-4*. It is also consonant with GEF's *Strategy for Financing Biosafety*, approved as part of the Biodiversity Focal Area Strategy in July 2007.

D. JUSTIFY THE TYPE OF FINANCING SUPPORT PROVIDED WITH THE GEF RESOURCES

As a capacity-building project, the GEF resources requested are for non-refundable GEF grant, derived from Costa Rica's Resource Allocation Framework for Biodiversity under GEF-4.

E. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES:

In light of the expansive potential of LMOs and of the contentions surrounding biotechnology food products, several global, regional and national initiatives have arisen to help developing countries put in place regulatory frameworks and acquire technical capacities. Among these initiatives is the IICA Hemispheric Programme on Biotechnology and Biosafety, of which Costa Rica is part and which is oriented towards establishing technical cooperation around issues of the CPB, capacity building, identification needs, scientific information for decision makers, and others.

The most relevant related initiatives, however, are also two approved interlinked WB multi-country GEF projects involving Costa Rica, Brazil, Colombia and Peru. The first of these (FSP "Biosafety in Centers of Biodiversity: Building Technical Capacity in Latin America for Safe Deployment of Transgenic Crops") and the second (MSP

[1] Document available at http://www.cbd.int/doc/world/cr/cr-nbsap-01-p1-es.pdf

"Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety") will be executed concomitantly through CIAT in Colombia. These WB-GEF-CIAT projects are complementary with the current proposal, as discussed further in Section 2.7 of the UNEP ProDoc where a close analysis of how these projects will support each other and avoid duplicities is presented. The distinctions initially made at PIF stage between these initiatives, which are outlined here, are still valid and were agreed between project teams during the project preparation phase of the current proposal. This involved meetings with the National Coordinator of the WB-GEF projects based at the University of Costa Rica, where the FSP was noted to be further ahead in its inception phase than the MSP.

The first WB-GEF project will centre exclusively on 2 components: (i) Strengthening technical capacity in knowledge-generation for biosafety risk assessment and management, focusing on five main crops of interest to participating countries and including socio-economic impact assessment. This component will include activities and studies conducted in situ in defined countries. (ii) Strengthening biosafety decision-making capacity in NCAs and for practitioners (public and private research community), through participatory scientific and technical training on risk assessment, risk management and risk communication. The second WB-GEF project is related to the first, in that it deals with the generation of biosafety research-based communication products and their delivery through a mix of media and channels, but has been formulated as a separate component for public awareness that is to be co-implemented with the first project. Whereas these WB-GEF projects will embark on a cross-country research program, technical training activities and communication efforts, centering on 5 key crops, the UNEP-GEF project proposed here will ensure the installation of these capacities and know-how within Costa Rican institutions, in particular by focusing on the needs of NCAs, by setting up permanent structures, procedures, mechanisms and programs, and by extrapolating the know-how and lessons-learnt to other areas of biosafety. Indeed, the UNEP-GEF project will focus on areas of national capacity-building and of the institutional framework that the WB-GEF projects will not address. Such areas include new capacities for regulated FFP use, risk assessment of novel LMOs, handling LMO requests and notifications, LMO detection and identification, transboundary issues, LMO monitoring, liability and redress, agricultural coexistence, information management, sustained state-of-the-art training and public education in biosafety. Maximizing the synergies between projects, however, will be of common interest, as the achievement of one project's outcomes will be of benefit to the other, and vice versa.

Costa Rica's participation in the first WB-GEF project will prove invaluable for gaining first-hand experience in evaluating LMOs in the field and in testing biosafety measures, and for carrying out research-based training of relevant professionals, in the areas of risk assessment, management and communication. It will also provide a strong knowledge-base and working relationship with the scientific and sub-regional communities. All these advances will feed into the UNEP-GEF project, as the basis on which LMOs assessment and management protocols will be generated, formalized and extended to other non-agricultural areas. Data quality standards and harmonization mechanisms can also be agreed upon for all LMOs types, on the basis of the results attained through the WB-GEF project; likewise for the base elements underlying the design and long-term maintenance of biosafety training programs to be generated through the UNEP-GEF project. The latter is looking to respond to ongoing NCA training needs through collaborations with biotechnology regulatory agencies, international organizations and universities in specific fields and through financially-viable mechanisms that will not be addressed by the short-term training of the WB-GEF projects. On the other hand, for the WB-GEF project to be most effective, LMOs authorization requirements must first be defined (technical and administrative), decision-making mechanisms and structures put in place, and training needs agreed together with relevant NCAs. These national definitions, as a function of existing capacities and needs arising from national regulations and the CPB, will be articulated through the UNEP-GEF project. Although the WB-GEF project will enhance the scientific-base of national decisions in biosafety and promote sub-regional collaboration, links to the relevant institutional and legal frameworks, including the biosafety policy, are needed in order for these achievements to be long-lasting in Costa Rica.

The second WB-GEF project, which will focus on specific risk communication, education and public awareness pertaining to five LMOs crops in participating countries, also has important synergies with the current UNEP-GEF proposal. These mostly relate to institutional tasks and to strengthening the science-base of LMOs decision-

making and biosafety information. The WB-GEF project will set the stage for a more cost-effective and targeted engagement of Costa Rican NCAs in outreach and information-management activities and in collaboration initiatives with other sectors, for the generation of relevant public information and educational material. The UNEP-GEF project on the other hand will generate a precedent in the country for the way public participation is to be channeled and promoted in biosafety, through the engagement of important private sector stakeholders, the recruitment of civil observers for biosafety monitoring, and the establishment of an education strategy (TEACH) for improving understanding of agrobiotechnology. In this respect, the WB-GEF project will provide information to adjust and optimize the execution of the UNEP-GEF project, and could also influence the manner in which the national biosafety legislation and the CPB are applied. The results of the WB-GEF project with regard to surveys and public opinion will be of great use for the design and testing of government policies and strategies through the UNEP-GEF project. It will offer a valuable barometer and feedback mechanism for defining or reviewing the contents, scope and implementation of the biosafety policy, and the biosafety communication and TEACH strategies. Public participation and the communication of Government decisions will thence become much more meaningful once relevant national information is made available, the involvement of educators, communicators and scientists is promoted, and a higher level of overall public awareness of biosafety issues is attained through combining initial WB-GEF communication and outreach activities, with informal education initiatives under the TEACH strategy.

Moreover, both the WB and UNEP projects will contribute to consolidating Costa Rica's BCH and other web-based information tools. While the BCH, as well as the national biosafety web page, will benefit significantly from the data generated by the WB-GEF project, the training and maintenance of the correct Costa Rican focal points, the responsibility for transparent and coordinated biosafety information management in NCAs, and the generation of official information on LMOs decisions, norms, location, statistics, research, monitoring, experts and management practices will remain the prerogative of the UNEP-GEF project. The latter will provide the means for NCAs to act in a coordinated fashion and continue meeting their BCH and information obligations and will integrate other sectors into outreach and communication efforts involving biotechnology and biosafety. The UNEP-GEF project will thus incorporate the regular generation of information into the workings of the administrative system, while also considering the need, scope and modalities for continuing the training activities initiated under the BCH Project.

Finally, the concomitant implementation of all WB and UNEP projects will require strong coordination between them, in particular at the national and institutional levels, to avoid duplicities and ensure an efficient use of GEF resources. For this, the University of Costa Rica, the National Technical Commission for Biosafety, and the Biotechnology Program of the Ministry of Agriculture and Livestock, as project partners, will guarantee linkages and information-flow among all three efforts. The UNEP-GEF project will create a national coordination platform, through which to involve all relevant stakeholders (including those not targeted by the WB-GEF projects), express national interests and link them to the other projects, while at the same time, channel WB-GEF outputs and achievements in a manner that is most complementary and synergistic to its own objectives. As a multi-sectorial group, the National Technical Commission for Biosafety will be key in this endeavor, with the Biotechnology Program as government counterpart in all cases also acting as coordinating agent for the integration and collaboration with other public and private stakeholders. The same Government representatives (MAG, MEP, MICIT, etc) especially at the decision-making level, will also be designated for the purpose of both the WB and UNEP projects, to ensure a high level of coordination and synergy, and intra-institutional coherence.

F. DISCUSS THE VALUE-ADDED OF GEF INVOLVEMENT IN THE PROJECT DEMONSTRATED THROUGH INCREMENTAL REASONING :

Even without GEF involvement, it is likely that the political commitment to biosafety in Costa Rica would continue, albeit with a much slower pace of capacity building. In the absence of this GEF project, technical tools for capacity building would not likely be harmonized or equal among NCAs, although regulations would probably be put in place in various sectors. Training of personnel and outreach activities for stakeholders would either not take place, not be sustained over time, or would be delivered to differing extents, with some sectors favored over others. This would also result in reduced coordination of NCA activities and decisions, and less stakeholder awareness for complying with biosafety regulations. The current GEF project would allow Costa

Rica to build capacity across the board, by making effective use of the tools generated by other initiatives and targeting a range of interested parties, all in a similar timeframe, which will be vital for making informed and integrated decisions regarding LMOs on the basis of formalized protocols and standards, and for control and monitoring activities. The reduction of these two functions would have the greatest consequences for the protection of the local environment, and for assuring the local population as well as other countries that biotechnology is managed safely in Costa Rica. In addition, there is a need for the establishment of scientific based decisions for LMOs used for food, feed and processing. Although other projects may provide an initial information base for this, the relevant institutional mechanisms and approval processes would be weak, especially in relation to non-agricultural activities with LMOs.

Costa Rica would probably advance slowly in the described field in the next years, meaning a lag in the control of LMOs to be released into the environment and commercialized, with no integrated risk assessment, poor risk management and a lack of coordination under situations of emergency. Incomplete regulations would probably be conducive to unregulated and illegal use of LMOs, as the completion of the country's regulatory and policy frameworks is the first step in sustained institutional strengthening. Such a void would also weaken the possibility of achieving agricultural coexistence as well as agreements with the private sector. In this respect, the GEF's incremental intervention is needed in order to guarantee global environmental benefits in the context of biosafety, as only the regulated oversight of LMOs that are subject to transboundary movements will effectively contribute to biodiversity protection at both local and global levels. In the case of Costa Rica, this implies strengthening Government processes that, under the WB-GEF multi-country projects, would not be fully addressed or allow full satisfaction of the CPB.

Thus, although GEF is already supporting biosafety capacity-building in Costa Rica, the value-added of further GEF investment in a national project lies in the need to complete and operationalize the country's regulatory and policy framework, and deploy institutional mechanisms through which LMOs-related decisions, management, information and follow-up actions can be administered. Other GEF-funded projects will have lower or short-lasting impacts if the right structures, rules and mechanisms are lacking. Likewise, the inputs and experiences gained need to be extended to other sectors (non-agricultural) and fed into the relevant national policies, programs and instruments, in order to be sustainable. The harmonization of legislation and Ministerial mandates as well as long-term capacity-building for the adoption of transparent decisions and civil society education are clearly dependent on the current project, and would suffer from slow development in the absence of GEF support.

G. INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS, THAT MIGHT PREVENT THE PROJECT OBJECTIVE(S) FROM BEING ACHIEVED AND OUTLINE RISK MANAGEMENT MEASURES:

Costa Rica is a politically stable country and has been managing LMOs for a sector of agriculture since the early 90's, but some of the risks that could occur during the project were considered at PIF stage and again during project preparation. Whereas initially, general risks identified related to: (i) change of Government and/or lack of political support for the approval of legislation; (ii) staff trained through the project leaving their positions; (iii) groups opposed to LMOs carrying out effective campaigns; and (iv) lack of local biosafety experts or expertise for training needs; the risks later reviewed during project preparation changed slightly and became somewhat more specific. These included: (a) Critical dependence on the Costa Rican government's commitment towards the implementation of policies and inter-agency collaboration; (b) Industry advances continue to outpace government capacity to respond to biosafety challenges; (c) NGOs and civil movements from detractors of biotechnology could compromise the achievement of project objectives by putting pressure on Ministers and Heads of Agencies; (d) Official approval of strategic, legal and regulatory proposals does not occur within the required or predicted timeframe; (e) Key stakeholders continue to have at least the present levels of interest in being involved in Project activities and acquiring and using the new knowledge and skills provided through the Project; and (f) WB-GEF-CIAT projects fail to deliver expected outcomes. The measures proposed to mitigate or respond to these risks are laid out in Section 3.5 of the UNEP ProDoc.

H. EXPLAIN HOW COST-EFFECTIVENESS IS REFLECTED IN THE PROJECT DESIGN:

The active participation of all relevant NCAs in the current project's design has been pivotal in moving towards a common vision of the needs, tasks and responsibilities already outlined in this proposal. The project's execution will be supervised at every level by the already operational CTNBio, a multi-disciplinary and multi-sectorial committee that resulted from the previous UNEP-GEF NBF Project, and that already has experience in the execution of such projects and has taken on the project's co-financing commitments.

The project's design therefore focuses on building capacity across all relevant NCAs, and not just the CPB or BCH Focal Point institution. It also makes best use of previous efforts, in that it seeks continuity and consolidation of what has already gained ground and institutional relevance with regard to the CPB, and aims to complement other efforts in order to cover all areas of the biosafety system. The component structure proposed for the project therefore focuses on priority areas where the highest impact or probability of success can be achieved (regulations, administration, decision-making, training, collaborations, participation and information) and where some level of institutional buy-in already exists, also contributing to the sustainability of results.

The emphasis on partnerships will also render the project more cost-effective by combining resources, strategies and programs by "spreading the load" between different public and private institutions. Addressing educational needs is also pivotal, as was recently recognized by the CPB (COP/MOP-4), given that the early definition and testing of an appropriate strategy constitutes a cost-effective approach, with a long-term vision, to increment the overall level of understanding of biotechnology and biosafety issues in the country, and also to sustain efforts in this field. Similarly, the project is cost-effective by looking to build a solid technical and information base, to better serve institutions in their environmental management functions in general, and to attend to biosafety requirements in particular. It is also designed to be complementary to the WB-GEF initiatives, so that best use is made of those project outcomes, while at the same providing enabling conditions for those projects, and avoiding thematic or institutional duplications.

PART III: INSTITUTIONAL COORDINATION AND SUPPORT

A. INSTITUTIONAL ARRANGEMENT:

B. PROJECT IMPLEMENTATION ARRANGEMENT:

The project's implementation scheme is outlined in pointform here; for further specifications, please refer to Section 4 of the UNEP ProDoc.

- The National Technical Commission on Biosafety (CTNBio) has been designated as the project executing organization (National Executing Agency).
- As Secretariat to the CTNBio, and Costa Rica's National Focal Point to the CPB and BCH, the Biotechnology Programme of the MAG will provide the necessary technical and logistical support for the project and its overall coordination
- A project co-ordination unit (PCU) will be created and supported within the CTNBio to administrate the project. The PCU will consist of a Project Coordinator and a Project Agency Junior Staff, who will report directly to the CTNBio.
- A National Coordination Committee (NCC) will be constituted for the project, in order to facilitate participation and consultations with groups not represented within the CTNBio. This Committee will provide guidance and feedback to the project, and will have general oversight functions but will not be responsible for project management.
- The PCU will implement work plans and overall strategies agreed among the CTNBio and the NCC. OIRSA will be consulted on a regular basis (at minimum every 3 months) to check up on financial management of the project. Any corrective measures suggested in these meetings will be taken accordingly.
- The International Regional Organism for Plant and Animal Health (OIRSA) will administrate and channel the GEF funds according to national and international financial procedures, and will assist the CTNBio in all its fund management functions.

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

Having conducted a consultation process with members of the NCAs and other stakeholders, and taken on board many of the suggestions of the CTNBio during the project design phase, the logical framework that resulted is very much in sync with that originally presented in the PIF. There are nonetheless significant differences, namely: the reduced number of outputs and their adaptation to be more in line with the country's current situation and priorities; the review of the original outcomes to confer "SMART" properties such as being measurable, time-bound and realistic; and the shortened planned duration of the project. The latter was deemed necessary due to economic considerations relating to the limited budget available for Project Management, in particular, for contracting a National Project Coordinator. This made it necessary to reduce the duration of the project from four to three years. Nevertheless, as the entity responsible for project execution, the CTNBio considered that a project duration of three years was unlikely to compromise project outcomes in any way, but would allow the relatively small project budget to be streamlined. Certain activities planned in the original PIF were hence eliminated, due to economic limitations.

Two other differences with the PIF are that: i) technical component costs have risen slightly, as conscientious costing of activities resulted in a higher budget allocation for Component 2, more equal allocations between Components 1 and 3, and the redistribution of financial administration costs across all technical components; ii) the cost of M&E was increased due to additional monitoring and evaluation activities arising after careful confection of a Costed M&E plan, and a more thorough consideration of M&E requirements and benefits. The M&E amount set at PIF stage was modest, and only considered a tentative estimate of external evaluation and audit costs. The inclusion of "performance tests" to determine the extent to which the project is able to generate positive impacts is an important feature of the current M&E plan, and in part explains the higher budget set for this component. Below is a summary table of the variation in component budgets, with respect to the PIF.

	At PIF	At CEO app
Component 1	$ 181000	$ 179,365
Component 2	$ 80,550	$ 111,394
Component 3	$ 212,850	$ 182,394
Component 4	$ 145,970	$ 108,677
M&E	$ 27,460	$ 66,000

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		10/15/2009	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
Below is the Result /Logical Framework contained in Appendix 4 of the UNEP ProDoc.

Intervention logic				
Project objective	Implement a country's National Biosafety Framework for the safe management of Living Modified Organisms (LMOs) in accordance with the CPB			
Outcomes	Objectively Verifiable Indicators		Sources of Verification	Risks and Assumptions (R & A)
	Baseline	Indicators (End of Project Year X)		
Component 1: Putting in place and applying a national biosafety legal framework and promoting a biosafety policy in accordance with the CPB				
Outcome 1.1. A comprehensive regulatory framework for biosafety is in place, providing the architecture of an integrated administrative and management system.	- The lack of a complete biosafety framework prevents the development of an adequate administrative and management platform for LMOs. - The country is only able to make decisions concerning LMO crops, so other sectors are precluded from using LMOs responsibly. - CTNBio has legal prerogative to recommend decisions on any kind of LMO but is not integrated by all relevant NCAs	- Approved at least 2 biosafety regulations which include administrative and management procedures. (PY1) - Representatives of SENASA and Ministry of Health have been officially integrated as members of CTNBio by PY1	- Regulations published in the Official Journal and posted in the national BCH. - Official document (e.g. resolution) reflecting new composition of CTNBio	Political willingness at national level to develop regulations in accordance with the CPB. (A)
Outcome 1.2. New policy in biosafety and its action plan is translates into ongoing	- There is no coordinated policy or plan in biosafety in Costa Rica. - Reduced Personnel at the	- Action plan in biosafety involves at least 2 NCAs and is endorsed (PY1) - Personnel responsible for functions relating to CPB's implementation are	- Minutes of CTNBio meetings - Ministries endorsements (at least	There is sufficient Government and institutional support to agree on a biosafety

NCA involvement in CPB implementation. Outcome 1.3. Legal and sectorial capacity is built for considering cases of liability and redress (L&R) and implementing a co-existence regime.	Ministries related to implementation or follow-up of CPB. - There is no legal mechanism in Costa Rica with which to address L&R regarding LMOs. - Organic and conventional farmers are misinformed about co-existence and L&R.	designated (PY2) - Costa Rica prepares a national position for COP/MOP-5 in which the main NCAs (3 Ministries) participate (PY1) - Costa Rica is able to present an official position regarding L&R at both COP/MOP-5. (PY1). One legal proposal on L&R regarding LMOs submitted to implementation procedure (PY 2) - At least 50% of agricultural companies and farmers known to use LMOs in the country, or that are potentially affected by LMO use, are better informed about co-existence rights and responsibilities, including L&R (PY3)	2) of the Policy and Action plan. - Biosafety personnel or Units identified in NCA organigrams. - Minutes of Normative Task Force meetings - Official file number assigned to the L&R proposal. - Survey about coexistence and L&R among farmers and LMO users. - COP/MOP reports.	action plan. (A) A resolution regarding Art. 27 about L&R may not be achieved during the COP/MOP 5 (R) The correct agricultural companies and farmers can be targeted and engaged. (A)
Outputs: 1.1.1 Biosafety regulation (/technical norms) for LMOs use in food, feed and processing, 1.1.2 Biosafety regulation (/technical norms) for LMOs in transboundary movements (transit, identification, etc) 1.2.1 National Policy and Action Plan (submitted) 1.2.2 National Reports to the CPB, prepared involving with at least 2 NCAs 1.2.3 National position paper for COP/MOP-5 1.2.4 Units and personnel in charge of biosafety are identified 1.3.1 List of agricultural companies and farmers known to use LMOs in the country, or that are potentially affected by LMO use. 1.3.2 Survey analysis on sectorial knowledge regarding coexistence and L&R 1.3.3 Draft guidelines for LMO users on liability and redress (L&R) 1.3.4 Draft guidelines for LMO users on agricultural coexistence 1.3.5 Regulatory proposal for L&R 1.3.6 Workshops and informative materials on coexistence, with takes into account CPB decisions related				

1.3.7 Position documents on L&R for COP/MOP-5 and COP/MOP-6				
Outcomes	Objectively Verifiable Indicators		Sources of Verification	Risk and Assumptions
	Baseline	Indicators (End of year X)		
Component 2: Making operational an administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms				
Outcome 2.1. NCAs needs are addressed so that administrative capacities are in place to handle requests, make informed decisions, and communicate decisions to applicants and the BCH.	- There are no administrative procedures to comply with national regulations on environment, human and animal health established. - Development of administrative procedures is precluded by low capacities on the subject. - All LMOs requests handled until now have meant low cost to the applicant. - The BCH system is working, although several NCAs lack information to be reported, and therefore are not frequent users.	- The administrative pathway which an LMO request must take in order to derive at a decision is officially established within each NCA by identifying: staff /Units involved and their roles, files to be kept, forms and formats to be used, procedures to be followed, reports to be generated and fees to be charged. (PY2) - By PY3 office equipment is provided to NCAs and an information management system is set up and operational in 1 NCA that allows: electronic reception, exchange and internal processing of confidential LMO dossiers; web site management for on-line availability of forms and formats, and posting regulatory requirements and procedures; periodic preparation and submission of information to the BCH; and on-line access to data on status of requests submitted.	- Memos specifying administrative pathways, procedures and fees. - NCA organigrams identify biosafety personnel and management units - NCA-specific guidelines, forms and formats - Biosafety filing systems - New infrastructure in NCAs - BCH records - NCA web sites with updated biosafety info, access to forms and formats, and request status data	Personnel is available in each NCA (A) Administrative system fails in providing enough income to achieve self-sufficiency. (R)
Outcome 2.2. Decisions on LMOs are based on risk	- Bases to make scientifically informed decisions are diminished or absent in most	- At least one request (either mock or real) has been processed by each NCA, evaluating: quality of risk assessment data,	- Biosafety documents filed within each NCA. - LMO dossiers (either	NCAs are unable to agree on which request to

assessments, timely, transparent and coordinated, and avoid duplicity or unnecessary bureaucracy.	NCAs. - The decision making process is uncoordinated, and has only taken place so far for small scale release of agricultural LMOs. - Administrative guidelines which could be used to fulfil CPB requirements have been proposed.	information management, coordination, time required, and communication requirements, and resulting in a single joint decision (mock or real) in less than 270 days. (PY2) - The annual % of LMO requests that are returned to applicants, due to incomplete information or dossiers, is reduced by half by PY3	mock or real requests) - Emails exchanges between NCAs and with applicant (real or mock) using a security information system. - Legal document (e.g. resolution) expressing official decision. - Data on requests received and requiring re-submission	consider as a real /mock decision-making case (R)

Outputs:

2.1.1 Permanent administrative structures in all NCAs for handling LMOs requests and notifications
2.1.2 Forms and formats for LMOs requests and notifications
2.1.3 Biosafety measures and standards established for each sector
2.1.4 BCH informed of national decisions, new procedures and standards
2.1.5 Information available upon request on procedures, requirements, standards and ongoing processes
2.1.6 Financial mechanisms to support the administrative system
2.1.7 Simplified procedures for LMOs authorization

2.2.1 Coordinated and consolidated LMOs evaluation and decision-making mechanisms
2.2.2 LMOs requests processed efficiently
2.2.3 Biosafety decision-makers and advisory structures appointed
2.2.4 Periodic administrative evaluation of LMOs sectorial authorization processes
2.2.5 Procedures for review of decisions

Outcomes and Outputs	Objectively Verifiable Indicators		Sources of Verification	Risk and Assumptions
	Baseline	Indicators (End of year X)		
Component 3: Building technical capacity in NCAs and related institutions for comprehensive biosafety management				
Outcome 3.1 Capacity to monitor and ensure regulatory compliance is increased.	- Coexistence between different production technologies is poorly understood in NCAs. - There are monitoring experiences and some inspection capacity in NCAs; however, expertise regarding LMOs is limited and personnel are untrained on regulatory issues. - There is a legal instrument for accreditation of biosafety auditors that allows the inspection function (and costs) of the Ministry of Agriculture & Livestock to be externalized for LMOs	- 15 NCA professionals and 5 official auditors receive training to increase their knowledge on monitoring and coexistence issues by at least 60%. (PY 3) - 5 civil (voluntary) observers are selected, officially recognized and accredited, and receive training to increase their knowledge on monitoring and coexistence issues by at least 40%. (PY3) - By PY3, CTNBio prepares, approves and implements an annual inspection plan for authorized LMOs that requires at least 5 field visits per year, for which funding is assured.	- Training workshops participant lists and curricula - Expressions-of-interest from civil observers (candidates) - Certificates and registration of newly appointed civil observers - Accreditation records 2010-2012 for biosafety auditors - Expert's evaluation based on initial and final tests to measure knowledge on monitoring and coexistence - Official CTNBio document approving execution of annual LMO inspection plan.	Personnel appointed by NCAs do not meet the suggested profiles. (R) Voluntary participation and financial sustainability allows coexistence and compliance to be monitored (A) Suitable and affordable experts (international /national) may not be available for training activities (R)
Outcome 3.2 Sufficient technical and	- There is limited capacity-building within NCAs on risk	- 10 regulators have been trained and increase their knowledge in LMO risk	Expert's evaluation based on initial and final tests	Sufficient and

human capacities are put in place for risk assessment and management for decision-making, considering both traditional and novel LMOs.	assessment and management - The country is receiving requests for both traditional and novel LMOs for use in agriculture, environment, health and animals.	assessment and management for decision-making by at least 85% (PY 3) - Leaflet for risk-benefit analysis and LMO management incorporates scientific and socio-economic factors, by explaining the sectorial and strategic relevance of novel LMOs, the methodologies that can be used to assess them, and the most cost-effective biosafety measures. (PY3)	and performance in using case studies. Corresponding sections of the risk-benefit and LMO management leaflet.	timely inputs are received from the CIAT-WB-GEF regional biosafety project. (A)
Outcome 3.3 Transboundary movements of LMOs will occur in accordance with the CPB, and in a manner that is understood and accepted by the private sector (exporters /importers)	- Trade procedures to date do not identify LMOs and there is limited border control capacity. - The CPB is unknown by customs and quarantine officers, though they may be aware of other environmental conventions such as CITES.	- 40 Customs and quarantine officers have been trained to process documentation related to importation /exportation of 2 of the 3 types of LMOs considered by the CPB. (PY3) - NCAs and border control authorities agree on LMO transit procedures and/or requirements (PY3)	- Expert's evaluation based case studies and performance in using case studies. - Register and filing system to log LMOs that are subject to transboundary movements	National authorities may not have adopted any decisions on LMO thresholds or types requiring identification. (R)
Outputs: 3.1.1 NCA-specific lists of personnel to be trained 3.1.2 Mechanisms to encourage the integration of civil observers into official monitoring and inspection plans 3.1.3 Official auditors and civil observers selected and trained 3.1.4 Annual inspection Plan for authorized LMOs is approved. 3.2.1 NCA-specific lists of personnel to be trained 3.2.2 Collaboration agreements for design and implementation of training activities 3.2.3 NCA professionals trained in specific areas of biosafety such as risk assessment and management of LMOs 3.2.4 Decision-makers briefed on the basics of biosafety and ongoing progress of the CPB 3.2.5 Leaflet for risk-benefit analysis and LMO management is available on decision making process. 3.3.1 NCA-specific quarantine and customs personnel selected and trained 3.3.2 Approved forms for identifying LMOs subject to transboundary movements				

Outcomes and Outputs	Objectively Verifiable Indicators		Sources of Verification	Risk and Assumptions
	Baseline	Indicators (End of year X)		
Component 4: Improved communication, education, public perception and participation in biosafety of all relevant stakeholders				
Outcome 4.1 Public awareness regarding the safe use of LMOs in Costa Rica is augmented through a formal educational strategy	- Civil society is either lacking information or misinformed about biotechnology & biosafety issues. - Formal education does not cover LMOs. - There is agreement between NCAs (technical level) that long-term formal and informal educational for dissemination of biosafety would be beneficial	- At least 90% of the components of a draft education strategy on LMOs and biosafety (TEACH: Training and Education in AgrobioteCHnology) and its action plan have been agreed between NCAs involved (PY3)	- Draft strategy officially received by the national authorities to be studied.	
Outcome 4.2 Public information sharing is promoted through greater access to biosafety information. (BCH)	- Current rate of "hits" on the BCH national portal is low (*actual rate will be determined by inception workshop*)	- Increase of 40% in BCH users of the national portal, by PY3	Comparison in number of BCH "hits" between PY1 and PY3.	Sufficient and timely inputs are received from the CIAT-WB-GEF regional biosafety project. (A)
Outputs: 4.1.1 Draft Education Strategy on LMOs and biosafety (TEACH: Training and Education in AgrobioteCHnology) and its Action Plan for carrying out long-term formal and informal educational actions for dissemination of biosafety 4.1.2 Cooperation agreements between NCAs, biotechnology industry, international organizations and/or other governments agencies 4.1.3 Improved knowledge and understanding of Ministry of Education advisors regarding safe use of biotechnology. 4.2.1 Internal tracking system for LMO requests 4.2.2 Informative dissemination material by sector 4.2.3 Mechanisms for public participation prior to granting LMOs authorizations is augmented 4.2.4 Biosafety guidelines, protocols, and updated data on national biotechnology and LMOs use (especially in the agricultural sector) are on the National Biosafety Webpage and/or BCH 4.2.5 Media tools and other informal education initiatives reproduced and expanded for other sectors				

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)

2. GEF SEC Review

GEFSEC Comments (MSP review date: 29 October 2009)	**Response**
Review Question 9. - Is the project design sound, its framework consistent & sufficiently clear (in particular for the outputs)? Table 3 on the Project Document (p. 29) provided the complementarities between UNEP-GEF and WB-GEF projects on BS in Costa Rica. There is one point that requires clarification: In Table 3 (p.34) it says "Workplan not yet defined at National Level". Since this refers to the WB-GEF project, how is that the coordination in communications has taken place? Please clarify what issues have not been coordinated so far and when they are going to be resolved. The PM at GEFSEC will be happy to have conference call to clarify this matter.	*At the time of elaboration of the ProDoc, specific information regarding the work plan for Component 1 (Development and implementation of pilot communication strategies) of the WB-GEF Communication MSP was not available. However, in the last months, the CNTBio -as the National Executing Agency of the UNEP-GEF Project- has begun to receive documentation from the National World Bank Project Coordinator about this subproject, which is a first step towards programming complementary activities, as intended under table 3.* *Coordination so far has taken the form of meetings and telephonic contacts, and has resulted in agreements to share information and outputs, and to mutually notify each other of key activities. Yet in concrete terms, it has not yet been possible to consider joining activities or efforts with the Communication MSP, given the incipient stage of its workplan. Greater clarity in this regard is expected however by inception of the current UNEP-GEF project; the National World Bank Project Coordinator will be invited to the inception workshop.* *In order to improve coordination and joint actions and activities, the CTNBio will be accompanying the development of guidelines, tools and information under the WB-GEF project and maintaining a constant link through two members of the CTNBio (and their substitutes) for technical discussions and cooperation.* *If further clarification is required, we would be happy to take up the offer of a three-way teleconference.*
Review Question 14. - Is the project structure sufficiently close to what was presented at PIF? There are significant differences between the PIF and the CEO Endorsement. First, the project was reduced from 4 to 3 years. Second, while the project management was kept	*Indeed the project was reduced from 4 to 3 years to facilitate execution and redistribute payments for the Project Manager. The 10% roof on project management was found to be insufficient to provide for a Project Manager over 4 years, and on further thought, the CTNBio also deemed that the project objectives could be achieved in 3 years, given Costa Rica's prior experience with UNEP-GEF*

at $71,043, the M&E was increased from $27,460 to $66,000 and a new component was added: Financial Administrative Costs for $35,141. All these three component add-up to $172,184 or 23% of the project total cost ($718,873). In all, the reduction in time (25%) is mirror by the increase in activities related to Project Management.

The GEF does not cover "Financial Administration Costs" as a separate component.

COMPARISON BETWEEN PIF and CEO ENDORSEMENT				
		PIF	CEO Endo	Change (PIF to CEO)
Comp	1	$181,000	$168,472	-$12,528
	2	$80,550	$104,717	$24,167
	3	$212,850	$171,500	-$41,350
	4	$145,970	$102,000	-$43,970
Sub-Total		$620,370	$546,689	-$73,681
M&E	5	$27,460	$66,000	$38,540
Proj Man	6	$71,043	$71,043	$0
Finance		$0	$35,141	$35,141
Sun Total		$98,503	$172,184	$73,681
TOTAL		$718,873	$718,873	$0

biosafety projects, and the progress already made in the country with regards to setting up institutional frameworks , mandates and targets for biosafety. Thus, the CTNBio considered it possible to accommodate the project's small budget across 3 years, without jeopardizing the expected outcomes.

With regards to the changes in budgeting, the GEF SEC PM kindly provided the comparative table inserted opposite, for ease of reference. Based on bilateral discussions, the following changes were agreed to and have now been incorporated into the ProDoc (Appendix 1) and CEO Approval Request (Results Framework table):

- Financial Administrative Costs have been reallocated and integrated into the technical components, and are no longer identified as a stand-alone component. That this resulted in increased amounts (with respect to PIF values) for each component is now mentioned in Part IV of the CEO Approval Request.
- The cost of M&E was increased due to additional monitoring and evaluation activities arising after careful confection of Appendix 7 (Costed M&E plan), and a more thorough consideration of M&E requirements and benefits. The M&E amount set at PIF stage was modest, and only considered a tentative estimate of external evaluation and audit costs. The inclusion of "performance tests" to determine the extent to which the project is able to generate positive impacts is an important feature of the current M&E plan, and in part explains the higher budget; this has now been explained in Part IV of the CEO Approval Request.

Review Question 19. - Is the GEF funding level of project management budget appropriate?

While the project management was kept at $71,043, the M&E was increased from $27,460 to $66,000 and a new component was added: Financial Administrative Costs for $35,141. All these three component add-up to $172,184 or 23% of the project total cost ($718,873). The GEF does not cover "Financial Administration Costs" as a separate component.

See above.

Review Question 20. – Is the GEF funding level of other cost items (consultants, travel, etc) appropriate?

GEF is contributing $392/week for local

Sharing experiences between projects managers resulted very useful in previous UNEP-GEF Biosafety projects and was a key means to learn from other countries; this is likely to be the case for the coming series of NBF Implementation

consultants and $2100/week for international consultant. Please clarify the purpose and need for 3 regional meetings with national and regional UNEP-GEF project coordinators. Is Costa Rica on board with this expense?	*projects where a more practical and operational focus will make the sharing of experiences and lessons learnt even more valuable.* *All NBF Implementation projects in the Latin American region led by UNEP have agreed to set aside a small amount of funding (amounts are to their discretion) for periodic regional meetings where project managers can meet as a group and also review implementation issues with the UNEP Task Manager. It is likely that the true number of meetings will be 2 rather than 3, but the budget has been formulated to consider the maximum number feasible; the resources for 1 meeting will be reprogrammed if this meeting does not take place.* *Not only are such exchanges a crucial means of project supervision but they also provide an opportunity to delve into technical issues that national projects may have in common. One example is the administrative component, which in operational terms carries the brunt of CPB tasks. The CTNBio is confident that regional meetings will be useful to move towards harmonizing legislation and administrative systems, facilitating joint training in risk assessment and learning about participatory processes and communication efforts carried out by other countries. Even when the project is not regional, is it important to be aware of the state of implementation of other projects in the same region, as well as country realities and complementarities, especially considering that most Central American countries are signatories of Free Trade Agreements, are part of the LAC cohort of UNEP-GEF NBF Implementation projects and that some activities could be developed in coordination.*
Review Question 23. - Has the Tracking Tool3 been included with information for all relevant indicators? The Tracking Tool for Biosafety, as protested in the GEF Web Site was not included in the Project Document or CEO Endorsement (http://thegef.org/interior_right.aspx?id=230). The Appendix 15 of the Project Document entitled 'Tracking Tool" is no substitute for the GEF Tracking Tool.	*The Tracking Tool for SO-3 has now been completed and exchanged for the correct format in Appendix 15.*

Annex C: Consultants to be hired for the project

Position Titles	US$/ person week	Estimated person weeks	Tasks to be performed
For Project Management			
Local	455.4	156	Project Manager: Coordination of the entire project
International	3850	4	Mid-Term Reviewer and Terminal Evaluator (external evaluations under M&E)
Justification for travel, if any: - Project Coordinator will travel up to 3 times to regional coordination workshop, in Panama City where UNEP is based, to meet with other Project Coordinators from concomitant NBF Implementation projects. - International consultants recruited for Mid-Term Review /Evaluation and Terminal Evaluation will require travel costs (air fare + DSA) to Costa Rica to be covered by the project.			
For Technical Assistance			
Local			
Legal expert	400	25	Coordinate with Public Business Manager to elaborate the Legal proposal
Public Business Manager	500	16	Prepare an administrative system proposal in coordination with the legal expert
Press and publicity expert	417	12	Design strategies to help the lobby expert in order to obtain the political support to implement the legal proposal
Expert in BCP with expertise in guidelines	312	16	Develop guidelines for summiting applications for article 1 (FFPs) and Article 18 to NCAs
Agriculture and regulation expert.	750	16	Design legal norms and guidelines for coexistence for 6 crops.
Biotechnology expert	400	25	Obtain political compromise, and prepare a draft policy on biotechnology and biosafety.
Legal expert	300	20	Prepare a draft mechanism to address Art. 27
Biotechnology expert	231	52	Design regulatory guidelines form LMOs, certification issues and liability and redress user.
Biotechnology expert	289	52	Elaborate guidelines on risk management and risk assessment based on national and international guidelines, harmonize and officialise the guidelines with NCAs.
Business Manager	625	8	Manage and implement the operative and administrative system.
IT expert	469	16	Create a safe NCA authority network for processing applications and making decisions
Biotechnology expert	270	26	Create guidelines and train official customs, human and animal health technicians, park rangers and civil observers.
Biotechnology expert	577	26	Develop a strategy of formal education about Biosafety of the Biotechnology for primary and secondary school
Advisors group (max 4 people)	555 (p/p)	36	Advisors: education specialist, pedagogues, Biotechnologist, Specialist in curricula and schools programmes
IT expert	250	12	Improve the Web page and linked with other national database and to harmonize the

			information of Costa Rica in FAO, IICA, BCH, AGBIOS, FDA, BIO, Europe database, etc, in the National Web Page
International			
Biotechnology Expert	3000	2	Lobbying regulations and national policy among Ministers, Vice ministers and law- and law-makers.
Biotechnology Regulation expert	1875	8	Elaborate 2 workshops on case studies of traditional and Novel LMOs (risk assessment and management) to decision makers

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 objective has been fully achieved in schedule due mainly to a close coordination among the PCU, the Biotechnology Programme and UNEP Task Manager.

B. Describe if any findings that might affect the project design or any concerns on project implementation. In considering the implementation of the project, the budgetary limitation on Project Management resulted in the project duration being shortened (from four to three years) and certain activities programmed in the original PIF eliminated, in order to remain within the 10% range. This also meant that an additional budget had to be calculated, over and above the project personnel and operational running costs considered under Project Management, to cover the fees for third party financial administration (by OIRSA) as receiving donor grants within the Costa Rican national treasury or institutional budget implies huge administrative difficulties, which could impair and significantly delay project implementation.

C. Provide detailed funding amount of the PPG activities and their implementation status in the table below:

Item	Implementation Status	GEF Amount ($)				Co-financing ($)
		Amount Approved	Amount Spent To-date	Amount Committed	Uncommitted Amount*	
Personnel Component	concluded	6,000.00	6,000.00			6,480.00
Consultants	concluded	2,400.00	2,400.00			
Administrative support	concluded					840.00
Meeting conferences	concluded					2,000.00
Total		8,400.00	8,400.00			9,320.00

* Uncommitted amount should be returned to the GEF Trust Fund. Please indicate expected date of refund transaction to Trustee.

PROJECT DOCUMENT

SECTION 1: PROJECT IDENTIFICATION

1.1	**Project title:**	Implementation of the National Biosafety Framework of Costa Rica
1.2	**Project number:**	GFL/_____ (GEF ID: 3629) PMS:
1.3	**Project type:**	MSP
1.4	**Trust Fund:**	GEF
1.5	**Strategic objectives:**	
	GEF strategic long-term objective:	BD1
	Strategic programme for GEF IV:	BD-SP6
1.6	**UNEP priority:**	Environmental Governance
1.7	**Geographical scope:**	National
1.8	**Mode of execution:**	External
1.9	**Project executing organization:**	The National Technical Commission for Biosafety
1.10	**Duration of project:**	36 months Commencing: March 2010 Completion: March 2013

1.11	**Cost of project**	**US$**	**%**
	Cost to the GEF Trust Fund	**718,873**	**45**
	Co-financing**: Govt contribution**		
	Cash		
	Sub-total		
	In-kind	**762,232**	**55**
	Sub-total		
	Total	**1,481,105**	**100**

1.12 Project summary

The project will help consolidate Costa Rica's national capacity for the implementation of the Cartagena Protocol on biosafety. The Government of Costa Rica, through its National Technical Commission, stakeholders and national competent authorities has identified the elements of a long-term national plan on Biosafety, and has placed a high priority on developing a framework as reflected in its National Development Plan by promoting research on biodiversity friendly goods, including supplies, demands, barriers and opportunities. This proposed GEF project will address short and medium-term aspects of the national biosafety framework related to the trans-boundary movement in compliance with the context of the Cartagena Protocol and other International agreements.

Specifically, the project will develop the national capacities in biosafety required to: evaluation and strengthening of legal and regulatory framework build capacity and establish an operational system for risk assessment and monitoring; and improved communication, public perception and participation in biosafety of all relevant stakeholders. The development of national capacities in these areas will consolidate the national framework for biosafety management. The project has been designed to ensure a high level of coordination and synergy with WB-GEF sub-regional project, and builds on the experience accrued in Costa Rica on public health, plant and animal health and biodiversity conservation efforts, especially the biodiversity enabling activities, and promotes cross-sector synergies.

The overall goal of the Medium-Sized GEF Project (MSP) is to implement Costa Rica's National Biosafety Framework and to fulfil the country's obligations as a Party to the Cartagena Protocol on Biosafety (CPB); in order to contribute to the safe use of biotechnology and reduce the potential risk associated to LMO use on biodiversity, human and animal health. Costa Rica began working towards this goal through the UNEP-GEF Project "Development of a National Biosafety Framework" (NBF), as a result of which a draft biosafety law was prepared and the ratification of the Cartagena Protocol was attained. In addition, Costa Rica has successfully implemented the Biosafety Clearing House mechanism, through the UNEP-GEF Project "Building Capacity for effective participation in the Biosafety Clearing House" (BCH). As a next step, Costa Rica needs to establish a policy in Biosafety, as well as specific regulations, particularly concerning Living Modified Organisms (LMOs) intended for Food, Feed or Processing (FFPs) in accordance with the CPB, also is necessary to establish regulation in human and animal health too. In this field of work, cross-sector regulations as well as in-country coordination need to be enhanced in order to integrate other Ministries into the processes of evaluation, authorization and inspection of FFPs and other LMOs in the livestock, industrial and bioremediation sectors. In addition, biosafety regulations need to be harmonized with current legislations, as well as with commercial and social considerations according to the CPB.

The proposed MSP aims, not only to allow Costa Rica to conclude efforts initiated through prior initiatives, but also to achieve sustainability for CPB implementation, by creating sufficient capacities, tools, and establishing a permanent mandate in National Competent Authorities (NCAs), which will allow the country to make technical and management decisions that will ensure greater safeguards to the environment as well as human and animal health. In Costa Rica, LMOs have so far been introduced in the agricultural sector at an experimental scale or for seed production purposes, but their continued use, up-scaling or commercial production for food and feed purposes are to be implemented.

ACRONYMS AND ABBREVIATIONS

BCH	Biosafety Clearing House
CBD	Convention of Biological Diversity
CONAGEBIO	National Commission for Biodiversity Management
CPB	Cartagena Protocol on Biosafety
CTNBio	National Technical Commission for Biosafety
FFPs	LMOs for Food, Feed or Processing
GM	Genetically Modified
IICA	Inter-American Institute for Agricultural Cooperation
LMOs	Living Modified Organisms
MEP	Ministry of Education
MAG	Ministry of Agriculture and Livestock
MINAET	Ministry of Environment, energy and telecommunications
MICIT	Ministry of Science and Technology
MSP	Medium Sized GEF Project
NBF	National Biosafety Framework
NGOs	Non Governmental Organizations
NCC	National Coordinating Committee
OIRSA	International Regional Organism for Plant and Animal Health
ONS	National Seed Office.
NCAs	National Competent Authorities
SFE	Phytosanitary Service of the State
SENASA	National Service for Animal Health
WB-GEF	World Bank-GEF National Project

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SECTION 2: BACKGROUND AND SITUATION ANALYSIS (BASELINE COURSE OF ACTION)

2.1. Background and context

1. To date, Costa Rica has been exceptionally successful in exploiting linkages between environmental protection, development and poverty reduction, e.g. by setting aside 25% of land to protected areas and putting in place innovative ways for encouraging citizens to adopt environmental practices. Nevertheless, the country -like many others- is still facing the increasing challenge of sustainably exploring the agriculture-environment nexus in a way that will favour economic growth, facilitate trade and maintain vital ecosystem services. Considering that the economy of Costa Rica depends on agriculture together with tourism and electronics, with the principal agricultural products being coffee, tropical fruits and beef, this is not a trivial issue. Fortunately, the Ministries of Agriculture and Environment are strongly committed to finding solutions that stimulate productive, sustainable agriculture, reduce poverty among smallholders and integrate conservation practices into rural landscapes. The Government has shown its strong commitment towards preserving biodiversity though progressive environmental policies that gives value to biodiversity resources and services. One example are the bioprospecting agreements pioneered by National Institute of Biodiversity that have granted access to the country's genetic richness in exchange for knowledge, opportunities and other monetary and non-monetary benefits. The country has thus become a global leader on environment issues and has developed markets for global and local environmental services, contributing to rural development and fostering conservation of biodiversity, preservation of forest eco-systems on private land, and the production and sale of environmentally friendly products.

2. Notwithstanding this ambitious environmental policy, Costa Rica has also taken steps towards better and more effective production technologies, including agricultural biotechnology, reason for which the National Technical Commission on Biosafety (CTNBio) was established in 1992 under the framework of the Biodiversity, Animal Health and Phytosanitary Protection Laws and its regulations, enforced by the Ministry of Agriculture and Livestock. Costa Rica's first applications for LMOs came between 1991 and 1992, and concerned the field testing of new genetically modified (GM) varieties of cotton, soya and maize. Today, the main cultivated LMOs are cotton and soya, none of which is commercialized nationally, as GM crops are currently permitted only for seed production or for field testing. For the time being, releases for commercial production or for internal use as food or feed have not taken place.

3. The sowing of cotton and soybean GM crops, has not meant an environmental important risk for several reasons: a) Costa Rica is not a center of origin of any of the liberated species, except the rice, which possesses three wild species recognized in the country (*Oryza latifolia, O. grandiglumis* and *O. glumaepatula*) and that are in localities identified and removed from the principal rice production zones; b) the sowings have not been realized to commercial scale and, c) the OVM more extensively cultivated, the cotton and the soybean, do not have relatives wild or related in the country, which limits the possibility of transfer of genes. But the principal reason is that the biosafety, annotated to the seeds GM productions, works if it has a solid scientific base.

4. As a result of these endeavors, and as the entity behind the authorization of GM crops in Costa Rica, the CTNBio has gradually gained confidence in its ability to make biosafety decisions. The in-

house experience gained over 17 years has allowed the country to accumulate substantial knowledge on LMO management and risk assessment, albeit circumscribed to the agricultural -and particularly seed-producing- sector. Socioeconomic benefits have also accrued from these agricultural practices: a) activation of local economy, b) development of national enterprises, c) employment d) demand of technical staff e) land use improvement f) cleaning off weeds of potentially productive lands, g) national and international investment in facilities and specialized equipment. Hence, Costa Rica views itself as an example and leader in the region, and sees GM technology as having major potential economic, social and environmental benefits. However, the continued use, up-scaling, diversification and possible commercialization of LMOs will undoubtedly put the country's biosafety system to test. The scenario that the country is indeed facing is one that will require agricultural co-existence mechanisms, food safety assessments and a more comprehensive and coordinated biosafety framework, in order to allow productive systems to innovate, agriculture to diversify, GM food consumption to be innocuous, and new biotechnology applications to develop locally.

5. Costa Rica, together with international collaborators, research partners and private companies, has invested -and is still investing- significant resources in LMO development and evaluation. Indeed, having first become a winter nursery for seed markets, the country now performs local research with LMOs. Costa Rica has got enough facilities, equipment and scientifically trained staff to perform genetic engineering in plant breeding of species locally important, or to solve local Phytosanitary issues which are not usually taken into account by large companies. This kind of situations have made possible that one of the main research lines currently, happens to be in banana diseases, which might have an economic, agricultural and environmental impact of importance for the country.

6. Thus, biosafety management in Costa Rica still represents a challenge and an ongoing effort and the lack of a comprehensive biosafety framework is considered a disabling condition for the diversification of agriculture and the search for solutions to sectorial or productive problems. Indeed, the development and application of biotechnology to solve food productions problems could have a positive impact in preventing the deforestation that results from expanding agricultural limits, as well as promoting an "environmentally friendly" research baseline. Food production and security and the trade of commodities are indeed increasingly strategic issues as developing countries move into the 21st century. Today, Costa Rica imports 99% of maize, soybean and cotton destined for human consumption and animal feed, mainly from countries that are currently producing LMOs. If the country is to consider the commercialization and consumption of locally produced LMOs, the regulatory system will likely need to incorporate their evaluation, as part of the safeguards that need to be in place for greater consumer confidence. Likewise, the increased use, production and marketing of drugs, produced or derived from recombinant DNA technology, for application in humans or animals, will also require increasing efforts and a new range of capacities in order to understand and manage the risks associated with these novel or non-agricultural LMOs. Indeed, the rate at which new LMO types are developing indicates that novel GM applications will likely soon be knocking at the regulatory door.

7. As an environmentally-conscious nation, Costa Rica was amongst those countries that signed the Cartagena Protocol for Biosafety (CPB) in May 2000, knowing full well that internal LMO production would steadily rise (the first application was received in 1991) and that its biosafety framework would need to be concomitantly and strategically strengthened. Costa Rica first began working towards this goal through the UNEP-GEF Project "Development of a National Biosafety Framework" (NBF), executed between May 2003 and August 2005, as a result of which the ratification of the CPB was attained in 2007. The country then opted for a second UNEP-GEF project to "Build Capacity for the Effective Participation in the Biosafety Clearing House (BCH) of the Cartagena Protocol" which took place between July 2006 and January 2008. From these important initial efforts, both the CTNBio and the Biotechnology Programme of the Ministry and Agriculture and Livestock (MAG) were consolidated as the main coordination mechanisms in biosafety. The active participation of various

public and private institutions interested in establishing a national regulatory framework for LMOs was also achieved and lead to a consensus law proposal, accompanied by other regulatory proposals and tools.

8. Since this project concluded, Costa Rica has not let down its guard with biosafety; there has been both institutional progress and scientific advances. There has also been a further UNEP-GEF project that successfully increased the country's capacity to effectively participate in, and benefit from, the CPB's Biosafety Clearing House (BCH), and a regional WB-GEF project with International Centre for Tropical Agriculture (CIAT). The latter initiative, which involves the University of Costa Rica at the national level and 3 other Latin American countries (Peru, Colombia and Brazil), entails two multi-country projects that, together, will address scientific, technical and communication capacities relating to biosafety. The current UNEP-GEF proposal is thus intended as a further extension and complement to Costa Rica's national biotechnology and biosafety efforts, aimed at increasing the country's capacity to manage new types of LMO risks, or risk factors, including those associated with transboundary movements, while at the same time being able to capitalize on the benefits of new biotechnology products, and to produce them locally.

9. In accordance with CPB guidance, strengthening biosafety risk assessment and management systems is a key concern in Costa Rica. For this, the current UNEP-GEF project is strongly focused on building and levelling technical capacities among different National Competent Authorities (NCAs). As the main NCAs, biosafety capacity has traditionally rested with the MAG and CTNBio, yet the current scenario and proposed project require that other public agencies become more pro-active as biosafety NCAs. Importantly, putting in place a harmonized system implies technical, operative, administrative and regulatory tasks, in order to create an articulated basis for biosafety decision-making, alongside policy definitions to guide NCAs over the medium-term. This project will not only allow the Costa Rican government to conclude and continue with on-going efforts, but will also create the necessary institutional framework for having transparent, sustained and coordinated biosafety procedures, and for continuous capacity-building. In all, Costa Rica aims to have in place a functional biosafety system that pivots around effective evaluations, consultations, science-based management decisions, inspections and follow-up, and permits full compliance with the CPB.

2.2. Global significance

10. Latin America is regarded as one of the richest regions in terms of biological diversity. Its natural resources and landscapes have allowed the region to build a large production platform and become one of the biggest food producing regions of the world. This southern continent is renowned for being centre of origin of global staple foods, such as maize and potato, added to economically important species like tomato, pumpkin and tropical fruits. Since agriculture was broadly adopted in Latin America several centuries ago, it still represents today a core component of region's economy. The region produced in 2007 alone more than 1 253 million tonnes in agricultural goods, across 187.3 million hectares, according to FAO.

11. The region is far from oblivious to biotechnological advances; in fact LMOs are grown in at least 10 Latin American countries, with Argentina and Brazil ahead as the main producers. In this sense, being mega diverse and key natural resource providers, Latin American countries participated intensely during the Cartagena Protocol negotiations and meetings, given the joint interest to stay ahead in the productivity race while at the same time take into account the environment and human health. Given the adoption rate of agricultural LMOs and the growth in traded commodities and agricultural goods in Latin American countries, biosafety has become an important means for competing more effectively and responsibly in the international market.

12. This situation is particularly important to Central American countries, which are frequent importers of most of their grain supplies, and yet, their agricultural sectors are an important income source for

big, medium and small producers. For this particular sub region, only Costa Rica and Honduras have been producing LMOs: Costa Rica has more than 1 000 hectares of LMOs as winter nursery or as experimental grounds, whilst Honduras produces GM maize commercially since 2002, reaching close to 9 000 hectares in 2008. Also particular to this sub region is the high global value of its biodiversity, with Mesoamerica being centre of origin and of genetic diversity for many domesticated species. Costa Rica is recognized as a mega-diverse country, and is home to many wild species related to crop varieties. This country is indeed well known for its natural beauty and unique biodiversity. Although half of the nation's 4 million people are concentrated in the Central Valley, deforestation for agriculture and timber production is an important biodiversity threat throughout the country. By contrast, national parks, forest reserves, and indigenous reservations, and other public and private protected areas account for 27% of total land surface in Costa Rica, giving the country one of the highest percentages of protected areas in Latin America and underscoring the importance ascribed to environmental protection by both Costa Rican society and Government.

13. Several Central American countries, including Costa Rica, have become aware of the costs and benefits of protecting their natural resources from hypothetical threats to biodiversity, particularly considering the potential of biotechnology and the likelihood that further developments will gradually include more animals and tropical crops. As a widely farming country, but also largely dependent on commodity imports, Costa Rica is convinced of the importance of carefully balancing its development goals in a way that will both benefit agriculture and preserve its natural resource base. For this, the introduction of a co-existence regime for all types of agricultural options may be the most sustainable strategy. Despite the fact that no harms on the environment have yet been documented, the potential impacts of novel LMOs on the local environment also need to be considered in light of the shifting scenario and uncertainty factors attributed to global warming. Costa Rican regulatory agencies must think carefully about novel LMO developments when designing science-based decision-making mechanisms, particularly for LMOs that present a comparative advantage in adverse environmental conditions, such as LMOs for sequestering contaminants (bioremediation) or atmospheric carbon, for bio fuels and sustainable energy uses, for plastic and garbage degradation, for water purification, for agricultural production under extreme weather conditions (e.g. drought, floods or chills) or as bio-factories for new DNA recombinant medicines, industrial compounds or animal products and sub-products. It is also yet to be seen if society will as readily accept these new products as it has other biotechnology applications that are not subject to the same controversy as GM foods.

14. In light of the expansive potential of LMOs and of the contentions surrounding biotechnology food products, several global, regional and national initiatives have arisen to help developing countries put in place regulatory frameworks and acquire technical capacities. Among these initiatives are the initial global UNEP-GEF projects that assisted over 130 countries to take the first steps towards creating their NBFs and participating effectively in the BCH, in which most Central American countries participated, and the current IICA Hemispheric Programme on Biotechnology and Biosafety, which is oriented towards establishing technical cooperation around issues of the CPB, capacity building, identification needs, scientific information for decision makers, among others. There is also the WB-GEF regional project in which Peru, Colombia, Brazil and Costa Rica are participating through CIAT and national partners, and the current generation of UNEP-GEF "implementation" projects, designed to step-up efforts to make countries' NBFs operational and fully compliant with the CPB. Given its commitment to biosafety, Costa Rica like many Latin American countries has signed up for several of these initiatives. It firmly believes that implementation of the CPB, through implementation of a national regulatory framework that contemplates an efficient administrative system, is responsive to the requirements of modern trade and international agreements, and allows for capacity-building and proper public information issues, will contribute to successfully integrate it into the globalized world.

2.3. Threats, root causes and barrier analysis

15. A number of significant issues preventing Costa Rica from properly implementing the CPB have been identified. Many of these represent barriers which the current project will seek to address, and relate to threats and root causes that effect biodiversity due to systemic failures.

Potential threats to biodiversity and the environment:

16. ***(A)*** *Threats from unauthorized releases or poor (unprepared) decision-making.* Despite the fact that Costa Rica has been performing risk assessments since 1991 for agricultural LMOs, there are still legal gaps that allow unregulated importations of LMOs intended for Food, Feed or Processing (FFPs). Likewise, an unintended liberation of any LMO (animal, microorganism, etc) might represent a threat to biodiversity, particularly if the responsible NCA has not fully developed its legal and administrative capacity to perform risk assessments and response promptly to mitigation measures. Capacities development in Costa Rican NCAs has also been uneven. Since agriculture LMOs are the only kind of LMOs that have been evaluated in Costa Rica, capacities concerning food safety, animal, environmental, human health and industrial LMOs are considerably lower or nonexistent. Despite the fact that capacities and research in biotechnology have been developed in universities and research centres, an asymmetrical demand has required more capacities on agriculture than any other area.

17. ***(B)*** *Threats from the foregone opportunity of using GM technology to increase the efficiency of agricultural and bioremediation methods.* Costa Rica is a megadiverse country that produces and trades in LMOs; it recognises the value of its natural resource base but also acknowledges that biotechnology, like all innovative technologies, can bring about benefits as well as risks. Biosafety measures are increasingly becoming a hurdle that needs to be adroitly overcome to both comply with the CBP and yet trade without mayor difficulties. Moreover, many biotechnology advances are being kept away from most Central American producers since their governments are still struggling with regulatory issues on many levels. Therefore, there are opportunity costs associated with the option of no-action or of over-regulating biosafety, whereby the threats to the environment (e.g. degradation from intensification of agricultural practices, or habitat loss from increasing agricultural surfaces, or contaminated lands unable to be remediated through traditional methods) accrued by failing to adopt GM technology may be more significant than those presented by the technology itself and which could be managed through biosafety. The costs of these foregone opportunities are not only potential threats to biodiversity but would also be part of undercurrents that undermine the country's sustainable development model.

Root causes underlying the potential threats:

18. ***(A)*** *Incomplete regulatory and policy frameworks, poor enforcement and coordination, with low budget and low priority assigned to biosafety.* The combination of insufficient budget, political priorities and legal gaps has prevented NCAs from developing minimally their biotechnology regulation. Moreover, the absence of an enforced policy or law stressing the obligation of all NCAs to comply with CPB regulations has created an unbalanced and –in some cases- weak baseline for a coordinated and appropriate framework. Since no NCA has yet needed to make decisions concerning biosafety, with the exception of the Phytosanitary Service of the State (from within the MAG), added to the absence of a unified legal obligation to do so, most responsible institutions are lacking a strategy to face these requirements and to integrate their efforts in order to jointly implement a biosafety framework.

19. ***(B)*** *Insufficient Research and Development (R&D) and technology renewal, misinformation about modern biotechnology, and the perception that its applications could harm agriculture and ecotourism (two very strong sectors)* Costa Rica is highly reliant on agriculture and ecotourism. This situation puts the Country in a particular condition where nature concerned groups -due to the importance given to natural resources in the tourism industry- have achieved a significant level of influence on the general

public which has had as a result a commonly negative view about GMOs. Therefore, even a misconception rose from a combination of factors such lack of accurate information and misunderstood risks to biodiversity; at national level a fiery debate has grown about the introduction and use of GM technology in agriculture. Moreover, misinformed producers are reluctant to agree that other producers might be interested in adopting the technology. This position is somehow motivated by the decreasing levels of R&D that production technologies have been given during the last two decades; generating a poor technological renewal culture among small and medium size producers. In addition, a debate dominated widely by environment protectionists NGOs has reduced significantly the acceptance of research results and scientific based opinions in the general public.

Barriers that need to be addressed to reduce potential threats:

20. ***(A)*** *Diminished biosafety capacities in technical, administrative and numeric terms, with the need for properly trained personnel in NCAs; putting biosafety on the political agenda.* Currently, Costa Rica has ratified the CBP, which will demand direct actions from NCAs. However, not having the necessary capacities in all NCAs represents a strategic hurdle in the implementation of a national biosafety framework that needs to be addressed promptly. In spite of this, Costa Rica has experience in endeavouring inter-institutional efforts in different areas but still relies on a national policy -to establish the bases for implementing the CPB and integrate national efforts- for this to occur. The main areas where capacities and procedures need to be developed are concerning FFPs and Advanced Informed Agreements (article 7 of the CPB); the decision to tackle these issues and put in place the necessary legal, technical and administrative instruments has tended to be delayed by the corresponding NCAs and authorities, until either a national law or ratification of the CPB materialized the need to act.

21. ***(B)*** *Raising awareness on the risks and benefits of different production models; putting coexistence on the private sector agenda.* The lack of legal and administrative measures to assure that coexistence between different productive practices occurs responsibly can jeopardize access to different national and international market niches. In light of its reduced terrestrial surface, Costa Rica is globally-speaking a minor producer of agricultural goods. Nevertheless, production technologies have been diversifying and growing steadily over the last years, with certain expertise attained in strengthening niche market strategies, such as organic exports. As a result, a significant number of producers have been certified as organic or have been producing under specific norms in order to meet niche market requirements. Since GMOs are relatively new and often banned from particular farming practices, there is a need to protect all forms of production. This means that regulatory agencies need to assure that coexistence among producers is based on technical and scientific criteria and also to raise awareness among those implicated. Although some resistance to coexistence practices can be expected from specialized producers, under Costa Rican law, private entities have the right to produce choosing different technologies, as long as no damage is inflicted between parties. Under this scenario, it is therefore strategic for regulatory agencies to prepare a proper response and liaise closely with the private sector, if the country is to ably face future production demands.

2.4. Institutional, sectors and policy context

22. In Costa Rica, most of the capacities and know-how in biosafety relate to GM crops; particularly winter nursery dynamics and seed production. The institutions with the most interaction with LMOs are therefore those of the MAG: firstly the Phytosanitary Service of the State (SFE) whose Departments of Quarantine and Exportations have the responsibility of controlling transboundary movements of plant species and keep a close coordination with the Biotechnology Program and the CTNBIO; and secondly, the National Seeds Office (ONS) responsible for supervising, in coordination with the SFE, those activities which purport the handling of seeds, GM or otherwise. Most regulatory actions in biosafety are contemplated within the agricultural legal framework: Phytosanitary Protection

Law (N° 7764); Seeds Law (N° 6289); Service for Animal Health General Law (N° 8495); Biodiversity General Law (N° 7788). In all of these, the CTNBIO is consistently acknowledged as the main mechanism for evaluating LMO submissions under technical-scientific bases, by naming the CTNBIO either as a decision-making body (N° 7788) or as a technical advisor (N° 7764 & 8495).

23. In addition to the MAG, the CTNBio represents the technical opinion of several Ministries: Environment, Energy, Mines and Telecommunications (MINAET); and Science and Technology (MICIT), and also represents the ONS, the National Science Academy, and NGO's from the environmental field. CTNBio was created in 1990, with the aim of elaborating norms, mechanisms and measures through which to guarantee greater control over aspects derived from the research, production, application, release and introduction of LMOs that could cause concern over human health and the environment. Based on these functions, the State is able to fulfil its constitutional mandate to provide and promote a healthy and ecologically balanced environment (Arjona, 2004).

24. Although CTNBio's mandate seems all-encompassing and its main function is to perform risk assessments in order to advise national authorities on the acceptance or refusal of specific LMOs, its scope is restricted to those LMOs considered under the three laws on which the CTNBio relies. Therefore, if those Laws do not cover an LMO, the Commission is unable to analyze and recommend decisions concerning its use. Furthermore, this Commission is an advisory body to the National Service for Animal Health (SENASA), yet SENASA has no representation within the CTNBio (unlike the MINAET that has two members). The same omission occurs with the Ministry of Human Health, an entity that has traditionally stayed on the margins of the development of the national biosafety framework, but that is presently showing a favorable disposition toward this task. Despite these formal exclusions, these institutions are recognized as key NCAs and are regularly invited to partake in meetings of the CTNBio. They have also been included in the planning of the current project, and will be involved throughout its implementation.

25. To date, the CTNBio has not approved any LMO intended for food or feed on the local market; all approvals have been intended for seed production of maize, soybean and cotton; and their traits were mainly insect resistance, disease tolerance, and weed tolerance, among others. Moreover, the University of Costa Rica, CATIE and private entrepreneurs have been granted authorization to perform research in crops such as rice, maize, banana, plantain and pineapple; the objective of such research varies from resistance to diseases and herbicide tolerance to the modification of carotenoids content or flowering control (Valdez et al. 2004a, Valdez et al. 2004b Valdez et al. 2004c).

26. From the beginning, this experience with LMOs favored the organization of a preliminary regulatory framework in biosafety, the strengthening of local research, the training of personnel and scientists in government institutions, the formation and growth of local companies, the contracting of qualified personnel, and the attraction of national and foreign investments in facilities and equipments. This in turn allowed to Costa Rica to position itself in Latin America as one of the first countries with local capacity in the fields of biotechnology and biosafety. At the international level, Costa Rica has also been a pro-active and consistent participant in all of meetings of the CPB, from the negotiations leading up to the signing and adoption of the Protocol, to more recent COP-MOPs, and in establishing working contacts with several countries. The discussions and commitments of the CBP have allowed Costa Rica to understand the needs and priorities of other Parties in biosafety, and the diverse meetings (IPPC, BCH, CBD and CBP), including those of the *Codex Alimentarius,* have provided an opportunity to exchange ideas and strategies with countries of the region as well as other mega diversity countries. In short, the cumulative effect of this biosafety experience has, over time, provided national authorities and organizations with the expertise needed to undertake effective technical-administrative processes for decision-making in a complex field.

27. Overall, the institutional facet of this experience has been positive, with important lessons learnt along the way. The first of these is that biosafety can be instrumental not only due to its environmental benefits, but also due to the opportunity (and means) it provides for mainstreaming biodiversity considerations into sectorial principles, decisions, plans and actions. Its multi-disciplinary and transversal social bases are conducive to a participatory approach and to building social capital, all assets that have proven to be beneficial for democracy and can be further reinforced through the information-sharing requirements of the CPB. Thus, promoting the safe adoption of agro biotechnology can be fully compatible with building trust among both its deterrents and users. Through the development and implementation of a strong biosafety framework, balances, commitments and synergies can be created and legal certainty and clarity provided. Furthermore, risk assessment based on scientific facts is an indispensable tool for abiding by firm principles and for attaining scientific clarity (though perhaps not full certainty). When it comes to decision-making, however, this technical approach should not preclude the proper consideration of social and economic issues, and the respect of participatory process and results.

28. The second lesson is that information exchange has proved to be the easiest way to achieve transparency and accountability among stakeholders. This conclusion was reached after finishing the UNEP-GEF project for Effective Participation in the BCH, whereby IT has shown to be a powerful tool in risk communication, able to create an accessible and updated mechanism to share information and build a solid, visible and respected regulatory system.

29. The third and most important lesson is that capacity building in biosafety is an ongoing process; the more prepared the NCAs and other organizations, the better the response that Costa Rica will have. Moreover, it functions differentially on several levels, so will unfold through different dynamics and paces. After regulating agricultural LMOs for over 15 years, Costa Rica is convinced that only through field experience can biosafety be understood. In the same spirit, NCAs have learnt that regulators need to make their decisions based on data, but these decisions will be strengthened by integrating feedback from a monitoring and control system.

30. A final (and related) lesson, learnt during the execution of different projects, is the importance of having a consultative national committee where stakeholders can be empowered during both the project planning stage and its implementation. In order to make the most of the resources available, and undertake efficient activities, it is necessary to first scope for support and lobby for the project among the Heads of the institutions involved. Likewise, the capacity building potential of regularly consulting the committee is a value-added. In effect, the broader the socialization of the project, the better the response obtained from stakeholders and participants, and the stronger the foundations laid for biosafety.

31. Though biosafety in Costa Rica did not begin with UNEP-GEF, it is clear that the two prior UNEP-GEF projects, from which many lessons were derived, did permit significant advances to arise across several institutions, sectors and even state powers. These projects (”Development of the NBF of Costa Rica” and “Building Capacity for Effective Participation in the BCH of the Cartagena Protocol”) were key in articulating a constructive analysis of CPB requirements and setting Costa Rica on the path of a more comprehensive biosafety framework, in line with the CPB and CBD. These lessons learnt have also fed into the current process of project design, by promoting a wider dialogue and the search for consensus among the different technical agencies of the CTNBio. This Commission has participated through the processes of project conception and formulation, and through its President, has maintained constant communications with UNEP and oversight of project preparation consultancies. Much the way the NBF Development project helps to open up the issue to discussion, the drafting process -and the CTNbio role within it- for the current project have helped to focus the Government’s priorities in relation to LMOs. Improved co-ordination and dialogue are hence key aspects of the proposed capacity building project with UNEP-GEF.

32. As the first initiative, an immediate result of the NBF Development project was a law proposal named the "Biosafety of Living Modified Organisms" bill. This proposal generated an ample parliamentary discussion regarding the need to create a new law or, alternatively, ratify and legalize the Cartagena Protocol, which were two mutually exclusive routes. This situation occurred at a time when the parliamentary environment was adverse to the approval of new laws, a trend that extended until the current administration after the approval of several laws linked to international negotiations, such as CAFTA and UPOV, and amendment of others, such as the Law on Intellectual Property and Telecommunications, was attained.

33. As a result of the NBF Development Project, a basal level of capacity building was achieved and interactions and initial coordination were built between NCAs. These results were crucial in allowing the parliament to reach a decision with regards to the ratification of the Cartagena Protocol, which was finally the preferred option and became Law N° 8537, thus excluding the draft bill derived from the UNEP-GEF Project. Another key element in reaching such a consensus was the proactive role of the CTNBio as an advisory group, gathering different visions from all the NCAs involved and delivering a sound position with a single voice, ultimately strengthening the links between NCAs and the regulatory role of the Executive.

34. In response to Law N° 8537 several sectorial regulations were proposed with different NCAs, aided by the UNEP-GEF project. One such regulation was developed originally to attend to Liability and Redress (L&R) issues resulting from other production technologies. However, unlike now, conditions at the time were not sufficiently mature to take this work further. Now, and with a view to better prepare Costa Rica for COP-MOP-5 meetings on the subject, a legal and technical task force will be organized to consider the implementation of article 27 of the CPB once again. Other regulations were however developed and adopted in the agricultural field, such as those currently applied by the SFE and SENASA. The SFE created and published an agricultural biosafety decree called "Biosafety Auditing" aiming at the monitoring and inspection of GM fields, and allowing a series of administrative measures to be adopted, such as company registries, GM project monitoring and forms, among others. Moreover, the inclusion of specific articles for the regulation of LMOs under SENASA's legal framework (N°8495) was promoted a year after the project finished.

35. The second UNEP-GEF project, "Capacity Building for Effective Participation in the Biosafety Clearing House", allowed the country to fulfill its obligations under Law N° 8537, specifically Article 20. As a direct result of this project, the national Biosafety Clearing House was created together with its link to the main BCH portal of the CPB. Likewise, capacities were built in NCAs to allow them to publish and post their decisions, interact, and share information between them and with other sectors (especially private sector and civil society), all of which was valued as a very positive result. Moreover, SENASA was able to start meetings with the private sector with a view to comply with Art. 11 and animal feed requirements. In summary, interactions between NCAs, the private sector, civil society, and the State's role in operative tasks of the CPB were strengthened through this project.

36. Though of all these efforts constitute positive advances, there is an evident inclination towards the agricultural (plant crop) arena that has left other areas of biosafety, such as food safety, pharmaceutical use of LMOs, animal health and transboundary controls, unattended and even unregulated. Part of the reason for this is the lack of appropriate regulatory and institutional frameworks. On the one side, current legislation has been addressed to cover basic characteristics in agriculture like herbicide tolerance or insect resistance, which differs from new LMOs intended for biopharming or biofactories. Generally speaking, current legislation cannot cover novel LMOs out of agriculture and strictly simple traits; this situation affects bioremediation, GM microorganisms intended for industry purposes, biological control of diseases' vectors, etc. On the other side, the lack of norms for livestock, environment and human health fields concerning use of LMOs is generating a regulatory void. T

37. Therefore, the current legal framework for biosafety, though based on the law for CPB ratification, largely relies (in operational terms) or will rely on existing, sector-specific regulations (mainly for agriculture, some for environment, and few for health) that can be adjusted to encompass both experimental and commercial applications of LMOs, and set biosafety standards. To address these limitations, which also translate into institutional capacity issues, the current UNEP-GEF project was conceived, and the CTNBio has promoted the establishment of an inter-sector working group on the legal framework for biosafety, to promote a broader dialogue and to help mitigate the continuous rotation of decision-makers in the agencies involved in biosafety. Costa Rica firmly believes that legal coherence and robustness are conducive to smoother development and decision processes. There is also reason to believe that completing and making the biosafety framework more functional will encourage the private sector to adopt biotechnological solutions, and perhaps novel LMO applications, to make their processes more efficient, less resource intensive and even more environmentally-friendly, and bring about human and biodiversity benefits. So, through the implementation of a coherent biosafety framework, institutional needs become apparent and can be tackled, stakeholder involvement is heightened, biotechnology opportunities are promoted, and effective and practical safeguards can be put in place.

2.5. Stakeholder mapping and analysis

38. There are several groups involved in biosafety in Costa Rica, since it is a multi-disciplinary area that requires the integration of different entities. The main supporting base is provided by the public sector, but other sectors such as academia, private companies, researchers, the food industry, NGOs, international and regional organisms are equally important. These groups have been identified as stakeholders whose inputs and approaches have been, and will be, important in the planning and implementation of the project. Table 1 in Section 6 summarizes the expected roles and participation of these main stakeholder groups. The project will seek their ongoing participation in order to receive inputs, validate results, ensure accountability and contribute to a multi-sectorial outlook within the biosafety framework.

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40. Among stakeholders in biosafety, there are civil society groups with concerns over LMOs, some of whom have expressed these views in unison with the government, others in complete disagreement. But there are also NGOs who participate as members of the CTNBio and whose criteria are considered in biosafety decision making. On the other hand, there are also NGOs that have influenced local governments into hastily declaring their communities as “transgenic free”, despite the absence of any legal or scientific basis for such declarations. Furthermore, within certain farming communities where GM planting takes place, the civil society has set up networks of “civil observers” who aid and strengthen monitoring activities by voluntarily checking and informing the authorities of potential irregularities in LMOs handling. As Costa Rica is an internationally recognized country for its conservation policies, environmental NGOs are well funded and play an important role in implementing biodiversity projects, which also means that they have accumulated valuable expertise to be taken into account. Furthermore, mechanisms for consultations with consumers and civil society

have been institutionalized, through national associations and official Agencies. As a whole, these groups are considered as well as stakeholders in planning and executing the Project

41. In the private sector, there are several national and international companies that work as LMO producers, through winter nursery agriculture, mostly using seasonal crops. Companies working in agriculture biotechnology research and in the seed market chose Costa Rica within the Central American region to develop their activities due mainly to its precise, clear and functional regulation in biosafety. Another less obvious group is the media whose campaigns against these types of crops have been highly influential often citing information with little scientific evidence. Studies have revealed that most people do not know about LMOs and that there is a high degree of misconception about biotechnology, which is an important barrier to its adoption. The academic sector is one which can provide tools and knowledge to strengthen biosafety. This group has conducted local studies and research, and also has appropriate infrastructure to further research particular biosafety areas. Lastly, international organizations that have supported biosafety studies in the country can be considered. Some of these entities have their dependencies in the country, or have historical links with Costa Rica, but many have expressed their interest in collaborating directly in the establishment of a biosafety framework for Costa Rica.

42. In order to identify biosafety needs, in 2007 a survey was performed with the objective, among others, of determining the importance of implementing a NBF in Costa Rica. Stakeholders from different sectors, involved or interested in biosafety, were consulted and subsequently classified, as shown below. The matrix (Table 1) represents the resulting data analysis, which by means of interviews, surveys and focal group activities, permitted insight into sectorial opinions and positions regarding biosafety challenges (or problems). The analysis uses a scale of 1 to 5, whereby 1 indicates least importance and least involvement of the part in the project, and 5 indicates most importance and most involvement. The parts that have shown opposition to solve a given problem are assigned a negative value; those that have proved to be supportive are given a positive value. As a result of this analysis, it was concluded that the national entities that will likely, by their own accord, be inclined to participate in the project or will exert influence over how issues are addressed, are the Ministries and other government entities, and research and technical institutes in a supportive way, and opposition groups and the media in a more antagonistic way.

Table 1. Legend

	Government
	Civil society groups
	Private sector
	Media
	Academic sector
	International organizations

Table 1. Sectorial analysis of the parts by expectation-force examination

Parts	Expectation	Force	Outcome
Ministry of Agriculture and Livestock	5	4	20
Biosafety National Technical Commission	5	4	20
Ministry of Environment, Energy and Telecommunications	4	3	12
Ministry of Health	4	3	12
COMEX (Ministry of Foreign Trade)	4	4	16
Ministry of Economy, Industry, and Commerce	4	4	16
Ministry of Science and Technology	4	4	16
National Seeds Office	5	3	15
ECA (National accreditation body)	4	4	16
Consumers NGOs	4	3	12

Food Industry NGOs	4	3	12
Environmental groups NGOs	-5	4	-20
Civil society	3	2	6
Private companies	3	3	9
Agricultural Biosafety Auditors	4	2	8
Agricultural Producers	3	4	12
CONARROZ (National Rice-Growers' Corporation)	4	4	16
LAICA (The Industrial Agricultural League of Sugar Cane)	4	4	16
ICAFE (Costa Rican Coffee Institute)	4	4	16
Organic Producers Chamber	-5	4	-20
National Chamber of Agriculture	4	3	12
Written press	5	4	20
Television	5	4	20
Radio	5	4	20
Cellular and Molecular Biology Research Centre	4	4	16
Biology School, UCR	4	4	16
CATIE (Tropical Agricultural Research and Higher Education Centre)	4	4	16
ITCR (Costa Rican Technological Institute)	4	4	16
CIGRAS (Seed and Grain Research Centre)	4	4	16
LEBI (Biological Research Laboratory)	4	4	16
CITA (Food Science and Technology National Research Centre)	4	4	16
CORBANA (Costa Rica's National Banana Corporation)	3	4	12
IICE (Economic Science Research Institute)	4	4	16
INCIENSA (Costa Rican Institute for Research and Education on Nutrition and Health)	4	4	16
INTA (National Institute of Agricultural Technology)	4	4	16
INBIO (National Biodiversity Institute)	4	4	16
EARTH (Agricultural School of the Humid Tropic Region)	4	4	16
PAHO (Pan American Health Organization)	3	5	15
GTZ (German Technical Cooperation)	3	5	15
FAO (Food and Agriculture Organization)	3	5	15
IICA (Inter-American Institute for Cooperation on Agriculture)	3	5	15
OIRSA (International Regional Organization for Plant and Animal Health)	4	4	16

2.6. Baseline analysis and gaps

43. Through a broad sector-based national dialogue on biosafety needs, carried out during project preparation, an overall analysis of the prevailing situation (baseline capacities and gaps) yielded several conclusions; the main one being that under the current regulatory and institutional framework, implementing the CPB is proving rather challenging.

44. The absence of a national policy on the sustainable use of biotechnology and its products, as a development tool, is one of several limitations. Costa Rica has an insufficient cadre of decision makers with adequate knowledge in biotechnology and biosafety, particularly within non-agricultural NCAs. Beside private companies and laboratories and a handful of experts in the field, there is very little knowledge on the nature of LMOs, or on methodologies to effectively estimate their potential risks and

benefits. Key institutions are underfunded, have inadequate infrastructure and lack trained staff. Capacities are also lacking in the areas of control, monitoring and evaluation, including the necessary laboratory analysis of LMOs. Together with asymmetrical availability of human resources and the relatively limited expertise in the specific field of biosafety, these are adduced as significant barriers to the implementation of the CBP.

45. At the same time, the decision-making apparatus is legally restricted and lacks adequate inter-institutional communications and harmonized processes, which are a reflection of a poor understanding of the impacts of those decisions. The CTNBio is only able to analyze and recommend decisions on LMOs considered within the scopes of the three laws on which it relies. As there are currently no specific biosafety regulations for animal health, environment and human health that allow the regulated use of LMOs in line with the CPB, this particular situation has generated a legal gap in which decision-making is prevented, and if made, is easily disputable.

46. Although scientific criteria will always prevail within the CTNBio and there is familiarity with risks assessments, nevertheless a strong legal cover is warranted when dealing with the complexities of biosafety. This technical organ needs not only flexibility but also institutional back-up, to be able to confidently make pronouncements in a highly challenging and fast changing field. The CTNBio therefore requires empowerment for decision-making and should be involved in research and policy-making for biosafety.

47. Moreover, since neither SENASA nor the Ministry of Health are part of CTNBio, this means that requirements such as advanced informed agreements, identification documentation, and risk assessment and management can only be carried out through existing national legislation. As a result, Articles 7-10 and 11 of the National Law 8537- which is the same as those of the CPB - is not implemented, since there not exists national specific legislation, procedures and personnel qualified to apply them. Furthermore, a weak and uncoordinated communications system, needed to notify approvals and coordinate with customs offices, considerably reduces the capacity to supervise the transboundary movements of LMOs, especially considering decisions on incoming FFPs, forestry LMOs, GM microorganisms and animal LMOs, and the need to safeguard against unapproved entries. Moreover, having coordinated information mechanisms in place would allow a better response from national authorities, and better accountability as a practice demanded by society in general and "civil observers" in particular.

48. On information sharing, Costa Rica has developed certain level in data management, including data of scientific origin through *in situ* monitoring for the areas of field research and seed production only. Despite ongoing efforts in installing information sharing mechanisms, the lack of standard methodologies and specific institutional interests in managing confidential business information, which is complicated to reconcile in an operational context, has become a difficult hurdle to overcome among NCAs. The use of appropriate IT, particularly acquisition of equipment and security systems for managing confidential dossiers, are gaps (with high start-up costs) that need be addressed if customer confidence is to be built, a co-existence model is to be successful, and CPB implementation is to be more efficient.

49. There is therefore a clear need to implement legal, technical and administrative actions that are better suited to the wider or more inclusive framework of the CPB. Under current conditions, and without a UNEP-GEF project, it is likely that legal modifications and progress in the administrative arena would continue at a slow pace, creating uneven capacities and an inefficient response to national and international obligations. Moreover, if the Government does not act promptly, showing a united front, it becomes more vulnerable to the lobbying power of opposition groups (mostly NGOs), some of whom are against the development of more biosafety mechanisms, as this translates into "opening the door to modern biotechnology" even if it is done in accordance with the CPB. The present UNEP-GEF

project is therefore timely, and will help to prompt the political and financial willingness, of current and future heads of NCAs, on which progress towards fully implementing the CPB will rely.

50. The design phase of this project provided a diagnosis of baseline capacities and gaps (needs) which is summarized below. Since the focus of the project is primarily institutional capacity-building, this analysis is more extensive where NCAs are concerned.

Ministry of Health (MS)

51. Concerning human health issues, the General Health law (N° 5395) from 1973 regulates food imports and drugs registration in general in Costa Rica. The inscription, control, imports and advertising of drugs are regulated by decree N° 28466-S of the year 2000, while the registration and commercialization of foods depends on decree N° 26725 of 1998. None of these regulations, or the technical norms that apply to food labelling, refer explicitly to LMOs.

52. Despite the fact that the regulation for drug registration is relatively new, there are no dispositions for LMOs or recombinant drugs. However, as importation, manufacture, handling, trade or consumption of drugs require prior registration with the Ministry of Health (Art. 24), this would entitle the Ministry to cover LMOs and products thereof, when related to human medicines. According to the registration programme and monitoring records, there are certain products derived from recombinant techniques authorized by the Ministry: Human Growth Hormone, Insulin; Alpha, Beta and Gamma interferon, Protein C, Human Luteinizing Hormone and Hepatitis B vaccine.

53. In Costa Rica, the Ministry of Health has been entrusted with the legal responsibility of regulating the food safety, including that of imports, and the commercialization of food products. From the perspective of the CPB, the Ministry would therefore be legally entitled to address issues concerning FFPs. However, there are gaps in its operations that preclude specific biosafety training activities for example, and administrative mechanisms are lacking, which are needed not only to take decisions in compliance with the CBP but also to be able to respond appropriately to new challenges posed novel food LMOs. So, in effect, though the Ministry of Health does have a registration and commercialization office, they lack procedures and trained staff in order to comply with Art. 11. In addition, the Ministry of Health is the focal point for the Codex Alimentarius as far as food stuffs are concerned; however Codex's norms and procedures for GM foods are not yet implemented in Costa Rica. In terms of information management, the Ministry will only be able to regularize BCH tasks once decisions concerning LMO regulations, norms and notifications have been made. This Ministry as NCA to the CPB would be of great benefit to a communication system which relied on the BCH but also included internal mechanisms and links with customs offices, together with the means to carry out food analyses.

Ministry of Environment, Energy and Communications (MINAET)

54. The Ministry of Environment is the institution in charge of executing CBD agreements and its purpose is to manage natural resources in a sustainable and rational manner, in order to preserve biodiversity, maintain healthy ecosystems and benefit future generations. In this spirit, Costa Rica created its Biodiversity Law (N° 7788) and is currently working on a proposal to regulate the Law's 3rd chapter, which would cover biotechnology-related issues such as the use of LMOs in research activities and access to genetic resources. The procedures relating to this regulation would involve the National Commission for Biodiversity Management (CONAGEBIO), which is an independent body of the Ministry enabled to manage and grant permission to perform research on biodiversity in the country.

55. As the guardian of the country's biodiversity, CONAGEBIO could play an important role in biosafety decision making for LMO releases. However and according to Art. 40 of the Biodiversity Law, CTNBio is the agency called upon to act as the Ministry's technical decision-making body for biosafety, and its composition includes two permanent representatives of the Ministry. On the other hand, CONAGEBIO has a veto power over the CTNBio, even though it has no participation in the CTNBio agenda. This situation has underscored the need to establish better contact between the two agencies (committees) and consolidate their working relationship. Though this task is an ongoing process, the legal framework under which these agencies are operating is creating hurdles in bringing them closer together.

56. In conclusion, in spite of the important role of the Ministry of Environment in biosafety, this entity's current interventions in LMO management are limited, and have so far not needed to be stretched given that all introduced LMOs have been of agricultural type and the Ministry's participation in the CTNBio has been sufficient in this respect. However, in light of future developments and applications in biotechnology, it is likely that more specific legislation will be needed, as well as procedures and trained personnel from the Ministry, if the country is to effectively comply with Arts 7 – 10 of the CPB.

Ministry of Agriculture and Livestock (MAG)

National Animal Health Service (SENASA)

57. This agency has the responsibility of guarding against animal diseases, and maintains standards of food (for human consumption) and feed (animal consumption) safety in the market. Biotechnology products for animal health (veterinary use) must be assessed, registered and regulated by SENASA as well. In this respect, permission has been granted to handle and commercialize RBST, recombinant bovine growth hormone produced in transformed *E. coli* and applied to cows for increased milk production.

58. There is a small molecular biology laboratory in SENASA for the detection of animal plagues and diseases. This laboratory is able to carry out qualitative PCR, but has no functions in the detection of LMOs. SENASA has national users authorized for the exchange of information through the BCH and technical staff to conduct monitoring and supervision in the field, according to their competences, but at present, these personnel has no training in biotechnology or biosafety. To date, the regulation of issues concerning livestock biosafety and the adoption of control mechanisms for LMO importation and monitoring is still pending.

59. Though not the current scenario, this agency would have the task of performing risk assessments on GM animals. Even though an SENASA representative is currently attending CTNBio meetings as an observer, this agency lacks CTNBio membership even though the General Service for Animal Health Law (N° 8495) establishes CTNBio as SENASA's advisory body. Any future members will require capacity building, especially in areas related to the analysis and management of GM animal and their by-products. Costa Rica has no expertise or experience with GM animals (vertebrate or invertebrate). Therefore, implementing a legal framework that includes risk assessment and risk management in a multi-disciplinary and interagency context will demand more effort and resources, particularly for capacity building and an initial identification of needs within the system.

National Seed Office (ONS)

60. The ONS is an independent agency of the MAG in charge of registering and regulating seed production and seed movements in Costa Rica. Under its current legal framework, comprised of the

Seeds Law (N° 6289) and the Phytosanitary Law (N° 7664), the ONS has been assigned to regulate the production, protection, breeding, control and encourage the use of, high quality seeds. This mandate includes the supervision of any kind of project involving LMO seeds, whether for research or production, and granting import permits when transboundary movements are entailed. Despite the fact that Costa Rica has been producing LMO seed since the 1990's, most of the work on monitoring and risk assessment has fallen to the SFE, which houses greater capacity to deal with plant LMOs "in the field" than the ONS. Nonetheless, the current legal framework does not recognize these needs and differences. Due mainly to the coordinated actions taken within the CTNBio, of which both ONS and SFE are members, Costa Rica has been able to effectively manage and control LMO seed production, but the current legal gaps still need to be addressed in order to create capacities and coordinate efforts among all the institutions involved.

Phytosanitary Service of the State (SFE)

61. The Phytosanitary Service is an agency of the MAG with a mandate to safeguard plant health and regulate plant movements in Costa Rica. The SFE's Biotechnology Programme is actively working in different areas such as BCH, Monitoring, Risk Assessment, Importation Permits, Coordination and CTNBio Secretariat, auditor controls and certifications, and international projects; the Programme's staffs has been trained to perform these basic tasks. The Biotechnology Programme is also the manager of the national BCH website and has authorized national users for exchanging information through the BCH. They also manage biosafety auditors who have been certified and registered to fulfil LMO monitoring functions, and are encouraged to increase their technical skills through continuous training. Lastly, the Biotechnology Program also deploys control mechanisms at entry points for the transboundary movements of declared LMOs.

62. The SFE has a small molecular biology laboratory in charge of pest detection and Phytosanitary controls. This facility is capable of performing qualitative LMO identification, yet does not have capacity for medium scale detections. This situation is expected to change with the association agreement with the EU, whereby resources to strengthen human capacities and equipments will be acquired to enable the lab to perform Phytosanitary molecular biology.

63. The current scenario is that, through the CTNBio, several agencies and Ministries are relying on the SFE to attend to agricultural biosafety issues; the underlying factor is that winter nursery constitutes the main biosafety-requiring activity in Costa Rica. However, one of the main problems to fully comply with the CPB is that Costa Rica has so far preferred to address biosafety issues through extending its own national legal framework. Nevertheless, this situation has not hindered capacity building within the SFE, nor its capacity to build momentum and lead the process of building basal capacity in other institutions. Despite this, the country still has significant differences between institutions, namely between SFE and the agencies required to regulate GM animals, FFPs and environmental LMO's. Further capacity building is therefore warranted in order to have comparable structures, not only at the level of legal architecture and technical decisions, but also in terms of administrative capacity and enforcement of decisions.

64. Although norms have been established in the agriculture field, these were designed around first generation LMOs, and are therefore weak tools for considering novel LMOs. For large scale cultivation, these regulations also lack procedures for articulating a coexistence model between different production technologies. The enforcement of coexistence norms would benefit biosafety by increasing awareness among farmers and minimizing possible negative influences between them.

Institutional Needs

65. Table 2 below summarizes the needs identified during project preparation, based on inputs received from NCAs and other institutions involved in the project execution.

66. As a newcomer to the field, there is one Government institution that has not been mentioned so far in the stakeholder analysis or baseline /needs analysis: INCOPESCA, the Costa Rican Institute of Fishing in charge of all activities regarding fisheries or aquaculture development. Though the project will not develop norms or regulations regarding the application of modern biotechnology to marine or freshwater resources, INCOPESCA has nonetheless been invited to partake in the planning and execution of the project, considering its potential role as a "future stakeholder", the growing importance of Marine Biotechnology in the productive sector, and the intention of this project to cover a variety of novel LMO types.

Table 2. Needs identified by field and Official Agency involved

Official Agencies	NEEDS / GAPS		
	Regulatory	**Administrative**	**Capacity Building**
Ministry of Agriculture and Livestock (MAG)	Compliance with Art. 27 of the CPB Norms and guidelines for coexistence between production technologies. Identification norms for LMOs	Lack of a coordinated multi-ministerial administrative system. Lack of an efficient and secure information sharing system between decision makers (management of public and business information) considering timeframes established in the CBP. Self-sustaining mechanism for the regulatory system. Forms for Art. 7 -11 applications (notifications, risk assessment, importation, management, among others for HM, EM and SENASA) Registration forms for Companies, Projects, etc Facilities such as labs and administrative buildings. There are no coordinated procedures for detection and sampling for LMOs intended for agriculture, livestock and health. IT system through which confidential information can be securely managed among	Dissemination of official norms among NCAs.
Phytosanitary Service of the State (SFE)	Legal procedures for compliance with Art's 26 y 27 of the CBP. Operational and ethic code for businesses and auditors. Procedures for implementing a simplified decision making system.		Short and long term training for decision makers. Capacity building for auditors and civil observers. Training in monitoring and biosafety audit techniques.
National Service of Animal Health (SENASA)	FFPs norms for compliance with Art. 11.		Training for decision makers about risk assessment of FFPs.
	Norms for compliance with arts 7-10 Environmental release of animal LMOs.		Training towards an operational administrative system
	Compliance with Art. 26 & 27 of the CPB Identification, transportation and handling of LMOs (Art 18) Norms for safe use of animal GM and products thereof. Implementation of internationally approved CODEX norms.		Training in supervising Training in risk assessment and management for GM livestock
Ministry of	Forms for Art. 7 -11		Training in norms and

Environment, Energy and Telecommunications (MINAET)	applications. Environmental release of LMOs (for industry, bioremediation, GM insects, etc)	responsible personnel in the NCAs Procedures for coordination on organic, LMO and conventional regulations. LMOs identification procedures. Data bases and access to scientific information.	procedures application concerning Arts 7-11, 15, 16 and 18.
	Compliance with Art's 26 & 27 of the CPB		Training in supervision, risk assessment and management of LMOs intended for environmental purposes.
Ministry of Health (MS)	FFPs norms for compliance with Art. 11		Training in supervision, risk assessment and management of LMOs intended for human health purposes.
	Compliance with articles Art. 26 & 27 of the PCB Norms for Identification, transportation and handling of LMOs (Art 18)		
CTNBio	Review of the structure, constitution and responsibilities of CTNBio members. Norm to integrate SENASA, MS and other members.		Training in risk assessment and management of novel LMOs.

2.7. Linkages with other GEF and non-GEF interventions

67. In addition to the initial global UNEP-GEF projects that assisted over 130 countries to take the first steps towards creating their NBFs and participating effectively in the BCH, the IICA has an ongoing Hemispheric Programme on Biotechnology and Biosafety, of which several Central American countries are part, including Costa Rica. However, for the purpose of the current project, the most relevant initiatives in course are the World Bank (WB) projects for biosafety. In 2008, the WB approved two regional GEF projects for biosafety; the multi-country project: "Biosafety in Centres of Biodiversity: Building Technical Capacity in Latin America for Safe Deployment of Transgenic Crops", comprising Brazil, Costa Rica, Colombia and Peru, and executed through the International Centre for Tropical Agriculture (CIAT) in Colombia; and a related project, also involving CIAT and the same four countries, titled: "Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety".

68. Both projects will involve the University of Costa Rica as the main national partner, with participation from the MAG (Biotechnology Programme) as government counterpart, and will generate scientific data, guidelines and experience concerning five specific crops -with the ultimate aim of aiding regulators to make more informed decisions-, as well as short-term outputs relating to informal education for stakeholders, communicators, opinion-makers and the general public. Given the scope of current proposal, and the more scientific and methodological focus of the first WB project, a full analysis was carried during project preparation of how best to build synergies between these initiatives (see Table 3). Meetings were also held with the National Coordinator of the WB-GEF-CIAT project, in order to establish early contact, exchange initial information, and agree on common goals and complementary areas.

69. Table 3 below shows the consonant and non-duplicative manner in which the WB-GEF-CIAT projects will be executed together with the current proposal, so that their activities may be mutually supportive.

Table 3. Complementarities between UNEP-GEF and WB-GEF projects

Components UNEP GEF	Outcome	Output	Activities
Component 1. Putting in place and applying national biosafety regulation and promoting a biosafety policy in accordance with the CPB	Comprehensive regulatory framework for biosafety is in place, providing the architecture of an integrated administrative and management system.	- Approved technical guidelines and support tools for NCAs to aid in application of biosafety regulations	**I- The project will have two experts developing guidelines different from WB-UNEP:** - One Expert will design guidelines for summiting applications for article 11: Food, Feed and Processing (FFPs) and article 18 to NCAs. - One expert, who will elaborate guidelines on risk management and risk assessment based on national and international guidelines on FFPs LMOs, Environmental release of trees, insect, animal, etc., and harmonize and officialise the guidelines with NCAs. The expert will consider the documentation, guidelines and tools generated by WB in order to complement food safety, tress, insect and animal guidelines. **II- The project will have meetings (4) with NCA and CTNBio to harmonize the guidelines and present the tools developed by WB –UNEP project to make official use of them into the biosafety national regulation:** (1)One meeting to allow WB-UNEP coordinator to present and teach how to use the documentation and adapted databases for assessing and monitoring gene introgression / persistence, and for mapping the distribution of crops/landrace/weedy, wild populations, for risk assessment (2)One meeting to discuss strategies and operational guidelines to minimize transgene flow. (3)A meeting to analyze adapted and standardized methodology for evaluating effects on non-crop (non-target) organisms. (4)A meeting to analyze adapted methodologies and tools for socio-economic impact assessment of LMOs in the tropics.

Components and subcomponent WB-GEF	**Outcome**	**Output**	**Activities**
Component 1: Biosafety Knowledge Generation and Validation. -Strengthening technical capacity for environmental risk assessment and management -Strengthening technical capacity for socio-economic impact assessment	Strengthened technical capacity of project countries for developing environmental risk assessment, management methodologies, and socio-economic impact assessment methodologies	(a) documentation and adapted databases for assessing and monitoring gene introgression / persistence, and for mapping the distribution of crops/landrace/weedy, wild populations; (b) crop management strategies and operational guidelines to minimize transgene flow; (c) adapted, standardized methodologies for large-scale monitoring of gene flow; (d) regionally-adapted and standardized methodology for evaluating effects on non-crop (non-target) organisms; (e) adapted methodologies and tools for socio-economic impact assessment of	<u>Gene Flow</u> (a) compilation and generation of baseline data for tracking and monitoring gene introgression/persistence of novel traits in crop-biodiversity; (b) generation and testing the use of GIS-referenced databases for mapping the distribution of crop/landraces/weedy/wild populations, and gene flow analysis; (c) adaptation and regional standardization of methodology for large scale monitoring of gene flow; and (d) development of crop management strategies and operational guidelines to minimize trans-gene flow <u>Non target</u> (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; and (c) national coordination Adaptation of methods and tools for socio-economic impact assessment of LMOs in the tropics. Development of analytical skills for analysis of potential socio-economic impacts of LMOs in centers of crop-diversity

		LMOs in the tropics; and (f) project-generated knowledge described in (a) – (e) above downloaded to and accessible in, depositories and project websites country based and at CIAT, and participating country BCHs.	
Components UNEP GEF	**Outcome**	**Output**	**Activities**
Component 3.	Outcome 3. Building technical capacity in NCAs and related institutions for comprehensive biosafety management.	NCAs professionals trained in specific areas of biosafety such as risk assessment of novel LMOs, risk management, liability and redress, identification, transboundary issues and coexistence	**The material developed by WB project will complement the training activities of the UNEP-GEF project, since the UNEP-GEF project will emphasis different approaches such as FFPs and risks management and assessment of insects, trees and animals.** The project will have workshops for training NCAs in risk assessment and risk management of food safety (FFPs), insect and animal release to the environment. -2 workshops for NCAs of 3 days each one for traditional and novel risk assessment during 12 months. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment. -2 workshops for NCAs of 4 days for risk management, liability and redress, identification and coexistence issues. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment.

			-2 group training for NCAs with international experts on risk management, including case studies and protocols elaboration. Workshop will include food safety, feed (FFPs) and environmental issues
Components and subcomponent WB-GEF	**Outcome**	**Output**	**Activities**
Component 2: Strengthening biosafety decision-making capacity *2.1 Training in environmental risk assessment, for competent authorities and practitioners* *2.2 Training in socio-economic impact assessment for competent authorities and practitioners*	Biosafety planning and national biosafety competent authorities' decision-making capacity strengthened (a) Training Plans and course materials developed for four countries; (b) Targeted authorities and experts trained by specialists in biosafety and environmental risk assessment and management; (c) Targeted authorities and experts trained by specialists in	(a) decision-making entities (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 socio-economic impact assessment of biosafety products for planning	(a) training in environmental risk assessment and, risk management for competent authorities and practitioners; and (b) Training in socio-economic impact assessment for competent authorities and practitioners.

	biosafety socio-economic impact assessment;	purposes	
Components UNEP GEF	**Outcome**	**Output**	**Activities**
Component 4.	Outcome 4. Outline a strategy towards communication and education in biosafety.	National BCH webpage updated with NCAs inputs in information sharing efforts. Education Strategy draft on LMOs and biosafety (project TEACH: Training and Education in Agro biotechnology) and its Action Plan for carrying out long-term formal educational actions for dissemination of biosafety	**I- The UNEP-GEF project will facilitate the BCH platform in order to linked with WB outputs obtained from project "Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety"** -The GEF project will hire an expert in TI to improve the BCH national Web page and linked with other national database, including those developed by WB project. The expert will harmonize the information of Costa Rica in FAO, IICA, BCH, AGBIOS, FDA, BIO, Europe database, etc, in the National Web Page -Campaign and forums for the access and use of BCH, as well as databases, tools and training modules developed by WB project. Integration and collaboration with the Ministry of Science and Technology for using CECI's (Intelligent Community Centers). The target population is the producers, export, imports and educators **II-The public communication strategy developed by the WB to inform the society will be integrated and used as baseline information to develop a National Strategy for Formal Education such as Primary and Secondary.**
Components and subcomponent WB-GEF	**Outcome**		**Outputs // Activities**
Communication and Public Awareness Capacity-Building for Compliance with the Cartagena Protocol on Biosafety	(a) Clear identification of the main stakeholders, their perceptions, attitudes and behaviors toward the project and its objective, and, if needed, toward the main implementation agencies involved in the process;		WORKPLAN NOT YET DEFINED AT NATIONAL LEVEL The main output will be the production of research based communication products delivered through an opportune mix of media and channels

COMPONENT 1 – DEVELOPMENT AND IMPLEMENTATION OF PILOT COMMUNICATION STRATEGIES	(b) Strengthened dialogue with stakeholders through effective mechanisms to obtain feedback; (c) Policy makers communicating coherently on the project related issues and increased awareness of the use of biosafety risk assessment methodologies; (d) Increased awareness of the use of biosafety socio-economic impact assessments; and (e) Clear understanding of the project objectives by the general public in order to obtain their support	CIAT will establish a Project website linked to all partner country collaborators, as a practical and inclusive tool for knowledge-sharing, and for fostering stakeholder participation including in the ongoing content of both the website and newsletter
COMPONENT 2 – REGIONAL TECHNICAL KNOWLEDGE SHARING	A mechanism for countries to learn from each other's experience and knowledge, get acquainted with the expertise available in the region, and establish mechanism for further collaboration, and thus, strengthen the sustainability of the project impacts after project completion.	(a) A project website which will be a practical and inclusive tool for knowledge-sharing, and for fostering stakeholder participation. The website will be accessible to all partner country collaborators and to biosafety management professionals and other interested people from other countries in the region and will be linked to the biosafety clearing houses (BCH) that are being put in place across the region; (b) a regional network of biosafety management professionals that are able to combine technical and communication skills towards better decisions and that are in touch with each other by means of a community of practice; (c) a series of training materials that bridge technical and communication issues, and that are publicly available; (d) A group of professionals that can lead knowledge sharing activities within their countries.
Component 3 –	A conference to share the outcomes of the two	Key outputs of this component are: (a) a conference website where

Regional Conference	CIAT led projects (FSP and MSP) and of other ongoing biosafety capacity building projects widely in the region through a regional conference	the different papers will be made available on line; (b) proceedings of the conference and other technical documents; (c) a paper that summarizes the state of the art on biosafety management and the different positions in the region for publication in an international peer reviewed journal; and (d) a paper that summarizes the topics that need future attention in biosafety management strategies in the region and its countries

SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)

3.1. Project rationale, policy conformity and expected global environmental benefits

70. Since ratifying the CPB, Costa Rica has taken steady and significant steps in biosafety yet progress involving operational CPB tasks and non-agricultural institutions has been somewhat slow. Institutional organs such as the Biotechnology Programme and the CTNBio have consolidated their roles as the main coordination, decision and control mechanisms in biosafety, though certain administrative, transboundary and evaluation mechanisms are still lacking. The current project is strongly focused on institutional needs and operational issues, on completing the regulatory framework, and on building technical capacity and levelling this capacity among the different NCAs. It is looking to set firmer foundations for the growth of biotechnology and its safe use in the country, through the design of an educational program to raise awareness on biotechnology and biosafety as complements, and the involvement of civil society in surveillance activities.

71. Information is recognized as an important component for having a technically-sound and transparent biosafety system. Therefore, much effort will go towards creating mechanisms for processing, presenting and analyzing the scientific and technical information obtained from international sources and regional initiatives (especially environmental data and methodologies); creating access mechanisms and making national information publicly available; informing stakeholders about biosafety; learning from experiences in risk communication and awareness-raising; formalizing information-gathering and -management as NCA requirements; and establishing dialogues and agreements with the education and academic sectors that will be responsive to the country's biosafety needs. Information as a compliance requisite for the CPB will be reinforced for continued participation in the BCH. Data, activities and decision-making tools and inputs, generated through the WB-GEF-CIAT initiatives, will also be valuable reviewed, fine-tuned, formalized, and fully integrated into the biosafety system in a complementary approach.

72. This project is based on the confidence that Costa Rica has acquired through its experience in the safe use of modern biotechnology. It is precisely the objective of the biosafety system to minimize the risks from the use of LMOs. So far, no negative effects from the use of GM crops have been detected, either in farming activities or in public health or the environment in general, yet biosafety needs to evolve and measure up to new LMO types if a safe situation in the use of biotechnology is to prevail. This current proposal is demonstrative of how Costa Rica is taking a step-by-step approach to biosafety, whereby the environmental release of LMOs has always been kept within the limits of national capacities. The rationale is that in order to avoid the risks and reap the benefits, regulatory and institutional frameworks need to keep up with scientific and technological advances. The case of GM rice in Costa Rica is an example of how this has taken shape. With the aim of improving rice plant materials for national producers, this endeavour has helped to develop biosafety information based on science. It comprises an integral perspective to environmental impacts; trials to observe ecological risks, public perception, and food safety; and the negotiation of intellectual property rights (over technological property and operative freedom). Studies are also being carried out to determine the overall public acceptance of biotechnological products. The purpose of the information generated has been to provide objective criteria with which to regard biotechnological practices and the future production and consumption of LMOs in the country.

73. The current world economic situation has impacted Costa Rica and created a new scenario whereby food security, climate change, dependency on oil derivatives and employment have become strong priorities for the Government. In this context, the implementation of the CPB and of Costa Rica's biosafety framework are seen as means to increase certainty in the use of LMOs, so that benefits derived from this use can be maximized and risks minimized. Providing an operative system with tools, guidelines, information and human resources as the basis for a functional biosafety framework should

facilitate the diversification of agriculture and of LMOs use, without jeopardizing food and feed production or agro exports. Moreover, providing technical instruments and decision-making processes to incorporate environmental safeguards into the use of biotechnology will also favour the consideration of LMOs technology as a means for facing climatic change, as bio-fuel options, as responses to challenges in agricultural productivity, as a pharmaceutical or industrial production method, and as a means of bioremediation. Given that these developments are becoming increasingly relevant to Costa Rica, and the accruement of environmental benefits has always been a concern to this "green" country, the completion and prompt operation of its biosafety system is now a priority concern.

74. The current proposal will therefore assist Costa Rica to expand its biosafety capacity and stay at the forefront of global biosafety efforts, in order to adequately protect the environment and human health from the potential risks associated with modern biotechnology. It will build on the foundations laid by previous UNEP-GEF biosafety projects, and make use of the technical expertise, centres of excellence and support networks that are available in the region. It will contribute directly to the expected outcome of the GEF Biosafety Program: "Sustainable operational national biosafety decision-making systems that contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health in conformity with the provisions and decisions of the Cartagena Protocol on Biosafety", and in this way, bring about global environmental benefits, particularly within Central America. The project's components coincide with the requirements identified in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol adopted at COP-MOP-3 of the CPB for the full implementation of the Protocol, and respond to the approach with which Costa Rica began developing its NBF. Implementation arrangements have also been built around integration, so that the MSP will be executed with full involvement as well as co-financing from key institutions such as the CTNBio, the Biotechnology Programme of the MAG, the MINAET, the Ministry of Health, the SFE, the Ministry of Science and Technology (MICIT) and the SENASA.

75. In general, the current project aims to consolidate the following components of Costa Rica's biosafety system:

i. Promote a National Biosafety Legislation in accordance with the CPB, and a Biosafety Policy which provides a unifying institutional framework for the CPB implementation.
ii. Development of a coordinated administrative system to fulfil obligations to the CPB and strengthen the decision-making base.
iii. Build technical capacities in NCAs and other institutions to manage LMOs, on basis of information, assessments and experience acquired through other related initiatives such as the WB-GEF regional project.
iv. Development of a national system for public information sharing using current mechanisms like the Biosafety Clearing house in order to promote information access to stakeholders, official biosafety auditors and civil collaborators in rural communities. Furthermore, future activities for designing a national strategy proposal aiming at including modern biotechnology issues into the national education system will been considered.

3.2. Project goal and objective

76. ***General Objective:*** The main objective of the project is to have a national biosafety framework feasible and transparent for Costa Rica by the year 2012, according to national development priorities and international agreements.

77. ***Specific Objectives:*** The major objectives for GEF support would be crossed-capacity-building among ministries and key stakeholders to analyze, inform, and make decisions to reduce potential risks related to LMOs, increase benefits to society, and protect biodiversity. Specific objectives would include:

- Establish mechanisms, either legal or administrative, for inter-ministerial coordination and decision making at the national level that will permit the safe environmental release, commercial production and transboundary movement of LMOs in compliance with the obligations of the Cartagena Protocol.
- Establish a core capacity in biosafety to enhance decision making in each of the participating ministries and their related institutions.
- Establish information sharing mechanisms involved along the educational system in order to raise public awareness on biosafety issues.

3.3. Project components and expected results

78. The components that are anticipated in this project are summarised below. The results (outcomes) for each component and their corresponding indicators are provided in Appendix 4 (Results Framework). Indicators have been expressed at targets in an attempt to make them as "SMART" as possible. At this stage, few targets have been set for accomplishment by mid-term (project month 18), therefore "process indicators" will be set at project inception to enable the Project Implementation Review and Mid-Term Review /Evaluation processes to determine the extent to which the project is making progress towards achieving targets that extend beyond 18 months.

Component 1:
Putting in place and applying a national biosafety legal framework and promoting a biosafety policy in accordance with the CPB

79. This component will combine regulatory, training and political tasks. Co-financing resources will be used to carry out an in-depth evaluation of the effectiveness of Costa Rica's current legal framework in the context of the CPB and make recommendations for modifications, which will themselves be later evaluated. Intensive, short-term trainings (funded by collaborators) on the issues and risks surrounding LMO will be offered to lawmakers including *inter alia*: FFP approvals, implementing identification protocols, possible benefits of a transboundary document control system and eventually, coexistence guidelines. Additional cross-sector charters and legal instruments would be explored to reinforce the operational capacity and mandate of the CTNBio, while eliminating overlaps in inter-agency work. GEF funds will be used to complement this effort by supporting targeted activities to complete the legal framework taking into account similar experiences in other highly biodiverse countries. A key task will be the preparation and adoption of a unifying biosafety policy with which to bring on board new NCAs. Efforts in promoting and creating consensus, in both political and technical-administrative spheres, will be given particular attention. MINAET's efforts to harmonise cross-sector legislation relating to environmental risks and damages would be extended to biosafety so as to address issues of liability and redress, regulations for GM animals, and drugs derived from modern biotechnology.

80. Importantly, putting in place an harmonized legal and policy framework to guide NCAs will not only allow Costa Rica to complete and give continuity to prior efforts, but will also create the necessary institutional framework for transparent, sustained and coordinated biosafety action. This will conducive to continued and targeted capacity-building through long-term biosafety training programmes, the adoption of information management strategies, the creation of an administrative system that may support biosafety decision-making, and the review, fine-tuning, formalization, and full integration of tools and inputs generated through other GEF-funded initiatives.

Component 2:
Making operational an administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms

81. GEF support will be use to develop a multiagency mechanism to specifically address administrative procedures in biosafety. This mechanism would integrate personnel from the main NCAs, would rely on the legal and institutional base contemplated in Component 1, would have an independent budget and would facilitate LMOs applications through simplification and standardization. This mechanism will take into account the specific needs of the different Ministries involved, and will develop a file-handling and reporting system in order to avoid duplication and misinformed procedures and decision, and allow greater efficiency while maintaining document confidentiality. An administrative system that operates through specific and permanent mandates in NCAs has clear procedures and formats for dealing with LMOs requests and notifications, and effectively supports LMOs evaluation and decision-making processes will thus be set up. For this, adequate structures and technologies will be put in place, responsibilities assigned, and decision-making and advisory bodies

mandated, together with making available user information and sufficient capacity and tools to allow internal NCA processes to match each other as well as concur with CPB dispositions.

82. An important outcome of this component will be the testing of the system through the handling of least one request (either mock or real) by each NCA, to evaluate the quality of risk assessment data, information management, coordination, deadlines, and communication, to result in a single joint decision (mock or real). The possibility of using a novel LMO for this exercise will be considered, but will depend on the feasibility of accessing the necessary documentation.

Component 3:
Building technical capacity in NCAs and related institutions for comprehensive biosafety management

83. The unavailability of local risk assessment knowledge is a critical barrier to the effective implementation of the CPB. NCAs and specific staff, as well as stakeholder groups, would benefit from the preparation of manuals and standardized methodologies for risk assessments. With baseline resources, CTNBio is implementing a medium term capacity building programme in order to train personnel from four different areas (health, environment, agriculture and livestock), aiming to fill gaps detected within institutions and level out their ability to perform risk assessment and generate risk management guidelines in their fields of expertise. These efforts are serving to generate information and databases that will provide Costa Rica with operational tools, studies and scientific data for better decision-making in favour of agro-biodiversity conservation.

84. GEF resources will be used specifically for training decision-makers and regulators in risk assessment and risk management under the amplified legal framework, which will include liability and redress measures, and novel LMOs. The capacity developed will increase national potential to monitor in-country movements of LMOs. More general training will be imparted for field technicians from the main Ministries, and for customs and quarantine officers, on basic information regarding LMOs as most of these staff have had no contact with modern biotechnology products. This training will allow personnel to supervise the implementation of biosafety measures and over the medium term to identify potential gene flow, as well as the effect on non-target species and customs procedures. Moreover, activities to strengthen the capacities of official biosafety auditors as well as civil observers will also help to increase Costa Rica's capacity to monitor LMO technology, as will the preparation of field annual inspecting plans. Data on transboundary shipments of LMOs at points of entry will be registered, collected and validated by Customs, through ad hoc methodologies designed through the project. This will be an important step for the creation of a register and LMO identification system, for agreeing on transit procedures, and for improving the overall handling of LMOs by customs offices.

Component 4:
Improved communication, education, public perception and participation in biosafety of all relevant stakeholders

85. Information and education are recognized as important elements of a technically-sound and transparent biosafety system, therefore much effort will go towards: creating mechanisms for processing, presenting and analyzing scientific and technical information obtained from international sources, research centres and sub-regional initiatives (especially environmental data and methodologies); creating access mechanisms and making relevant national information publicly available; informing stakeholders about biosafety; learning from experiences in risk communication and awareness-raising to generate a biosafety education strategy; formalizing information-gathering and -management as NCA requirements; and establishing dialogues and agreements with the education and academic sectors that will be responsive to the country's biosafety needs. Outreach oriented towards rural collaborators, farmers and other LMO user groups, to increase the likelihood of compliance with national legislation, will also be considered, yet the Project is not planning to carry

out many open events or informal activities for raising awareness or for outreach, as these are expected to ensue from WB-GEF project.

86. The preparation of a strategy, to be implemented in the future, for Training and Education in AgrobioteCHnology (TEACH) will allow the country to have a comprehensive programme for carrying out formal and informal, long-term education, capacity-building and awareness-raising in biosafety. Exploring financing options for this strategy will be a key task. Though implementation of the TEACH strategy will not be possible during this project, given the limited timeframe and funding, the current effort will nonetheless lay the seed capital needed to design the strategy and scope for Government and private sector support. One key communication issue that will however be considered is the use and reinforcement of the BCH as an information diffusion mechanism for biotechnology and biosafety. Information as a compliance requisite for the CPB will also be addressed through continuing Costa Rica's participation in the BCH. BCH management as part of the biosafety system, as well as periodic BCH training needs are therefore incorporated into the project.

3.4. Intervention logic and key assumptions

87. Costa Rica has several areas in biosafety in need of improvements. Assuming that the political and international arena will remain undisturbed and favourable towards the implementation of a biosafety framework, the current project will be able to address most of these needs, attending on the one hand to those considered priority or chosen by consensus, and on the other, to those that are pivotal to respond to both the CPB and national development goals. The main assumptions in this project are summarized in Appendix 4 (Results Framework) of the UNEP ProDoc, and relate mostly to societal and sectorial attitudes towards biosafety.

88. Institutional development is absolutely essential for meeting the challenges presented in the CBP. Therefore this is principally a capacity-building project aimed at benefitting key institutions to enable them to take on more tasks and responsibilities. A key objective of the project will be to develop a minimum human resource base to meet the decision-making demands of the CBP, and related necessities such as coexistence policies, and thus ensure that Costa Rica contributes together with other countries to sustaining biodiversity benefits through the implementation of the CPB. The project's structure shows the components that require the most effort, that have the highest start-up costs for implementation, or that are crucial for sustainability and strategic. An example of a strategic content is the foundations that will be laid to educate teachers and students to become better acquainted with biosafety and biotechnology issues. The symmetry of the project's structure with the components of the previous NBF Development project is indicative of the gaps that remained following this first effort. The current project therefore takes into account the advances and learning achieved from previous projects, so that the areas in most need of attention will receive more emphasis within the project, while those that have a prior base will be reinforced or taken to a further level.

89. In this respect, the project does not only look at immediate needs, but also looks ahead at impending issues and expectations. This is why coexistence, liability and redress, risk assessments and management of novel LMO types, education and ongoing training, food safety assessments, and information management (to balance transparency and awareness-raising with confidentiality and customer assurance) are key issues in this project. It is also responsive to society's demands, and respective of national decisions that condition available options. It is important to note that debates over the possibility (and costs and benefits) of putting forward a specific law for biosafety, versus the option of regulating via legal modifications and administrative routes, came out in favour of the latter, meaning that the notion of a biosafety law was written off once the ratification of the CBP became part of a busy Parliamentary agenda, and resulted in the National Law 8537. This decision also explains why much of the regulatory work that is pending relates to NCAs acting partially or disjointedly, and without harmonized or integrated administrative procedures.

90. Given the complexities and conflicts associated with biosafety, and since current initiatives for capacity building are mostly personal and resources to promote them are scarce, the value-added of aiding capacity building efforts through a GEF project is undeniable. There are also political benefits to be had from implementing a project under UNEP-GEF, as such an option entails a medium-term political commitment, which needs to be confirmed at project start and then maintained over time, and requires a certain level of guarantee for the sustainability of the capacity being built. Under a co-financing scenario, implementing legal adjustments and enforcing a coordinated inter-institutional administrative platform also becomes less onerous for NCAs budgets, yet once initiated, continued action over time through self-sustaining mechanisms is made more viable. Through this project, not only will NCAs access financial support to help them get started in adapting and adopting legal responsibilities that, otherwise, would have materialized after a long process of small uncoordinated steps, but opposition movements may also be empowered, monitored, informed and encouraged to work alongside the project instead of lobbying against it, as they recognize the UNEP-GEF initiative as a valid platform on which to stand their ground and air their concerns. Such an intervention therefore allows better capitalization of both institutional and personal motivations.

91. This is also the case with the network for evaluation, monitoring and communication in biosafety that the project aims to establish. This network is intended to link the human resources developed in the project with national technical capacity through strategic alliances with related national and international institutions, and will make information generated available to the national and international community through the BCH and other information mechanisms. But a novel aspect is that the project will home in on existing tendencies (and take lessons learned from prior experiences) to create and exploit non-regulatory mechanisms for recruiting self-motivated volunteers as civil observers for LMO monitoring and control, in exchange for specialized training and their recognition as conservation stewards. Such an approach will allow the mobilization of more extensive enforcement and surveillance efforts than if only institutionalized or formal mechanisms are relied upon, and will transmit the message that biosafety is not the exclusive task of regulatory bodies, but implies joint responsibilities.

3.5. Risk analysis and risk management measures

92. A number of project risks were identified during the course of project preparation, and the project design was adapted accordingly. These risks differ slightly from those considered at the PIF stage. The following table was developed through a national consultation with stakeholders from official (NCAs) and non official agencies and summarises likely risks and describes abatement measures within the scope of the project.

Table 4. Risk analysis and risk management measures

Risk	***Abatement Measures***	***Risk Level***
Critical dependence on the Costa Rican government's commitment towards the implementation of policies and inter-agency collaboration.	*CTNBio, as the executive branch of the project, will consolidate the agencies support through administrative agreements and decisions, and will foresee any changes in government structures, posts and administration or shifts in sectorial positions towards bio technology.*	*L*
Industry advances continue to outpace government capacity to respond to biosafety challenges	*Stakeholder consultations have included many representatives of the private sector, and there is consensus that either CTNBio like related Agencies should take a proactive approach. Therefore, The sector will be fully engaged in training and research activities under the project implementation.*	*M*
NGOs and civil movements from	*A project co-ordination unit has been designed to*	*M*

detractors of the technology could compromise the achievement of project objectives by putting pressure on Ministers and Heads of Agencies	*provide appropriate guidance to project implementation. NGOs and civil society representatives have been and will be consulted constantly in order to increment transparency and where possible, achieve consensus during the project.*	
Official approval of strategic, legal and regulatory proposals does not occur within the required or predicted timeframe.	*Although the level of country ownership of the project is high, legislative processes in Costa Rica tend to be slow. This risk will be mitigated through the strategic use of lobbying and communications to inform and raise awareness of political representatives, decision makers, and policy makers.*	*M*
Key stakeholders continue to have at least the present levels of interest in being involved in Project activities and acquiring and using the new knowledge and skills provided through the Project.	*The Project was designed and will be implemented with strong input from a broad range of stakeholders. Training strategies will be based on training needs assessments and will guide learners through activities, in which they will be required to participate and apply their knowledge. The project will promote incentives for personal and career development.*	*L*
WB-GEF-CIAT projects fail to deliver expected outcomes	*The most critical inputs that the WB-GEF-CIAT project will provide the current project relate to regulatory issues. Establishing deadlines for the expected outcomes of the WB-GEF-CIAT project, and programming coordination meetings between NEAs, CTNBio and WB-GEF National and /or International Project coordinator, and UNEP-GEF Task Manager when relevant, will help to mitigate this risk and determine at early stages the extent to which current outputs may need to be reformulated or reprogammed.*	*L*

3.6. Consistency with national priorities or plans

93. The Government of Costa Rica ratified the Convention on Biological Diversity in August 1994 and the Cartagena Protocol on Biosafety in February 2007. The CPB was published in November 2006 and is now Law Nº 8537. In addition, Costa Rica has elaborated a National Strategy in Biodiversity Conservation and Sustainability, in which the tenth strategic point relates to capacity building for the prevention of socioeconomic and environmental risks derived from the management of modern biotechnology and LMOs through biosafety capacity building projects. Increasing capacity in biosafety is therefore a specific line of action of this Strategy.

94. As stated in section 3.1, the current project responds to the need to contextualize biosafety within the country's development goals with regards to increased productivity, commerce and international trade, R&D and environmental protection. Under the current government, biosafety has remained on the agenda with the recognition in the State of the Nation 2008 report (Agriculture: Recent trends and environmental implications. One year of climatic and environmental crisis) that LMO risk assessment and management measures under Tropical conditions are urgently needed. In this respect, Costa Rica is committed to integrating biosafety into sectorial practices, as a safeguard and precautionary mechanism to allow modern biotechnology to be used to its maximum potential, while ensuring an adequate level of protection to biodiversity and human health and building confidence in the Executive.

3.7. Incremental cost reasoning

95. *BROAD DEVELOPMENT GOALS:* Costa Rica will be able to implement the basic objectives of the Cartagena Protocol, including the assessment, management, monitoring of the potential risks posed by transboundary movement of LMOs to the conservation and sustainable use of biodiversity, including human health risks and liability and redress. On the other hand, Costa Rica will implement regulation and norms in seeds, human and animal health and trade of FFPs.

96. *GLOBAL ENVIRONMENTAL OBJECTIVE:* Within three years, the country will build sufficient capacity to assess and manage risks associated with the trans-boundary movement of LMOs through strengthening of the legal, administrative and regulatory frameworks, enhanced institutional capacity and effective communication strategies. This enhanced capacity will assist Costa Rica to further protect its globally relevant bio- and agro-biodiversity in agricultural system, protected areas, biological reserves and national parks.

97. *BASELINE:* Costa Rica will develop its capacities in evaluating, monitoring, and managing the risks associated with the trans-boundary movement of LMOs. CTNBio co-ordination efforts will develop and disparate capacities between the different ministries that make up its technical committee will continue to hamper a more integrated effort. Strengthening CTNBio is based on incrementing the capacity of each of its institutional partners. GEF support will help right these unequal capacities and will ensure that the governmental system operates in unison. The WB-GEF project through University of Costa Rica and other national and international academic institutions will continue carrying out research in support of CTNBIO to LMOs risks assessment in not target organisms, socioeconomic considerations, gene flow in rice and cotton crops and presence in imported grains. A national policy in biotechnology and biosafety will increase Costa Rican capacity to perform biotechnology research and to further promote national projects through technology transfer towards successful business applications through CENIBiot or another governmental o private institution. Biosafety is one of the key aspects of the government programme and CTNBio capacity building programme will provide needed –if limited- supports.

98. *GEF PROJECT ALTERNATIVE:* GEF's participation in strategic elements of Costa Rican biosafety capacity building effort over the medium-term horizon (3 years) will permit the longer-term consolidation of the strategy. The GEF alternative provides support in legal, administrative, capacity building and formulates a strategy in formal education components that will substantially increase Costa Rican immediate response to the provisions of the Cartagena Protocol. The project will have a catalytic and consolidating effect on the national effort spearheaded by the CTNBio and NCAs. The project will focus on the assessment, regulation, administration, capacity building, education and management of the risks derived from the release, research, commercialization and utilisation of LMOs, that might present adverse risks to the conservation and sustainable use of biological diversity, taking also in account potential risks to human health. This national approach to capacity building contemplates risk assessment and management, monitoring and evaluation, legal and regulatory reform/strengthening, broad social participation, a dissemination strategy and institutional strengthening in the context of the Advanced Informed Agreement.

99. SYSTEM BOUNDARY: The system boundary of the project is the Costa Rican national territory, with expected benefits and lessons learned for other regions in the world. Project resources assigned to capacity-building efforts will be concentrated in NCAs and other autonomous institutions that support biosafety activities, principally Ministry of Health, MINAET, SENASA, ONS, etc.

100. *ADDITIONAL BENEFITS:* Costa Rica's national biotechnology policy will benefit from increased national capacity to evaluate and manage risks associated with LMOs, contributing to the possibility of increasing yields in rural environments and diminishing pressures on arable lands and protect areas. Increased food production and security may also prove to be eventual benefits of the

project. The process of project development has built trust and increased technical exchange between CTNBio and other sectors of the government. The project component on capacity-building identified by CTNBio has been enriched and strengthened through this consensus-based approach and through stakeholder consultations and inter-agency processes.

101. *COSTS:* As further explained in the Incremental Cost Analysis (Matrix) presented in Appendix 3, the total costs of the project are estimated at US$ 1.481 M of which GEF is requested to provide US$ 718,873 as agreed full cost funding, or 49% of the project cost. Costa Rican government and other national Institutions will fund a total of US$ 762,232 through CTNBio, SFE, ONS, CONAGEBIO, MS y MINAET, etc. Considering only technical elements, the baseline costs are US$ 450,000 and the incremental costs total US$ 764,960 for the technical components of the project.

3.8. Sustainability

102. The current project is designed keeping in mind the sustainability of the capacity being built. It has also considered the best means to ensure long-term impacts of the project; for this, lessons learnt and experience gained are key assets. Costa Rica's experience has shown that the NBF can sustain itself, if functional and well managed, and if capacity is built around three main pillars: LMO users, biosafety executers and political commitment. Users are key elements in achieving sustainability, and may be an important source of revenue and technical assistance. Adoption of the NBF by current companies and universities, and its putting into practice, will ensure that the system is not only able to work properly but also evolve. NCAs may consider introducing new administrative charges for LMO authorizations and follow-up, as a means to sustain the expansion of the NBF and its operations.

103. Thus, a working relationship between the regulators and the regulated is recommended and can lead to better understanding of what an effective NBF entails. Likewise, the involvement of NCAs throughout the regulatory planning, harmonization, approval and enforcement processes will lay the foundations on which the NBF's sustainability will rest. Political commitment can best accrue if society is witness to an efficient and transparent system, and if laws, executive decrees, ministerial decrees, official procedures and other legal measures are in place to enable NCAs to take specific lines of action, enforce, and reassure the public that potential risks from LMOs can be managed. The preparation of a policy is also a concrete way to seal this political commitment. In institutional terms, sustainability can be vulnerable to staff turnovers and Government changes, but the functioning of the CTNBio has proved useful in mitigating against such a tendency. In this respect, the project's components focus on outcomes that are CPB requirements, that are of sectorial interest and that need to be sustainable in order for the NBF to be fully functional. The project must therefore take into account sustainability in all its interventions.

3.9. Replication

104. As a project to be executed nationally in a tropical country with significant experience in agricultural LMOs, there is potential to replicate positive experiences and know-how, particularly within the Central American region. Experience gained from project management and from the coordination of various participatory processes will not only be beneficial considering other endeavours within the Costa Rican government, but may also provide lessons and best practices that can be shared with other countries. These could in turn be used for better project design and implementation in other similar capacity building projects, or could serve as replicable examples of methodologies that have proved effective when dealing with complex multi-sectorial and transversal issues such as biosafety. Thus the current project contemplates periodic regional meetings, to promote exchanges and networking between project staff and other experts involved in biotechnology and biosafety.

3.10. Public awareness, communications and mainstreaming strategy

105. The project has been designed to work towards developing consensus among producers, environmentalists, decision-makers and technicians on key biosafety issues, and has been extended to incorporate other relevant NCAs and sectors, including health, education, communication and customs, among others. Though most outreach efforts and awareness-raising activities are being deputized to the WB-GEF-CIAT project, this project will nonetheless make a substantive contribution to public awareness and education in biosafety, in the future, through the preparation of and lobbying for the TEACH strategy. Formulating a biosafety policy, and looking to include biosafety within educational curricula, are two key steps towards mainstreaming biodiversity considerations into sectorial activities. Another is the involvement of civil society in support of regulatory functions, whereby public participation is mainstreamed into biosafety management and civil society groups are empowered to act in favour of the environment. To enhance further public participation and communications, NCAs and the general public will be encouraged to access newly compiled biosafety information through the national BCH web site. By means of the BCH and clear data management tasks, biosafety communications in this case will go hand-in-hand with transparency and visibility.

3.11. Environmental and social safeguards

106. As the project supports the implementation of relevant international agreements (CPB in this case), it is intended to have beneficial effects on the environment and socio-economics of the country and the region. The project will be executed by a Government agency with a mandate in biosafety, and as such, environmental safeguards will be taken in any aspects of the proposed intervention that may impact on the natural environment. Social safeguards will be taken for any public or multi-sectorial activities to be carried out, yet the participatory nature of the project and the incorporation of socio-economic considerations to improve the management of biosafety will in themselves ensure that equal opportunities and favourable conditions are provided to all sectors and stakeholder groups, irrespective of gender, creed or status.

SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS

Implementation arrangements

107. The Project will be executed by the Government of Costa Rica, through the National Technical Commission on Biosafety (CTNBio) as the National Executing agency (NEA). All the institutions, agencies and participants who are members of the CTNBio have had an active role in executing previous biosafety projects, including the development of the NBF and the BCH project. Accordingly, all have participated in the planning and design process of the current proposal, and have shown interest and disposition in sharing the responsibility of executing the project. Their accumulated experience in executing GEF projects is therefore an asset. As the government executing agency, CTNBio will be responsible for the coordination and management of the project and will monitor compliance with work plans as the basis for Project execution. This group will ensure the political oversight of the project, and will be ultimately responsible for overall project performance and delivery. Among its attributions will be the approval and review of Annual work plans and budgets, the designation of responsible persons or institutions for the execution of different component of the project, and any substantial changes to these project management tools.

108. Furthermore, each member of the CTNBio represents a stakeholder of the biosafety system, and as such, will carry out communication and coordination functions, and supervise the activities, strategies and expected outcomes that are of interest to their respective institution. In this spirit, the CTNBio has the added advantage of providing not only managerial services, but also a means for participation and consultations within the project.

109. To act as NEA, the CTNBio will be supported by various functional structures for which the implementation arrangements are described below and depicted schematically in Figure1; notwithstanding this division of functions, the CTNBio will ultimately (and legally) remain responsible to UNEP for the entirety of the project. As secretariat to the CTNBio, and Costa Rica's National Focal Point to the CPB and BCH, the Biotechnology Programme of the MAG will provide the necessary technical and logistical support for the project and its overall coordination. Meetings of the CTNBio will be planned on regular basis to monitor the project's development and to make adjustments as required.

National Coordination Committee (NCC)

110. More than a managerial role, the project's National Coordination Committee will fulfil a role in facilitating participation and consultations with groups not represented within the CTNBio, such as other NCAs, representatives from social groups and NGOs, industrial sector representatives, members of the academic world and researchers. Its function as a "steering committee" will ensure general project oversight, in as far as reviewing the validity of the project and its objectives as time progresses is necessary to guarantee its effectiveness. This Committee is expected to session on a quarterly basis; further details on the NCC are provided in Section 5.

Project Management Unit (PMU)

111. A Project Management Unit (PMU) will be based and supported within CTNBio to administrate the project. The PMU will be responsible for the day to day coordination of project activities, and among its main functions it will be required to draft the project´s Annual work plan and Annual budget, coordinate project implementation with key partners, keep records and files in order, and draft TOR's for project consultants and other consultancies commissioned by the project. The PMU will follow instructions and directives of the CTNBio. The PMU will consist of a Project Manager and a Project Junior Staff provided by the SFE- Biotechnology Programme of the MAG.

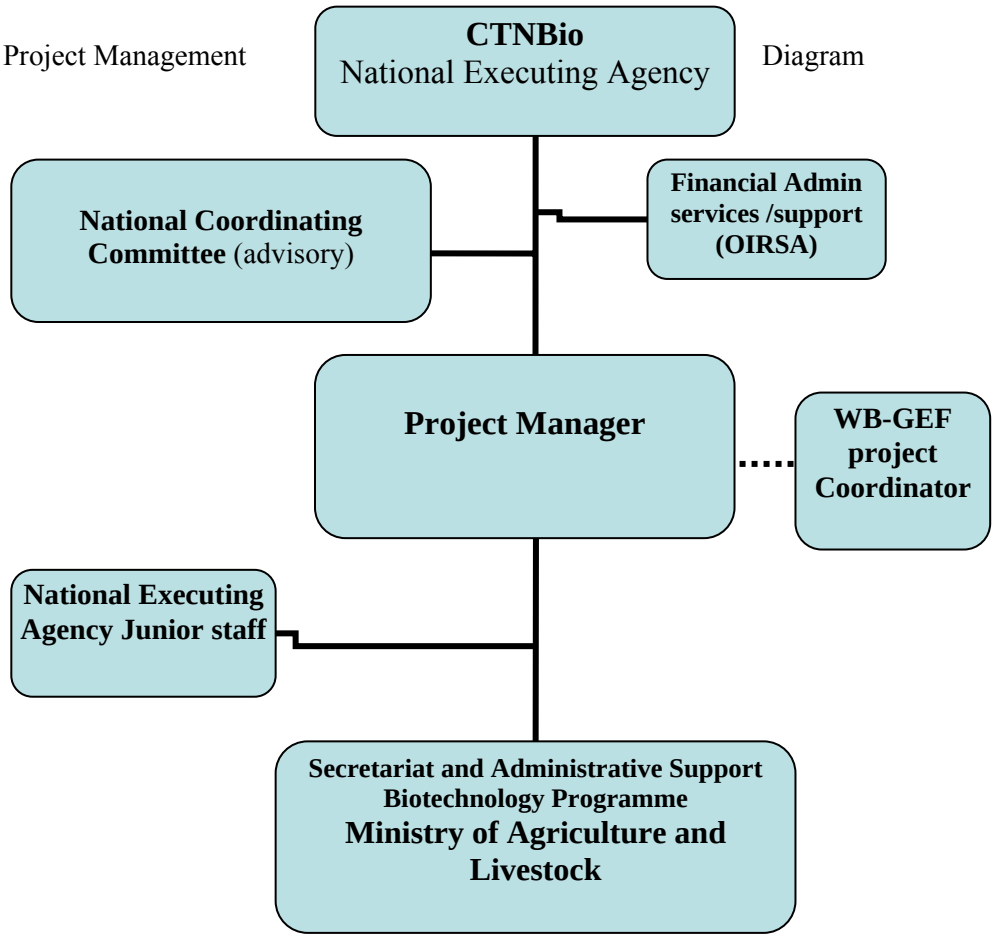
Project Manager (PM)

112. The Project Manager will be hired by the NEA (CTNBio) according to the TORs included in Appendix 11, and will be responsible for running the project's day-to-day operations, leading and managing project activities and ensuring that the project progresses on schedule and delivers the expected results. The Project Manager will implement work plans and overall strategies approved by the NEA and the NCC, and will report to both instances. .The Project Manager will prepare and disseminate information on the project, and will have monthly meetings with the CTNBio and every three months with the NCC to present periodic reports and updates. The Project Manager will be in charge of contracting services for the project and supervising the work of consultants, and will lead efforts to coordinate field activities with associated programmes taking into account those areas in which synergies between the WB-GEF and the UNEP-GEF were identified.

Financial management

113. The International Regional Organism for Plant and Animal Health (OIRSA) will be the financial institution to be hired by the NEA to manage the project's GEF funding, and will be responsible for issuing financial reports, keeping accounting records, obtaining best-value offers for contracts and services, processing procurements and facilitating administrative and financial information at the request of the NEA or UNEP. The financial services to be sub-contracted to OIRSA will be in accordance with national and international legal and administrative norms and in strict compliance with OIRSA's rules and procedures as stipulated in the Manual for Procedures on Purchases and Supplies for Nationally Executed Projects. OIRSA will send the NEA regular reports (minimum every 3 months) to check aid the NEA in its reporting tasks to UNEP. OIRSA will only process payment requests made by the Project Manager and approved by the President of the CNTBio. As project NEA, the CTNBio maintains full responsibility for all financial and technical aspects of MSP implementation.

Figure 1. Project Management Diagram



SECTION 5: STAKEHOLDER PARTICIPATION

114. As part of project preparation, CTNBio recently hosted a workshop in order to identify national priorities, gaps, and potential activities, assess needs among NCAs and other stakeholder with regards to the biosafety system in general and the CPB in particular, and obtain updated information to develop the project's baseline. Stakeholders included NCAs and government representatives, NGOs, private sector, academics, WB-GEF Coordination Unit, and international cooperation agencies and institutes. The main focus was to elucidate priorities, exchange views, discuss options and based on current information and needs, develop a logical framework matrix for the project.

115. The participation of stakeholders during the planning and formulation of this project has proved essential in empowering these groups to voice their views, respect the views of others, and seek further information when needed. This is expected to be beneficial when the project comes to the point of having to disseminate rules, regulations, technical norms and administrative procedures, as these agents will be in a better position to communicate these developments to their circles of influence circles, and generate trust for creating a feedback process on which the NBF will evolve and adapt to the changing needs of the country.

116. Over the last few years, multiple workshops on environmental biosafety have been organized in Costa Rica directed at stakeholders, policy makers, the scientific community, and civil society, thus broadening the information base and strengthening public participation in environmental issues. Indeed, broad-based public consultations on biosafety issues are currently underway in the context of the integration of the National Development Plan. Participants include representatives from all sectors in Costa Rica. Public consultations on biosafety previously undertaken have been published in the State of the Nation, proving not only the importance of the concerns raised by the groups consulted, but also the deep commitment of the authorities in complying with these public manifestations. What is more, Costa Rica has put in place autonomous agencies to represent the interests of civil society and convey their worries through established channels. Likewise, consumers and civil society groups are consulted through national associations and official Agencies, which for the purpose of the present project, are relevant mechanisms to support the participatory processes to be conducted.

117. As an internationally recognized country for its stance on conservation, environmental NGOs in Costa Rica are well funded and play an important role in implementing biodiversity projects and attracting public support, which means that they have valuable expertise that should be taken into account. Through the project, opportunities will be provided to NGOs, academics and the research community to publish opinions and to disseminate them to the public. Additionally the BCH will offer the opportunity to create forums on relevant/important biosafety subjects for the purpose of obtaining input from the public at large and feedback on the projects outcomes, particularly at the institutional level.

118. Though there are several life science companies in Costa Rica, and links with these stakeholders have historically been positive, a challenge for the current project will be to develop a working relationship with new segments of the private sector. Those most familiar with biosafety are the seed companies, yet there are many other productive sector stakeholders, such as the food processing industry or pharmaceuticals, who will have to be gradually brought on board in order to enrich the NBF and consider novel types of LMOs. The possibility of becoming a regulated sector may also imply a certain level of resistance from these groups, so care will have to be taken to form a working relationship that can benefit all parties and provide constructive feedback.

119. The project's NCC will play a central role in articulating the project's participatory processes. Most consultations and activities for integration will take place through the NCC, who will also serve as a sort of "steering committee" providing advice on the project, and indirectly offering guidance for

the biosafety system in general. Table 5 below describes the roles of the main stakeholder groups contemplated for the execution this project, and who have so far been involved in project planning.

Table 5. Roles of Stakeholders

Stakeholders	Role
CTNBio	CTNBio will be the executing branch of the project; therefore it will be emitting technical and operative directions during project's execution. Representing the National Competent Authorities which currently are members of CTNBio.
National Institutions (SENASA, INCOPESCA and Ministry of Health)	Other National Competent Authorities which are not part of CTNBio but still have an important role in the planning and further implementation of activities within the project. These institutions are planned to become active members of the National Coordination Committee (NCC).
Civil Society and NGOs	Representatives from social groups and other NGOs (particularly farmers associations and environmentally concerned groups) will be fully integrated into the NCC conveying social approaches to the planning and implementation of the project. Likewise, civil collaborators in rural communities will be identified and working closely within group of social stakeholders.
Private Sector	Industrial sectors representatives from the Food industry, seed producers and future technology users will be included as active members of the NCC.
Academia	Representatives from the academia, public education, and researchers will be consulted during development of guidelines, procedures, and communication and education strategies. One spokesperson will represent the academia in the NCC.
International and Regional organizations	Strategic alliances with regional and international cooperation agencies will be considered in order to facilitate the implementation and accountability process. These alliances will include feedback practices and technical support from the agencies.

SECTION 6: MONITORING AND EVALUATION PLAN

120. The project will follow UNEP standard monitoring, reporting and evaluation processes and procedures. Substantive and financial project reporting requirements are summarized in Appendix 8. Reporting requirements and templates are an integral part of the UNEP legal instrument to be signed by the executing agency and UNEP.

121. At the time of project submission a high degree of baseline data was available. If needed, baseline data gaps will be addressed during the first year of project implementation, and a plan for collecting this information will be agreed between the Project Team and UNEP at the inception workshop.

122. The project M&E plan is consistent with the GEF Monitoring and Evaluation policy. The Results Framework presented in Appendix 4 includes SMART indicators for each expected outcome as well as mid-term and end-of-project targets. These indicators along with the key deliverables and benchmarks included in Appendix 6 will be the main tools for assessing project implementation progress and whether project results are being achieved. The means of verification and the costs associated with obtaining the information to track the indicators are summarized in Appendix 7 and also Appendices 1 & 2. Other M&E related costs, such as external evaluations to the project, are presented in the Costed M&E Plan (Appendix 7) and are fully integrated in the overall project budget.

123. The M&E plan will be reviewed and revised as necessary during the project inception workshop to ensure project stakeholders understand their roles and responsibilities vis-à-vis project monitoring and evaluation. Indicators and their means of verification may also be fine-tuned at the inception workshop. Day-to-day project monitoring is the responsibility of the project management team but other project partners will have responsibilities to collect specific information to track the indicators. It is the responsibility of the Project Manager to inform UNEP of any delays or difficulties faced during implementation so that the appropriate support or corrective measures can be adopted in a timely fashion.

124. The NCC serving as the project's Steering Committee will receive periodic reports on progress and will make recommendations to UNEP concerning the need to revise any aspects of the Results Framework or the M&E plan. Project oversight to ensure that the project meets UNEP and GEF policies and procedures is the responsibility to the Task Manager in UNEP-DGEF. The Task Manager will also review the quality of draft project outputs, provide feedback to the project partners, and establish peer review procedures to ensure adequate quality of scientific and technical outputs and publications.

125. Project supervision will take an adaptive management approach. The Task Manager will develop a project supervision plan at the inception of the project which will be communicated to the project partners during the inception workshop. The emphasis of the Task Manager supervision will be on outcome monitoring but without neglecting project financial management and implementation monitoring. Progress vis-à-vis delivering the agreed project global environmental benefits will be assessed with the Steering Committee at agreed intervals. Project risks and assumptions will be regularly monitored both by project partners and UNEP. Risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR. Key financial parameters will be monitored quarterly to ensure cost-effective use of financial resources.

126. A mid-term management review or evaluation will take place on July 2011 as indicated in the project milestones. The review will include all parameters recommended by the GEF Evaluation Office for terminal evaluations and will verify information gathered through the GEF tracking tools, as relevant. The review will be carried out using a participatory approach whereby parties that may benefit or be affected by the project will be consulted. Such parties were identified during the stakeholder analysis (see sections 2.5 and 5 of this Project Document). The project NCC, PMU and CTNBio will participate in the mid-term review and the CTNBio will develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented.

127. An independent terminal evaluation will take place at the end of project implementation. The Evaluation and Oversight Unit (EOU) of UNEP will manage the terminal evaluation process. A review of the quality of the evaluation report will be done by EOU and submitted along with the report to the GEF Evaluation Office not later than 6 months after the completion of the evaluation. The standard

terms of reference for the terminal evaluation are included in Appendix 9. These will be adjusted to the special needs of the project.

128. The GEF tracking tools are attached as Appendix 15. These will be updated at mid-term and at the end of the project and will be made available to the GEF Secretariat along with the project PIR report. As mentioned above the mid-term and terminal evaluation will verify the information of the tracking tool.

SECTION 7: PROJECT FINANCING AND BUDGET

7.1. Overall project budget & Co-financing

129. The overall project budget is set at USD 1,481,105 with USD 718,873 being provided by the GEF on the basis of Costa Rica's current Resource Allocation Framework for Biodiversity, and USD 762,232 being provided by the Costa Rican Government as co-financing. Project costs are being shared at a ratio close to 1:1. For further information on budgeting of GEF funds, please refer to Appendix 1. Co financing shall be provided in kind, as set out in Appendix 2. Below a summary table is presented, and includes the amounts spent in project preparation.

	Project Preparation a	*Project b*	*Total c = a + b*	*Agency Fee*	*For comparison: GEF and Co-financing at PIF*
GEF financing	*8,400*	*A 718,873*	*727,273*	*72,727*	*718,873*
Co-financing	*9,320*	*B 762,232*	*771,552*		*750,102*
Total	*17,720*	*1,481,105*	*1,498,825*	*72,727*	*1,468,975*

7.2. Project cost-effectiveness

130. The current project's design is cost-effective for a number of reasons:

- A stocktaking assessment and consultation exercise was carried out during the project preparation phase to ensure sectorial representation and the inclusion of targets that are relevant and responsive to real country needs.
- The proposed intervention focuses on priority areas where the highest impact or probability of success can be achieved and where some level of institutional buy-in already exists, and builds on the progress made in these areas during the initial development of the NBF. Continuity and consolidation are therefore important factors that contribute to this project's cost effective design.
- The project incorporates lessons learnt from previous UNEP-GEF projects.
- The project's execution will be supervised at every level by an already operational, multi-disciplinary and multi-sectorial committee (CTNBio) with prior experience in the execution of such projects, and takes into account administrative limitations so as to propose the most cost-effective implementation arrangements.
- The project is complementary other related efforts in order to cover all areas of the biosafety system, maximise opportunities and avoid duplicities.
- The project takes advantage of alliances to promote partnerships and will cost-effectively combine resources, strategies and programs in order to "spread the load" between public and private institutions, but make biosafety capacity building more sustainable.
- The project addresses long-term educational needs as a cost-effective approach to increment the overall level of understanding of biotechnology and biosafety issues in the country.
- The project is also cost-effective by looking to build a solid technical and information-management base, to better serve institutions in their administrative functions in general, and to attend to biosafety requirements in particular.

APPENDICES

Appendix 1. (a): Budget by project components and UNEP budget lines

Project Component	UNEP-GEF budget ($)	%	Government contribution ($)	%	Total budget
1. Putting in place a national biosafety regulation and promoting a biosafety policy in accordance with the CPB.	179,365	51	175,000	49	354,365
2. Making of an operational and administrative system to fulfil obligations to the CPB and strengthen the decision processes - making base and its mechanisms.	111,394	48	120,000	52	231,394
3. Building technical capacity in NCAs and related institutions for comprehensive biosafety management.	182,394	46	212,130	54	394,524
4. Improved communication, education, public perception and participation in biosafety of all relevant stakeholders	108,677	46	126,000	54	234,677
SUBTOTAL	**581,830**		**633,130**		**1,214,960**

OTHER			
M&E costs	66,000		66,000
Project Management	71,043 (*)	129,102 (**)	200,145
TOTAL	**718,873**	**762,232**	**1,481,105**

(*) Exclusive funds for Project Manager

(**) Government funds for official personnel working closely with the Project Manager.

Appendix 1. (b): Budget by project components and UNEP budget lines

1	Putting in place and applying National biosafety regulation and promoting a biosafety policy in accordance with the CPB				
Sbln	Description	Year 1	Year 2	Year 3	Total
1200	Individual consultants				
	Legislation Expert to coordinate with NCAs and Public Business Manager to elaborate the regulation proposal (decrees, norms, guidelines, rules) that must include financial mechanism, administrative, simplified procedures, responsibilities, coordination procedures), negotiate, harmonize and obtain the approval of NCAs as well as a CTNBio decree modification for including SENASA and Ministry of Health.	10,000			10,000
	Expert in Public Business Manager to prepare an administrative system proposal in coordination with the legal expert and NCAs	8,000			8,000
	Expert in press and publicity (must work in coordination with the Legislation and business administration experts and NCAs) for designing strategies to help the lobby expert in order to obtain the political support to implement the legal and administrative proposal.	5,000			5,000
	Expert to design guidelines for summiting applications for article 11: Food, Feed and Processing (FFPs) and article 18 to NCAs.	5,000			5,000
	One expert to design legal and technical norms and guidelines for coexistence for 6 crops: soybean, cotton, maize, musaceas, ornamental and vegetables. Expose those norms and guidelines for the discussion through workshops with organic, traditional and GMO representatives and NCAs (20 people). Approval of NCAs	12,000			12,000
	Expert to obtain political compromise, prepare a draft document and action plan about biotechnology and biosafety in feed , food , environment and human and animal health	10,000			10,000
	Lawyer expert to, based on the supplementary protocol of article 27, inform, harmonize and prepare a national position to be presented in COP-MOP5, and prepare a proposal to NCAs according with Nagoya agreements	6,000			6,000
	Expert to prepare to design regulatory guidelines for LMOs, certification issues, and liability and redress users of the Ministry of Health, Environment, Agriculture and SENASA	12,000			12,000
	One expert, who will elaborate guidelines on risk management and risk assessment based on national and international guidelines on FFPs LMOs, Environmental release of trees, insect, animal, etc., and harmonize and officialise the guidelines with NCAs. The consultant must participate in the workshops of case studies at least the first day to complement the workshop together with the international consultant in charge of the study cases.	15,000			15,000
	Subtotal				**83,000**
1300	Translators				
	3 translation for political meetings	2,700	2,700	2,700	8,100
	Subtotal				**8,100**
2200	Subcontracts				
	OIRSA financial administration services	6,845	3,168	880	10,893
	Subtotal				**10,893**
3200	Group training workshops				
	6 Workshop to present FFP guidelines and article 18 during the		12,000		12,000

	second year, after the Legal system is approved. Period 6 months.				
	3 Workshop (1 each 2 months) of coexistence. During the first 6 months of the second year.		6,000		6,000
	3 workshops with NCAs, in order to harmonize the guidelines for LMOs users (based on administrative system derived of the legislation approved) The second year of the project,		6,000		6,000
	workshop with NCAs to know and approve the National Report CPB	2,000			2,000
	workshop with NCAs for National Position in COP-MOP 5 (Liability and redress national position)	2,000			2,000
	Workshops with judges, operators and tribunals in order to present and harmonized Legal proposal according with Nagoya agreements. The proposal must be presented and harmonized during Second year of the project		4,500		4,500
	Subtotal				**32,500**
3300	Meeting/conferences				
	4 Meetings every 2 months, with NCC and NCAs for to discuss regulations in administrative system. One meeting may include the financial issues. One meeting may include administrative issues. One meeting may include the operative mechanism. One meeting of technical issues describe in the article 18 of Law 8537 (BCP) and coexistence.	8,000			8,000
	4 Meetings (4) with NCAs and CTNBio to harmonize the guidelines and present the tools developed by WB project to make official use of them the biosafety national regulation.			8,000	8,000
	Subtotal				**16,000**
4100	Expendable equipment				
	Consumables and office materials	2,800	2,800	2,900	8,500
	Subtotal				**8,500**
4200	Non-expendable equipment				
	One laptop computer	1,500			1,500
	One fax	180			180
	Two printer-scanners	1,360			1,360
	One multimedia projector	2,332			2,332
	Subtotal				**5,372**
5105	Rental of meeting rooms and equipment				
	Rental of meeting rooms		15,000		15,000
	Subtotal				**15,000**
	SUBTOTAL COMPONENT 1	112,717	52,168	14,480	**179,365**

2	**Making operational an administrative system to fulfil obligations to the CPB**				
1200	Individual consultants				
	Consultant to manage and implement the operative and administrative system for NCAs: including financial resources, human needs, equipments, buildings and others harmonized, during the second year.		5,000		5,000
	Informatics Expert to create a safe Competent authority network for sharing and making decisions.		7,500		7,500
	An International Expert for political meetings with Minister and Vice Minister of Human Health, Environment, Agriculture and Science and Technology and other Institutions involved in the project execution.	6,000			6,000

	Subtotal				**18,500**
1600	Travel on official business				
	3 Regional meeting of NBF Implementation Project Managers (LAC)	7,500	7,500	7,500	22,500
	Subtotal				**22,500**
2200	Subcontracts				
	OIRSA financial administration services	1,132	4,907	638	6,677
	Subtotal				**6,677**
3200	Group training/ workshops				
	3 workshops with 30 people each meeting. NCAs, NCC and stakeholders (biotech, importers, agriculture, researchers, etc). 1 Each 2 months, to study proposal of implementation for the operative and administrative system		6,000		6,000
	1 Workshop to define responsibilities on technical, administrative and coordination mechanism between NCAs		2,000		2,000
	Subtotal				**8,000**
3300	Meeting/conferences				
	Three Political Meetings with Minister and Vice Minister of Human Health, Environment, Agriculture and Science and Technology and other Institutions involved in the project execution: At the beginning of the project to inform agreements, compromises and action plan, the second meeting will be to inform the advances, in the third meeting to inform about results and future actions.	2,500	2,500	2,500	7,500
	Subtotal				**7,500**
4100	Expendable equipment				
	Software and security system of CBI information		10,000		10,000
	Consumables and office supplies		7,000		7,000
	Subtotal				**17,000**
4200	Non-expendable equipment				
	Computer system: Servers, computers, terminals, internet, cable, etc. Condition Air.		15,000		15,000
	Digital Archive with backup		5,000		5,000
	Two GPSs equipment		4,460		4,460
	1 colour laser printer	1,757			1,757
5105	Rental of meeting rooms and equipment		5,000		5,000
	Subtotal				**31,217**
	SUBTOTAL COMPONENT 2	18,889	81,867	10,638	**111,394**

3	**Building technical capacity in NCAs and related institutions for comprehensive biosafety management**				
1200	Individual consultants				
	One international expert to elaborate 2 workshops of one week of training session on traditional and novel LMOs risk assessment and management with case studies for decision makers.			15,000	15,000
	One expert (with NCA's involved in project execution) to create guidelines and train official customs, human and animal health technicians, park rangers and civil observers. During the third year of the project.			7,000	7,000
	Subtotal				**22,000**
1600	Travel on official business				
	Travel and per diem for three international consultants			14,000	14,000
	Subtotal				**14,000**

2200	Subcontracts				
	OIRSA financial administration services		1,842	9,052	10,894
	Subtotal				**10,894**
3200	Group training/ workshops				
	2 workshops for NCAs of 3 days each one for traditional and novel risk assessment during 12 months. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment.		6,000		6,000
	2 workshops for NCAs of 4 days for risk management, liability and redress, identification and coexistence issues. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment.		8,000		8,000
	2 group training for NCAs with international experts on risk management, including case studies and protocols elaboration. Workshop will include food safety, feed (FFPs) and environmental issues.			10,000	10,000
	Training session in an international government regulation agency for risk assessment and risk management during the last year of the project (Spain, Brazil, USA, Canada, EU) Each NCA (1 MINAE, 1 MAG, 1 HEALTH, 1 MICyT.)			28,000	28,000
	1 workshops with organic, traditional and GMO representatives and NCAs. 1 each 3 months, during the second year of the project. 20 people. For to discuss coexistence guidelines in different crops.		5,000		5,000
	1 workshop of 3 days of training for official auditors and civil observers in monitoring and integration of GPS techniques, regulation. 20 people			13,000	13,000
	Training of quarantine and customs officers, human and animal health technicians and park rangers: Read and interpreted documents, according with Article 18 PCB, 4 meeting 50 people for 2 days during the third year.			25,000	25,000
	Long term training of National Competent Authorities. Example: MSc degree in UNIDO, National and international universities or excellence centres.			20,000	20,000
	Subtotal				**115,000**
3300	Meeting/conferences				
	A seminar with 100 people (stakeholders) that explains the Identification system. Publication in the website.			10,500	10,500
	Seminar about coexistence. 200 people. The meeting will be in the afternoon, with coffee, CDs, brochure, programme, invitations, folders, pens, pencils, and a place for the meeting, multimedia, translation, videoconference, and a link with a national web site for international event.		10,000		10,000
	Subtotal				**20,500**
	SUBTOTAL COMPONENT 3		30,842	151,552	**182,394**

4	**Improved communication, education, public perception and participation in biosafety of all relevant stakeholders**				
1200	Individual consultants				
	Hire an expert that must have knowledge in Biotechnology, Biosafety and education. The expert has to develop a strategy of formal education about Biosafety of the Biotechnology for primary and secondary school. The expert must identify a task Force with people related (MEP).			15, 000	15,000

	4 advisors: Education specialist, pedagogues, Biologist, a Specialist in curricula in schools programme			20,000	20,000
	Expert in TI. The expert will improve the Web page and linked with other national database including those developed by WB project. The expert harmonize the information of Costa Rica in FAO, IICA, BCH, AGBIOS, FDA, BIO, Europe database, etc, in the National Web Page.			3,000	3,000
	Subtotal				**38,000**
3200	Group training workshops				
	8 workshops of the task force. 1 per month to discuss strategy in formal education			7,000	7,000
	A workshop for presenting the final webpage to the NCAs			4,000	4,000
	Subtotal				**11, 000**
2200	Subcontracts				
	OIRSA financial administration services			6,677	6,677
	Subtotal				**6,677**
2300	Subcontracts				
	Elaborate the materials for the implementation of the strategy (formal education)			17,000	17,000
	Campaign and forums for the access and use of BCH and databases and tools developed by the WB project. Integration and collaboration with the Ministry of Science and Technology for using CECI's (Intelligent Community Centres). The target population is the producers, export, imports and educators			15,000	15,000
	Subtotal				**32,000**
3300	Meeting/conferences				
	2 political meetings with the Ministry of Education, CONARE, MICIT, CONESUP, etc. At the beginning and one at the end of the Strategy Draft.			5,000	5,000
	Meetings with UNESCO, IICA, FAO, CBD, UNEP, GEF, WB, BIO, GTZ, Universities Michigan State, Brazil Universities, ANBio, Governments, American Soybean Society, etc, that are developing or are interested in developing education programmes, to present the strategy of formal education and establish the mechanism of coordination and financial cooperation.			10,000	10,000
	Subtotal				**15,000**
4200	Non-expendable equipment				
	Consumables			6,000	6,000
	Subtotal				**6,000**
	SUBTOTAL COMPONENT 4			108,677	**108,677**
		Year 1	**Year 2**	**Year 3**	
	Subtotals by year for technical components	**131,606**	**164,877**	**285,347**	**581,830**

	Project Management				
Sbln	Description	Year 1	Year 2	Year 3	Total
1100	Project Personnel				
	Project Manager	23,681	23,681	23,681	71,043
	Proj Mangmt SUBTOTAL	**23,681**	**23,681**	**23,681**	**71,043**

	Project M&E				
3300	Meetings/Conferences				
	Project Inception Workshop	3,000			3,000
	Steering Committee Meetings	1,500	1,500	1,500	4,500
	Work Meetings	2,000	2,000	2,000	6,000
	Subtotal				**13,500**
5200	Reporting				
	Project Inception Report	500			500
	Annual Project Report and PIR	1,000	1,000	2,000	4,000
	Information needs				10,000
	- Initial and final tests on monitoring, L&R and coexistence	2,000	2,000	-	
	- Initial, final tests and case studies on risk assessment and management performance.	-	2,000	2,000	
	- Evaluation based on case studies of performance LMOs in trade procedures.	-	-	2,000	
	Periodic Reports to UNEP	400	400	400	1,200
	Terminal Report			800	800
	Subtotal				**16,500**
5500	Evaluation				
	Indicators:				6,000
	- Measuring indicators of project objectives	1,000	1,000	1,000	
	- Measuring means of verification of project progress	1,000	1,000	1,000	
	External Evaluations				30,000
	- Mid-term Evaluation		10,000		
	- Final Evaluation			10,000	
	- Audits	3,000	3,000	4,000	
	Subtotal				**36,000**
	M& E SUBTOTAL	**15,400**	**23,900**	**26,700**	**66,000**

Appendix 2: Co-financing by source and UNEP budget lines

Sbln	Description	Year 1	Year 2	Year 3	Total	Source
1100	Project Manager	43,075	42,952	43,075	129,102	GOV
	National personnel /technical staff involved in project execution (NCAs, training, workshops, steering committee, etc).	45,450	138,065	132,715	316,230	GOV + autonomous /semi-autonomous institutions
1300	Administrative and technical support personnel	48,000	52,800	57,600	158,400	GOV
3300	Rental of meeting rooms	15,000	15,000	20,000	50,000	GOV
4100	Expendable equipment	9,000	15,000	20,000	44,000	GOV
4300	Premises	6,000	7,000	10,000	23,000	GOV
5100	Maintenance of equipment	12,000	12,000		24,000	GOV
5300	Sundry (communications, postage,freight, clearance charges, etc.)	5,000	5,500	7,000	17,500	GOV
	TOTAL	**183,525**	**288,317**	**290,390**	**762,232**	

The main co-financier is CTNBio, an inter-institutional Government entity that will provide *in kind* contributions to the project.

Appendix 3: Incremental Cost Analysis (Matrix)

Project Outputs	Baseline	Alternative	Increment
1. Putting in place and applying a national biosafety regulation and promoting a biosafety policy in accordance with the CPB.	Costa Rica has not specific regulations o policy on Biotechnology and biosafety and LMOs for human and animal consumption and processing. The processes, procedures, guidelines and actions to take should be created and standardized for incorporation into the national legal system. The harmonization of regulation and Ministerial mandates including the administrative, operational, financial and technical system are clearly dependent on the current project, and would suffer from slow development in the absence of GEF support. *Cost: US$ 150,000*	A discussion about of biosafety normative in Costa Rica's in the context of the CP approved in our country in November 2006 would be carried out, and recommendations made for modifications, Additional or news regulations would be explored to reinforce the capacity and mandate of the institutions that integrate CTNBio and other involved in the project execution. GEF funds will be used to complement this effort and help establish guidelines, standards and procedures to be followed by the NCAs in order to regulate the transboundary movement of LMOs. Environment's efforts to harmonize cross-sector legislation related to environmental potential risks would be included to the biosafety regulation. *Cost: US$ 179,365(GEF)* *US$ 175,000 (GOV)* _____ *US$ 354,365*	The Biosafety regulation would be incorporated into all institutions involved in risk assessment and management and participating in a new agile and operational administrative structure. Increased cross sector integration would be attained. *Cost: US$ 204,365*

Project Outputs	Baseline	Alternative	Increment
2. Making operational and administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms.	Costa Rica does not have an administrative system agile, coordinated or efficient that meets users of LMOs needs (importers / exporter). There are not financial, operational and technical coordination for to comply with the law stipulates on international transboundary movement of LMOs *Cost: US$ 100,000.00*	A logical and harmonized inter-agency coordination (approved by the ministries) to enable the implementation of the administrative and operational system, including: financial, technical, operational, logistical and others, in connection with CPB obligations and responsibilities. *Cost: US$ 111,394 (GEF)* *US$ 120,000 (GOV)* *US$ 231,394*	Administrative and logistical system approved *Cost: US$ 131,394*
Project Outputs	**Baseline**	**Alternative**	**Increment**

3. Building technical capacity in NCAs and related institutions for comprehensive biosafety management	Costa Rican government authorities do not currently have technical institutional capacity to carry out risk assessments in feed and foods and human and animal health. This situation difficult the normal and efficient resolution to import, export and in national and international trade. Also is necessary formal and informal training in implementation of the new legal and administrative system. This situation is unlikely to change in the absence of GEF resources. CTNBio would continue to integrate its agricultural risk assessment model in support of applications from the governmental, non-governmental and industry sectors, but other important issues like economic considerations, coexistence, etc, will not considered. CTNBio would also continue to carry out risk assessment based on their institutional capacity and experience. *Cost: US$ 100,000*	GEF support for training will consolidated the capacity to carry out analysis and studies necessary to determine environmental risk evaluation. Agriculture's significant baseline capacity to carry out experimental and seed production field tests and to manage experimental data would be strengthened through expert support and training. Risk assessment will be carried out with science-based, biological and agro-biological criteria in this mega diversity country. Targeted field studies on the effect of gene flow in rice and cotton and the LMOs effects on not target insects in tropical conditions would be carried out for WB project and the guidelines produced will be discussed, harmonized and approved in UNEP/GEF project. *Cost: US$ 182,394 (GEF)* *US$ 212,130 (GOV)* *US$ 394,524*	Risk assessment, capacities developed and consolidated in a mega diversity country. *Cost: US$ 294,524*

Project Outputs	**Baseline**	**Alternative**	**Increment**
4- Improved communication, education, public perception and participation in biosafety of all relevant stakeholders	The formal education system doesn't include issues on Biosafety in courses programmes. The civil society doesn't have scientific information about risk and benefits of LMOs. *Cost: US$ 100,000*	The elements generated during the participatory process leading up to the integration of this proposal provide sufficient input to create a national proposal for biosafety education, designed for adoption in undergraduate and advanced degree programmes. CTNBio will have a website or use BCH national website to concentrate information and links to different databases in line ministries *Cost: US$ 108,677 (GEF)* *US$ 126,000 (GOV)* *US$ 234,677*	A national curriculum in biosafety prepared and negotiate with international agencies (TEACH strategy) BCH mechanism operational. *Cost: US$ 134,677*
Domestic Environmental Benefits	As institutional capacity gradually increments for risk assessment and risk management, genus of regional importance and commercial importance would be better protected.	CTNBio will become totally operational and will see its inter-agency co-operation framework strengthened. Other government agencies will produce reliable and science-based information on biosafety.	Costa Rica's commercial environment will be strengthened. Bio-technology issues will develop with appropriate safeguards in place and operational.
		Total: US$ 581,830 (UNEP/GEF) ***US$ 633, 130 (GOV)***	

Costs	***Total: US$ 450,000***	***Total: US$ 1,214,960***	***Total: US$ 764,960***

Appendix 4: Results Framework

Intervention logic				
Project objective	Implement Costa Rica's National Biosafety Framework for the safe management of Living Modified Organisms (LMOs) in accordance with the CPB			
Outcomes	**Objectively Verifiable Indicators**		**Sources of Verification**	**Risks and Assumptions (R & A)**
	Baseline	**Indicators (End of project month X)**		
<u>Component 1:</u> Putting in place and applying a national biosafety legal framework and promoting a biosafety policy in accordance with the CPB				
Outcome 1.1. A comprehensive regulatory framework for biosafety is in place, providing the architecture of an integrated administrative and management system.	- The lack of a complete biosafety framework prevents the development of an adequate administrative and management platform for LMOs. - The country is only able to make decisions concerning LMO crops, so other sectors are precluded from using LMOs responsibly. - CTNBio has legal prerogative to recommend decisions on any kind of LMO but is not integrated by all relevant NCAs	- Approved biosafety regulations (target: at least 2 by project month 12) which include administrative and management procedures. - Representatives of SENASA and Ministry of Health have been officially integrated as members of CTNBio by project month 8	- Regulations published in the Official Journal and posted in the national BCH. - Official document (e.g. resolution) reflecting new composition of CTNBio	Political willingness at national level to develop regulations in accordance with the CPB. (A)
Outcome 1.2. New policy in biosafety and its action plan is translates into ongoing NCA	- There is no coordinated policy or plan in biosafety in Costa Rica.	- Action plan in biosafety involves at least 2 NCAs and is endorsed by project month 12 - Personnel responsible for functions	- Minutes of CTNBio meetings - Ministries	There is sufficient Government and institutional support to agree on a biosafety action

involvement in CPB implementation. **Outcome 1.3.** Legal and sectorial capacity is built for considering cases of liability and redress (L&R) and implementing a co-existence regime.	- Reduced Personnel at the Ministries related to implementation or follow-up of CPB. - There is no legal mechanism in Costa Rica with which to address L&R regarding LMOs. - Organic and conventional farmers are misinformed about co-existence and L&R.	relating to CPB's implementation are designated by project month 18 - Costa Rica prepares a national position for COP/MOP-5 in which the main NCAs participate (target: 3 Ministries by project month 6) - Costa Rica is able to present an official position regarding L&R at COP/MOP-5 (Oct 2010 – approx project month 10). - One legal proposal on L&R regarding LMOs submitted to implementation procedure by project month 24 - At least 50% of agricultural companies and farmers known to use LMOs in the country, or that are potentially affected by LMO use, are better informed about co-existence rights and responsibilities, including L&R (by project month 24)	endorsements (at least 2) of the Policy and Action plan. - Biosafety personnel or Units identified in NCA organigrams. - Minutes of Normative Task Force meetings - Official file number assigned to the L&R proposal. - Survey about coexistence and L&R among farmers and LMO users. - COP/MOP reports.	plan. (A) A resolution regarding Art. 27 about L&R may not be achieved during the COP/MOP 5 (R) The correct agricultural companies and farmers can be targeted and engaged. (A)

Outputs:

1.1.1 Biosafety regulation (/technical norms) for LMOs use in food, feed and processing,
1.1.2 Biosafety regulation (/technical norms) for LMOs in transboundary movements (transit, identification, etc)

1.2.1 National Policy and Action Plan (submitted)
1.2.2 National Reports to the CPB, prepared involving with at least 2 NCAs
1.2.3 National position paper for COP/MOP-5
1.2.4 Units and personnel in charge of biosafety are identified

1.3.1 List of agricultural companies and farmers known to use LMOs in the country, or that are potentially affected by LMO use.
1.3.2 Survey analysis on sectorial knowledge regarding coexistence and L&R
1.3.3 Draft guidelines for LMO users on liability and redress (L&R)
1.3.4 Draft guidelines for LMO users on agricultural coexistence

1.3.5 Regulatory proposal for L&R 1.3.6 Workshops and informative materials on coexistence, with takes into account CPB decisions related 1.3.7 Position documents on L&R for COP/MOP-5 and COP/MOP-6				
Outcomes	**Objectively Verifiable Indicators**		**Sources of Verification**	**Risk and Assumptions**
	Baseline	**Indicators (End of project month X)**		
<u>Component 2:</u> Making operational an administrative system to fulfil obligations to the CPB and strengthen the decision-making base and its mechanisms				
Outcome 2.1. NCAs needs are addressed so that administrative capacities are in place to handle requests, make informed decisions, and communicate decisions to applicants and the BCH.	- There are no administrative procedures to comply with national regulations on environment, human and animal health established. - Development of administrative procedures is precluded by low capacities on the subject. - All LMOs requests handled until now have meant low cost to the applicant. - The BCH system is working, although several NCAs lack information to be reported, and therefore are not frequent users.	- The administrative pathway which an LMO request must take in order to derive at a decision is officially established within each NCA by identifying: staff /Units involved and their roles, files to be kept, forms and formats to be used, procedures to be followed, reports to be generated and fees to be charged. (by project month 24) - By project month 30, office equipment is provided to NCAs and an information management system is set up and operational in 1 NCA that allows: electronic reception, exchange and internal processing of confidential LMO dossiers; web site management for on-line availability of forms and formats, and posting regulatory requirements and procedures; periodic preparation and submission of information to the BCH; and on-line access to data on status of requests	- Memos specifying administrative pathways, procedures and fees. - NCA organigrams identify biosafety personnel and management units - NCA-specific guidelines, forms and formats - Biosafety filing systems - New infrastructure in NCAs - BCH records - NCA web sites with updated biosafety info, access to forms and formats, and request status data	Personnel is available in each NCA (A) Administrative system fails in providing enough income to achieve self-sufficiency. (R)

Outcome 2.2. Decisions on LMOs are based on risk assessments, timely, transparent and coordinated, and avoid duplicity or unnecessary bureaucracy.	- Bases to make scientifically informed decisions are diminished or absent in most NCAs. - The decision making process is uncoordinated, and has only taken place so far for small scale release of agricultural LMOs. - Administrative guidelines which could be used to fulfil CPB requirements have been proposed.	submitted. - At least one LMO request (either mock or real) has been processed by each NCA, evaluating: quality of risk assessment data, information management, coordination, time required, and communication requirements, and resulting in a single joint decision (mock or real) in less than 270 days. (by project month 24) - The annual % of LMO requests that are returned to applicants, due to incomplete information or dossiers, is reduced by half by project month 36	- Biosafety documents filed within each NCA. - LMO dossiers (either mock or real requests) - Emails exchanges between NCAs and with applicant (real or mock) using a security information system. - Legal document (e.g. resolution) expressing official decision. - Data on requests received and requiring re-submission	NCAs are unable to agree on which request to consider as a real /mock decision-making case (R)

Outputs:

2.1.1 Permanent administrative structures in all NCAs for handling LMOs requests and notifications
2.1.2 Forms and formats for LMOs requests and notifications
2.1.3 Biosafety measures and standards established for each sector
2.1.4 BCH informed of national decisions, new procedures and standards
2.1.5 Information available upon request on procedures, requirements, standards and ongoing processes
2.1.6 Financial mechanisms to support the administrative system
2.1.7 Simplified procedures for LMOs authorization

2.2.1 Coordinated and consolidated LMOs evaluation and decision-making mechanisms
2.2.2 LMOs requests processed efficiently
2.2.3 Biosafety decision-makers and advisory structures appointed
2.2.4 Periodic administrative evaluation of LMOs sectorial authorization processes
2.2.5 Procedures for review of decisions

Outcomes and Outputs	Objectively Verifiable Indicators		Sources of Verification	Risk and Assumptions
	Baseline	**Indicators (End of project month X)**		
Component 3: Building technical capacity in NCAs and related institutions for comprehensive biosafety management				
Outcome 3.1 Capacity to monitor and ensure regulatory compliance is increased.	- Coexistence between different production technologies is poorly understood in NCAs. - There are monitoring experiences and some inspection capacity in NCAs; however, expertise regarding LMOs is limited and personnel are untrained on regulatory issues. - There is a legal instrument for accreditation of biosafety auditors that allows the inspection function (and costs) of the Ministry of Agriculture & Livestock to be externalized for LMOs	- 15 NCA professionals and 5 official auditors receive training to increase their knowledge on monitoring and coexistence issues by at least 60% (target: by project month 30) - 5 civil (voluntary) observers are selected, officially recognized and accredited, and receive training to increase their knowledge on monitoring and coexistence issues by at least 40% (by project month 30) - By project month 30, CTNBio prepares, approves and implements an annual inspection plan for authorized LMOs that requires at least 5 field visits per year, for which funding is assured.	- Training workshops participant lists and curricula - Expressions-of-interest from civil observers (candidates) - Certificates and registration of newly appointed civil observers - Accreditation records 2010-2012 for biosafety auditors - Expert's evaluation based on initial and final tests to measure knowledge on monitoring and coexistence	Personnel appointed by NCAs do not meet the suggested profiles. (R) Voluntary participation and financial sustainability allows coexistence and compliance to be monitored (A) Suitable and affordable

			- Official CTNBio document approving execution of annual LMO inspection plan.	experts (international /national) may not be available for training activities (R)
Outcome 3.2 Sufficient technical and human capacities are put in place for risk assessment and management for decision-making, considering both traditional and novel LMOs.	- There is limited capacity-building within NCAs on risk assessment and management - The country is receiving requests for both traditional and novel LMOs for use in agriculture, environment, health and animals.	- 10 regulators have been trained and increase their knowledge in LMO risk assessment and management for decision-making by at least 85% (by project month 30) - Leaflet for risk-benefit analysis and LMO management incorporates scientific and socio-economic factors, by explaining the sectorial and strategic relevance of novel LMOs, the methodologies that can be used to assess them, and the most cost-effective biosafety measures. (by project month 36)	Expert's evaluation based on initial and final tests and performance in using case studies. Corresponding sections of the risk-benefit and LMO management leaflet.	Sufficient and timely inputs are received from the CIAT-WB-GEF regional biosafety project. (A)
Outcome 3.3 Transboundary movements of LMOs will occur in accordance with the CPB, and in a manner that is understood and accepted by the private sector (exporters /importers)	- Trade procedures to date do not identify LMOs and there is limited border control capacity. - The CPB is unknown by customs and quarantine officers, though they may be aware of other environmental conventions such as CITES.	- 40 Customs and quarantine officers have been trained to process documentation related to importation /exportation of 2 of the 3 types of LMOs considered by the CPB. (by project month 33) - NCAs and border control authorities agree on LMO transit procedures and/or requirements (by project month 30)	- Expert's evaluation based case studies and performance in using case studies. - Register and filing system to log LMOs that are subject to transboundary movements	National authorities may not have adopted any decisions on LMO thresholds or types requiring identification. (R)

Outputs: 3.1.1 NCA-specific lists of personnel to be trained 3.1.2 Mechanisms to encourage the integration of civil observers into official monitoring and inspection plans 3.1.3 Official auditors and civil observers selected and trained 3.1.4 Annual inspection Plan for authorized LMOs is approved. 3.2.1 NCA-specific lists of personnel to be trained 3.2.2 Collaboration agreements for design and implementation of training activities 3.2.3 NCA professionals trained in specific areas of biosafety such as risk assessment and management of LMOs 3.2.4 Decision-makers briefed on the basics of biosafety and ongoing progress of the CPB 3.2.5 Leaflet for risk-benefit analysis and LMO management is available on decision making process. 3.3.1 NCA-specific quarantine and customs personnel selected and trained 3.3.2 Approved forms for identifying LMOs subject to transboundary movements				
Outcomes and Outputs	**Objectively Verifiable Indicators**		**Sources of Verification**	**Risk and Assumptions**
	Baseline	**Indicators (End of project month X)**		
Component 4: Improved communication, education, public perception and participation in biosafety of all relevant stakeholders				
Outcome 4.1 Public awareness regarding the safe use of LMOs in Costa Rica is augmented through a formal educational strategy **Outcome 4.2**	- Civil society is either lacking information or misinformed about biotechnology & biosafety issues. - Formal education does not cover LMOs. - There is agreement between NCAs (technical level) that long-term formal and informal educational for dissemination of biosafety would be beneficial	- At least 90% of the components of a draft education strategy on LMOs and biosafety (TEACH: Training and Education in AgrobioteCHnology) and its action plan have been agreed between NCAs involved (by project month 36) - Increase of 40% in BCH	- Draft strategy officially received by the national authorities to be studied. Comparison in	Sufficient and timely inputs are received

Public information sharing is promoted through greater access to biosafety information. (BCH)	- Current rate of "hits" on the BCH national portal is low (*actual rate will be determined by inception workshop*)	users of the national portal, by project month 36	number of BCH "hits" between PY1 and PY3.	from the CIAT-WB-GEF regional biosafety project. (A)
Outputs: 4.1.1 Draft Education Strategy on LMOs and biosafety (TEACH: Training and Education in AgrobioteCHnology) and its Action Plan for carrying out long-term formal and informal educational actions for dissemination of biosafety 4.1.2 Cooperation agreements between NCAs, biotechnology industry, international organizations and/or other governments agencies 4.1.3 Improved knowledge and understanding of Ministry of Education advisors regarding safe use of biotechnology. 4.2.1 Internal tracking system for LMO requests 4.2.2 Informative dissemination material by sector 4.2.3 Mechanisms for public participation prior to granting LMOs authorizations is augmented 4.2.4 Biosafety guidelines, protocols, and updated data on national biotechnology and LMOs use (especially in the agricultural sector) are on the National Biosafety Webpage and/or BCH 4.2.5 Media tools and other informal education initiatives reproduced and expanded for other sectors				

Appendix 5: Work plan and timetable

PROJECT ACTIVITIES													
MANAGEMENT	**TIME (annual trimester of the project)**												
	Year 1				***Year 2***				***Year 3***				***ex-post***
Project management, coordination and M&E	**I**	**II**	**III**	**IV**	**I**	**II**	**II**	**IV**	**I**	**II**	**III**	**IV**	
Establishment of the Project Management Unit, contracting of key project staff and sub-contracting of OIRSA.													
Inception workshop													
PMU operations													
CTNBio project oversight /management meetings													
NCC meetings													
Reporting to UNEP (progress and financial reports)													
Mid-Term Review/ Evaluation													
Project Implementation Reviews													
Regional coordination meetings of NBF Implementation Project Managers													
Terminal Evaluation													
Audits													

TECHNICAL PRINCIPAL ACTIVITIES													
COMPONENT I	**outcome**	**TIME (annual trimester of the project)**											
		Year 1				***Year 2***				***Year 3***			
Putting in place and applying National biosafety regulation and promoting a biosafety policy in accordance with the CPB		**I**	**II**	**III**	**IV**	**I**	**II**	**II**	**IV**	**I**	**II**	**III**	**IV**
Hire a Legislation Expert to coordinate with NCAs and Public Business Manager to elaborate the regulation proposal and CTNBio decree modification for including SENASA and Ministry of Health.	1.1												
Expert in Public Business Manager to prepare an administrative system proposal in coordination with the legal expert and NCAs.	1.1.												
Recruitment of Expert in press and for designing strategies to help the lobby expert in order to obtain the political support to implement the legal and administrative proposal.	1.1												
Hire an Expert to design guidelines for summiting applications for article 11: Food, Feed and Processing (FFPs) and article 18 CPB to NCAs.	1.1												
Recruitment expert to design legal and technical norms and	1.3.												

guidelines for coexistence for 6 crops: soybean, cotton, maize, musaceas, ornamental and vegetables.														
Contract one Expert for to obtain political compromise, prepare a draft document and action plan about biotechnology and biosafety in feed , food , environment and human and animal health	1.2													
Hire a Lawyer expert to, based on the supplementary protocol of article 27, inform, harmonize and prepare a national position to be presented in COP-MOP5, and prepare a proposal to NCAs according with Nagoya agreements	1.2 1.3													
Expert to prepare to design regulatory guidelines for LMOs, certification issues, and liability and redress users of the Ministry of Health, Environment, Agriculture and SENASA	1.1													
One expert, who will elaborate guidelines on risk management and risk assessment based on national and international guidelines on FFPs LMOs, Environmental release of trees, insect, animal, etc., and harmonize and officialise the guidelines with NCAs.	1.1													
6 Workshop (1 each month) to present FFP guidelines and article 18 during the second year, after the Legal system is approved. Period of time 6 months.	1.1													
3 Workshop (1 each 2 months) of coexistence. During the first 6 months of the second year.	1.3.													
3 workshops with NCAs, in order to harmonize the guidelines for LMOs users (based on administrative system derived of the legislation approved) The second year of the project, 1 each 2 months	1.1													
workshop with NCAs for to know and approve the National Report CPB	1.3.													
workshop with NCAs for National Position in COP-MOP 5 (Liability and redress national position)	1.3.													
Workshops with judges, operators and tribunals in order to present and harmonized Legal proposal according with Nagoya agreements.(L&R). The proposal must be presented and harmonized during Second year of the project	1.3.													
4 Meetings every 2 months, with NCC and NCAs to discuss regulations in administrative system. One meeting may include the financial issues. One meeting may include administrative issues. One meeting may include the operative mechanism. One meeting of technical issues describe in the article 18 of Law 8537 (BCP) and coexistence.	1.2.													
4 Meetings (4) with NCAs and CTNBio to harmonize the guidelines and present the tools developed by WB project to make official use of them the biosafety national regulation. (Available by the end of second year)	1.1													

TECHNICAL PRINCIPAL ACTIVITIES													
COMPONENT II		**TIME (annual trimester of the project)**											
	outcome	***Year 1***				***Year 2***				***Year 3***			
Making operational and administrative system to fulfil obligations to the CPB		**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**
Consultant to manage and implement the operative and administrative system for NCAs, during the second year.	2.1.												
Informatics Expert to create a safe Competent authority network for sharing and making decisions.	2.2.												
An International Expert for political meetings with Minister and Vice Minister of Human Health, Environment, Agriculture and Science and Technology and other Institutions involved in the project execution.	2.1.												
3 Regional meeting of Implementation Project Managers.	2.1.												
3 workshops with 30 people each meeting. NCAs, NCC and stakeholders (biotech, importers, agriculture, researchers, etc). 1 Each 2 months, to study proposal of implementation for the operative and administrative system	2.1.												
1 Workshop to define responsibilities on technical, administrative and coordination mechanism between NCAs.	2.2												
Three Political Meetings with Minister and Vice Minister of Human Health, Environment, Agriculture and Science and Technology and other Institutions involved in the project execution. At the beginning of the project to inform agreements, compromises and action plan, the second meeting will be to inform the advances, in the third meeting to inform about results and future actions.	2.1.												
Acquisition of office equipment and computing for integrated management of confidential information and making coordinated decisions in real time between the NCAs.	2.2.												
At least one LMO dossier (either mock or real) will be processed by each NCA, evaluating: quality of risk assessment data, information management, coordination, time required, and communication requirements, and resulting in a single joint decision (mock or real).	2.2.												

TECHNICAL PRINCIPAL ACTIVITIES														
COMPONENT III		**TIME (annual trimester of the project)**												
	outcome	***Year 1***				***Year 2***				***Year 3***				
Building technical capacity in NCAs and related institutions for comprehensive biosafety management		**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**
One international expert to elaborate 2 workshops of one week of training session on traditional and novel LMOs risk assessment and management with case studies for decision makers.	3.2.												
One expert (with NCA's involved in project execution) to create guidelines, review leaflets and train official customs, human and animal health technicians, park rangers and civil observers. During the third year of the project.	3.3.												
Initial, final tests and case studies performance on risk assessment and management.	3.2.												
2 workshops for NCAs of 3 days each one for traditional and novel risk assessment during 12 months. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment.	3.2.												
2 workshops for NCAs of 4 days for risk management, liability and redress, identification and coexistence issues. 1 each 6 months, during the second year of the project. Workshop will include food safety issues, feed and processing (FFPs), as well as animal risk and environmental assessment.	3.2.												
2 group training for NCAs with international experts on risk management, including case studies and protocols elaboration. Workshop will include food safety, feed (FFPs) and environmental issues.	3.2.												
Training session in an international government regulation agency for risk assessment and risk management during the last year of the project (Spain, Brazil, USA, Canada, EU) Each NCA (1 MINAE, 1 MAG, 1 HEALTH, 1 MICyT.)	3.2.												
1 workshops with organic, traditional and GMO representatives and	3.1.												

NCAs. 1 each 3 months, during the second year of the project. 20 people. For to discuss coexistence guidelines in different crops.													
1 workshop of 3 days of training for official auditors and civil observers in monitoring and integration of GPS techniques, regulation 20 people	3.1.												
Training of quarantine and customs officers, human and animal health technicians and park rangers: Read and interpreted documents, according with Article 18 PCB. 4 meeting 50 people for 2 days during the third year.	3.3.												
Evaluation based case studies performance LMOs in trade procedures.	3.3												
Long term training of National Competent Authorities. Example: MSc degree in UNIDO, National and international universities or excellence centres.	3.2.												
A seminar with 100 people (stakeholders) that explains the identification system. Publication in the website.	3.1.												
Initial and final tests on monitoring, L&R and coexistence	1.3 3.1												
Seminar about coexistence. 200 people. The meeting will be in the afternoon, with coffee, CDs, brochure, programme, invitations, folders, pens, pencils, and a place for the meeting, multimedia, translation, videoconference, and a link with a national web site for international event.	3.1.												
Preparation, approbation and implementation of an annual inspection plan for authorized LMOs.	3.1.												

TECHNICAL PRINCIPAL ACTIVITIES													
COMPONENT IV		**TIME (annual trimester of the project)**											
	outcome	***Year 1***				***Year 2***				***Year 3***			
Improved communication, education, public perception and participation in biosafety of all relevant stakeholders		**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**	**I**	**II**	**III**	**IV**
Hire an expert that must have knowledge in Biotechnology, Biosafety and education. The expert has to develop a strategy of formal education about Biosafety of the Biotechnology for primary and secondary school. The expert must identify a task Force with people related.	4.1.												
Hire 4 advisors: Education specialist, pedagogues, Biologist, a Specialist in curricula in schools programme	4.1.												
Contract one Expert in TI. The expert will improve the Web page and linked with other national database including those developed by WB project. The expert harmonize the information of Costa Rica in	4.2.												

FAO, IICA, BCH, AGBIOS, FDA, BIO, Europe database, etc, in the National Web Page.													
Make 8 workshops of the task force. 1 per month to discuss strategy in formal education	4.1.												
Elaborate a workshop for presenting the final webpage to the NCAs	4.2.												
Elaborate the materials for the implementation of the strategy (formal education)	4.1.												
Make a Campaign and forums for the access and use of BCH and databases and tools developed by the WB project. Integration and collaboration with the Ministry of Science and Technology for using CECI's (Intelligent Community Centres). The target population is the producers, export, imports and educators.	4.2.												
Carry out two political meetings with the Ministry of Education, CONARE, MICIT, CONESUP, etc. At the beginning and one at the end of the Strategy Draft.	4.1.												
Make meetings with UNESCO, IICA, FAO, CBD, PNUMA, GEF, WB, BIO, GTZ, Universities Michigan State, Brazil Universities, ANBio, Governments, American Soybean Society, etc, that are developing or are interested in developing education programmes, to present the strategy of formal education and establish the mechanism of coordination and financial cooperation.	4.1.												

Appendix 6: Key deliverables and benchmarks

Key deliverables /Benchmarks	Time line (months after project have started)	Benchmark
Approved a national biosafety regulation that includes administration system and designation of National Competent Authority (NCA) responsibilities and functions	12-18 months	Having a national biosafety regulation system approved working in a coordinated fashion technically and administratively, represents a significant leap in Costa Rican capacity to address biosafety issues responsibly. In comparison to the mechanism which Costa Rica has before the project, the country will be able to comply with international commitments related to trade, moreover, the NCAs will be capable of performing risk assessments and risk management, allowing the country to respond effectively to any request for LMOs introduction. This will represent a significant improvement, since currently the system is able to address agriculture LMOs only.
Functional administrative structure implemented in all NCAs for handling LMOs requests and notifications	18 months	The country will have developed an inter-agencies system sharing requests information and manage responsibilities in an integrated office which allows the distribution of responsibilities rapidly and effectively, in order to improved the decision making process. This result will set a milestone in Costa Rican regulatory services, since an administrative measure will be coordinating at least five agencies working in different fields yet related by a technology which very likely will increase its complexity level and set new standards in regulation.
Project's PIR rankings and Mid-Term Review /Evaluation	18 months	Project progress and results will be measured, providing an important check-point to determine whether the project is on track for meeting its objectives, and offer interested parties (eg NCC) with feedback and concrete indications of project performance. Recommendations will also result from the Mid-Term Review /Evaluation that will lead to adaptive management measures.
Processing an LMO request	24 months	Gaining experience in handling LMO requests through a trial run (mock application) will allow the direct evaluation of the quality of risk assessment data, the demands of information management and coordination, the timeframes required, and communication requirements, and the capacity of NCAs to come to a joint decision in line with the specifications of the CPB.
Permanent Officials of the NCAs capable and trained in analysis and risk management and claims handling and customs documents	30-36 months	Costa Rica will have a solid team and permanent staff trained in risk analysis and management for the transboundary movement of LMOs. Also, customs officials and others will be trained in appropriate technical and management documents accompanying shipments. Communitarian observers and official auditors will be trained in vigilance of biosafety measures established by the regulatory authorities. above, will allow scientific and technical management of applications for the transboundary movement of LMOs
Education Strategy draft on	36 months	Designing a strategy to include in formal education biosafety issues and biotechnology

LMOs and biosafety (project TEACH) and its Action Plan for carrying out long-term formal educational actions for dissemination of biosafety		concepts represents a change of paradigm when facing a technical, commercial and political issues such biosafety. By increasing the knowledge and awareness levels in school students, the country will be investing wisely in adapting and informing Costa Ricans about the food and products that current and future generations will be consuming. This ambitious approach will set an example of addressing permanently public awareness and participation issues about biotechnology and biosafety.

Appendix 7: Costed M&E plan

Budgeted under UNEP budget line BL 5500 for "Evaluation", "Meetings" (BL 3300) and "Reporting" (BL 5200) as indicated below. Details are also provided in Appendix 1.

Category and budget line	Activity	Responsible Parties (bold letters) and Parties Involved	Budget (US$)	Time Frame	
MEETINGS **BL 3300**	**(a)** **Project Inception Workshop**	- **CTNBio** (coordination) - Project Team - UNEP	3,000	Within the first three months once the Project starts	Y1
	(b) **Steering Committee Meetings**	- **CTNBio** - National Coordinating Committee (NCC) - Project Management Unit (PMU) - Project Manager	4,500	At project start and Half-Yearly	Y1, Y2 and Y3 at $1,500 each
	(c) **Work Meetings**	- **Project Manager** - CTNBio - PMU - NCC	6,000	To be determined by the responsible parties.	Y1, Y2 and Y3 at $2,000 each
GENERAL MONITORING & REPORTING **BL 5200**	**(a)** **Project Inception Report**	- **CTNBio** - PMU - NCC - Project Manager	500	Immediately after the Inception Workshop	Y1
	(b) **Annual Project Report and PIR**	- CTNBio (coordination) - OIRSA - NCC - UNEP - **Project Manager**	4,000	Annual	Y1, Y2, Y3 and after closure (Y3) at $1,000 each
	(c) **Information needs** (a) Initial and final tests on monitoring, L&R and coexistence (b) Initial, final tests and case studies performance on risk assessment and management. (c) Evaluation based case studies performance LMOs in trade procedures.	- **Project Manager** - CTNBio - PMU - NCC	10,000	During project execution	(a) Y1 and Y2 (b) Y2 and Y3 (c) Y3 at $2,000 each
	(d) **Periodic Reports to UNEP** - Progress reports - Financial reports - Inventory report	- **CTNBio** (supervision) - NCC (supervision) - Project Manager - OIRSA - Hired Consultants	1,200	Every semester (by 31 Jan and 31 July)	Y1, Y2 and Y3 at $ 400 each
	(e) **Terminal Report**	- **CTNBio** (coordination) - PMU - OIRSA - Project Manager	800	At least a month prior to the end of the project	Y3

Category and budget line	Activity	Responsible Parties (bold letters) and Parties Involved	Budget (US$)	Time Frame	
INDICATORS **BL 5500**	**(a)** **Measuring indicators of project objectives**	- **Project Manager** - CTNBio - PMU	3,000	At the beginning, mid-term and end of the project	Y1, Y2 and Y3 at $1,000 each
	(b) **Measuring means of verification of project progress**	-**Project Manager** - CTNBio -PMU	3,000	Annually	Y1, Y2 and Y3 at $1,000 each
EXTERNAL EVALUATIONS **BL 5500**	**(a)** **Mid-term Evaluation**	-**CTNBio** - PMU - OIRSA - **UNEP** - Project Manager - External consultants	10,000	In the middle of project implementation	Y2
	(b) **Final Evaluation**	- CTNBio - PMU - OIRSA - **UNEP** - External consultants - Project Manager	10,000	At end of the project	Y3
	(c) **Audits**	- **CTNBio** - PMU - OIRSA - External company	10,000	Annually	Y1 and Y2 at $3,000 each and Y3 at $4,000
		TOTAL GEF (US$)	66,000		
		TOTAL (US$)	66,000		

Appendix 8: Summary of reporting requirements and responsibilities

Reporting requirements	Due date	Format appended to legal instrument as:	Responsibility of
Procurement plan (goods and services)	2 weeks before project inception meeting	N/A	Project Manager
Inception Report	1 month after project inception meeting	N/A	Project Manager
Expenditure report accompanied by explanatory notes	Half-yearly on or before 31 July and 31 January	**Annex 11**	Project Manager
Cash Advance request and details of anticipated disbursements	Half-yearly , or when justifiably required	**Annex 7B**	Project Manager
Progress report	Half-yearly on or before 31 January	**Annex 8**	Project Manager
Audited report for expenditures for year ending 31 December	Yearly on or before 30 June	N/A	NEA to contract firm
Inventory of non-expendable equipment	Yearly on or before 31 January	**Annex 6A**	Project Manager
Co-financing report	Yearly on or before 31 July	**Annex 12**	Project Manager
Project implementation review (PIR) report	Yearly on or before 31 August	**Annex 9**	Project Manager, UNEP TM & FMO
Minutes of National Coordinating Committee meetings	Yearly (or as relevant)	N/A	Project Manager
Mission reports and "aide memoire" for executing agency	Within 2 weeks of return	N/A	UNEP TM and FMO
Final report	2 months of project completion date	**Annex 10**	Project Manager
Final inventory of non-expendable equipment		**Annex 6A**	Project Manager
Equipment transfer letter		**Annex 6B**	Project Manager
Final expenditure statement	3 months of project completion date	**Annex 11**	Project Manager
Mid-term review or Mid-term evaluation	Midway though project	N/A	UNEP TM or EOU (as relevant)
Final audited report for expenditures of project	6 months of project completion date	N/A	NEA to contract firm
Independent terminal evaluation report	6 months from project completion date	Appendix 9 to current ProDoc	UNEP EOU

Appendix 9: Standard Terminal Evaluation TOR

Terminal Evaluation of the UNEP GEF project Implementation of the National Biosafety Framework of Costa Rica

1. PROJECT BACKGROUND AND OVERVIEW

Project rationale

The objective was stated as:

The indicators given in the project document for this stated objective were:

Relevance to GEF Programmes
The project is in line with:.

Executing Arrangements
The implementing agencies for this project were UNEP-GEF; and the executing agencies were:

The lead national agencies in the focal countries were:

Project Activities
The project comprised activities grouped in four components.

Budget

At project inception the following budget prepared:

	GEF	Co-funding
Project preparation funds:		
GEF Medium Size Grant		
TOTAL (including project preparation funds)		

Co-funding sources:

Anticipated:

APPENDIX 9
TERMS OF REFERENCE FOR THE EVALUATION

1. Objective and Scope of the Evaluation

The objective of this terminal evaluation is to examine the extent and magnitude of any project impacts to date and determine the likelihood of future impacts. The evaluation will also assess project performance and the implementation of planned project activities and planned outputs against actual results. The evaluation will focus on the following main questions:

1. Did the project help to { } among key target audiences (international conventions and initiatives, national level policy-makers, regional and local policy-makers, resource managers and practitioners).
2. Did the outputs of the project articulate options and recommendations for { }? Were these options and recommendations used? If so by whom?
3. To what extent did the project outputs produced have the weight of scientific authority and credibility necessary to influence policy makers and other key audiences?

Methods

This terminal evaluation will be conducted as an in-depth evaluation using a participatory approach whereby the UNEP/DGEF Task Manager, key representatives of the executing agencies and other relevant staff are kept informed and consulted throughout the evaluation. The consultant will liaise with the UNEP/EOU and the UNEP/DGEF Task Manager on any logistic and/or methodological issues to properly conduct the review in as independent a way as possible, given the circumstances and resources offered. The draft report will be circulated to UNEP/DGEF Task Manager, key representatives of the executing agencies and the UNEP/EOU. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary or suggested revisions.

The findings of the evaluation will be based on the following:

1. A desk review of project documents including, but not limited to:
   (a) The project documents, outputs, monitoring reports (such as progress and financial reports to UNEP and GEF annual Project Implementation Review reports) and relevant correspondence.
   (b) Notes from the Steering Group meetings.
   (c) Other project-related material produced by the project staff or partners.
   (d) Relevant material published on the project web-site:{ }.

2. Interviews with project management and technical support including {NEED INPUT FROM TM HERE}

3. Interviews and Telephone interviews with intended users for the project outputs and other stakeholders involved with this project, including in the participating countries and international bodies. The Consultant shall determine whether to seek additional information and opinions from representatives of donor agencies and other organizations. As appropriate, these interviews could be combined with an email questionnaire.

4. Interviews with the UNEP/DGEF project task manager and Fund Management Officer, and other relevant staff in UNEP dealing with {relevant GEF focal area(s)}-related activities as necessary. The Consultant shall also gain broader perspectives from discussions with relevant GEF Secretariat staff.

5. Field visits[1] to project staff

Key Evaluation principles.
In attempting to evaluate any outcomes and impacts that the project may have achieved, evaluators should remember that the project's performance should be assessed by considering the difference between the answers to two simple questions ***"what happened?***" and ***"what would have happened anyway?"***. These questions imply that there should be consideration of the baseline conditions and trends in relation to the intended project outcomes and impacts. In addition it implies that there should be plausible evidence to **attribute** such outcomes and impacts **to the actions of the project**.

Sometimes, adequate information on baseline conditions and trends is lacking. In such cases this should be clearly highlighted by the evaluator, along with any simplifying assumptions that were taken to enable the evaluator to make informed judgements about project performance.

2. Project Ratings
The success of project implementation will be rated on a scale from 'highly unsatisfactory' to 'highly satisfactory'. In particular the evaluation shall **assess and rate** the project with respect to the eleven categories defined below:[2]

A. Attainment of objectives and planned results:
The evaluation should assess the extent to which the project's major relevant objectives were effectively and efficiently achieved or are expected to be achieved and their relevance.

- *Effectiveness:* Evaluate how, and to what extent, the stated project objectives have been met, taking into account the "achievement indicators". The analysis of outcomes achieved should include, *inter alia*, an assessment of the extent to which the project has directly or indirectly assisted policy and decision-makers to apply information supplied by biodiversity indicators in their national planning and decision-making. In particular:
  - Evaluate the immediate impact of the project on biosafety monitoring and in national planning and decision-making and international understanding and use of biodiversity indicators.
  - As far as possible, also assess the potential longer-term impacts considering that the evaluation is taking place upon completion of the project and that longer term impact is expected to be seen in a few years time. Frame recommendations to enhance future project impact in this context. Which will be the major 'channels' for longer term impact from the project at the national and international scales?
    - *Relevance*: In retrospect, were the project's outcomes consistent with the focal areas/operational programme strategies? Ascertain the nature and

[1] Evaluators should make a brief courtesy call to GEF Country Focal points during field visits if at all possible.
[2] However, the views and comments expressed by the evaluator need not be restricted to these items.

significance of the contribution of the project outcomes to the CBP and the wider portfolio of the GEF.

- *Efficiency*: Was the project cost effective? Was the project the least cost option? Was the project implementation delayed and if it was, then did that affect cost-effectiveness? Assess the contribution of cash and in-kind co-financing to project implementation and to what extent the project leveraged additional resources. Did the project build on earlier initiatives, did it make effective use of available scientific and / or technical information. Wherever possible, the evaluator should also compare the cost-time vs. outcomes relationship of the project with that of other similar projects.

B. Sustainability:

Sustainability is understood as the probability of continued long-term project-derived outcomes and impacts after the GEF project funding ends. The evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, e.g. stronger institutional capacities or better informed decision-making. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes. The evaluation should ascertain to what extent follow-up work has been initiated and how project outcomes will be sustained and enhanced over time.

Five aspects of sustainability should be addressed: financial, socio-political, institutional frameworks and governance, environmental (if applicable). The following questions provide guidance on the assessment of these aspects:

- *Financial resources.* Are there any financial risks that may jeopardize sustenance of project outcomes? What is the likelihood that financial and economic resources will not be available once the GEF assistance ends (resources can be from multiple sources, such as the public and private sectors, income generating activities, and trends that may indicate that it is likely that in future there will be adequate financial resources for sustaining project's outcomes)? To what extent are the outcomes of the project dependent on continued financial support?
- *Socio-political:* Are there any social or political risks that may jeopardize sustenance of project outcomes? What is the risk that the level of stakeholder ownership will be insufficient to allow for the project outcomes to be sustained? Do the various key stakeholders see that it is in their interest that the project benefits continue to flow? Is there sufficient public / stakeholder awareness in support of the long term objectives of the project?
- *Institutional framework and governance.* To what extent is the sustenance of the outcomes of the project dependent on issues relating to institutional frameworks and governance? What is the likelihood that institutional and technical achievements, legal frameworks, policies and governance structures and processes will allow for, the project outcomes/benefits to be sustained? While responding to these questions consider if the required systems for accountability and transparency and the required technical know-how are in place.
- *Environmental.* Are there any environmental risks that can undermine the future flow of project environmental benefits? The TE should assess whether certain activities in the project area will pose a threat to the sustainability of the project outcomes. For example; construction of dam in a protected area could inundate a

sizable area and thereby neutralize the biodiversity-related gains made by the project; or, a newly established pulp mill might jeopardise the viability of nearby protected forest areas by increasing logging pressures; or a vector control intervention may be made less effective by changes in climate and consequent alterations to the incidence and distribution of malarial mosquitoes.

C. Achievement of outputs and activities:

- Delivered outputs: Assessment of the project's success in producing each of the programmed outputs, both in quantity and quality as well as usefulness and timeliness.
- Assess the soundness and effectiveness of the methodologies used for developing the technical documents and related management options in the participating countries
- Assess to what extent the project outputs produced have the weight of scientific authority / credibility, necessary to influence policy and decision-makers, particularly at the national level.

D. Catalytic Role

Replication and catalysis. What examples are there of replication and catalytic outcomes? Replication approach, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated or scaled up in the design and implementation of other projects. Replication can have two aspects, replication proper (lessons and experiences are replicated in different geographic area) or scaling up (lessons and experiences are replicated within the same geographic area but funded by other sources). Specifically:

- Do the recommendations for management of Implementation of the National Biosafety Framework of Costa Rica coming from the country studies have the potential for application in other countries and locations?

If no effects are identified, the evaluation will describe the catalytic or replication actions that the project carried out.

E. Assessment monitoring and evaluation systems.

The evaluation shall include an assessment of the quality, application and effectiveness of project monitoring and evaluation plans and tools, including an assessment of risk management based on the assumptions and risks identified in the project document. The Terminal Evaluation will assess whether the project met the minimum requirements for 'project design of M&E' and 'the application of the Project M&E plan' (see minimum requirements 1&2 in *Annex 4* to this Appendix). GEF projects must budget adequately for execution of the M&E plan, and provide adequate resources during implementation of the M&E plan. Project managers are also expected to use the information generated by the M&E system during project implementation to adapt and improve the project.

M&E during project implementation

- *M&E design.* Projects should have sound M&E plans to monitor results and track progress towards achieving project objectives. An M&E plan should include a baseline (including data, methodology, etc.), SMART indicators (see Annex 4) and data analysis systems, and evaluation studies at specific times to assess results. The time frame for various M&E activities and standards for outputs should have been specified.

- *M&E plan implementation.* A Terminal Evaluation should verify that: an M&E system was in place and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period (perhaps through use of a log frame or similar); annual project reports and Progress Implementation Review (PIR) reports were complete, accurate and with well justified ratings; that the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs; and that projects had an M&E system in place with proper training for parties responsible for M&E activities.
- *Budgeting and Funding for M&E activities.* The terminal evaluation should determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

F. Preparation and Readiness

Were the project's objectives and components clear, practicable and feasible within its timeframe? Were the capacities of executing institution and counterparts properly considered when the project was designed? Were lessons from other relevant projects properly incorporated in the project design? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities), enabling legislation, and adequate project management arrangements in place?

G. Country ownership / driveness:

This is the relevance of the project to national development and environmental agendas, recipient country commitment, and regional and international agreements. The evaluation will:

- Assess the level of country ownership. Specifically, the evaluator should assess whether the project was effective in providing and communicating biodiversity information that catalyzed action in participating countries to improve decisions relating to the conservation and management of the focal ecosystem in each country.
- Assess the level of country commitment to the generation and use of biodiversity indicators for decision-making during and after the project, including in regional and international fora.

H. Stakeholder participation / public awareness:

This consists of three related and often overlapping processes: information dissemination, consultation, and "stakeholder" participation. Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the GEF-financed project. The term also applies to those potentially adversely affected by a project. The evaluation will specifically:

- Assess the mechanisms put in place by the project for identification and engagement of stakeholders in each participating country and establish, in consultation with the stakeholders, whether this mechanism was successful, and identify its strengths and weaknesses.
- Assess the degree and effectiveness of collaboration/interactions between the various project partners and institutions during the course of implementation of the project.
- Assess the degree and effectiveness of any various public awareness activities that were undertaken during the course of implementation of the project.

I. Financial Planning

Evaluation of financial planning requires assessment of the quality and effectiveness of financial planning and control of financial resources throughout the project's lifetime. Evaluation includes actual project costs by activities compared to budget (variances), financial management (including disbursement issues), and co- financing. The evaluation should:

- Assess the strength and utility of financial controls, including reporting, and planning to allow the project management to make informed decisions regarding the budget and allow for a proper and timely flow of funds for the payment of satisfactory project deliverables.
- Present the major findings from the financial audit if one has been conducted.
- Identify and verify the sources of co- financing as well as leveraged and associated financing (in co-operation with the IA and EA).
- Assess whether the project has applied appropriate standards of due diligence in the management of funds and financial audits.
- The evaluation should also include a breakdown of final actual costs and co-financing for the project prepared in consultation with the relevant UNEP/DGEF Fund Management Officer of the project (table attached in *Annex 1* to this Appendix Co-financing and leveraged resources).

J. Implementation approach:

This includes an analysis of the project's management framework, adaptation to changing conditions (adaptive management), partnerships in implementation arrangements, changes in project design, and overall project management. The evaluation will:

- Ascertain to what extent the project implementation mechanisms outlined in the project document have been closely followed. In particular, assess the role of the various committees established and whether the project document was clear and realistic to enable effective and efficient implementation, whether the project was executed according to the plan and how well the management was able to adapt to changes during the life of the project to enable the implementation of the project.
- Evaluate the effectiveness and efficiency and adaptability of project management and the supervision of project activities / project execution arrangements at all levels (1) policy decisions: Steering Group; (2) day to day project management in each of the country executing agencies and NCC.

K. UNEP Supervision and Backstopping

- Assess the effectiveness of supervision and administrative and financial support provided by UNEP/DGEF.
- Identify administrative, operational and/or technical problems and constraints that influenced the effective implementation of the project.

The ***ratings will be presented in the form of a table***. Each of the eleven categories should be rated separately with **brief justifications** based on the findings of the main analysis. An overall rating for the project should also be given. The following rating system is to be applied:

HS = Highly Satisfactory
S = Satisfactory
MS = Moderately Satisfactory
MU = Moderately Unsatisfactory
U = Unsatisfactory
HU = Highly Unsatisfactory

3. Evaluation report format and review procedures

The report should be brief, to the point and easy to understand. It must explain; the purpose of the evaluation, exactly what was evaluated and the methods used. The report must highlight any methodological limitations, identify key concerns and present evidence-based findings, consequent conclusions, recommendations and lessons. The report should be presented in a way that makes the information accessible and comprehensible and include an executive summary that encapsulates the essence of the information contained in the report to facilitate dissemination and distillation of lessons.

The evaluation will rate the overall implementation success of the project and provide individual ratings of the eleven implementation aspects as described in Section 1 of this TOR. ***The ratings will be presented in the format of a table*** with brief justifications based on the findings of the main analysis.

Evidence, findings, conclusions and recommendations should be presented in a complete and balanced manner. Any dissident views in response to evaluation findings will be appended in an annex. The evaluation report shall be written in English, be of no more than 50 pages (excluding annexes), use numbered paragraphs and include:

i) An **executive summary** (no more than 3 pages) providing a brief overview of the main conclusions and recommendations of the evaluation;

ii) **Introduction and background** giving a brief overview of the evaluated project, for example, the objective and status of activities; The GEF Monitoring and Evaluation Policy, 2006, requires that a TE report will provide summary information on when the evaluation took place; places visited; who was involved; the key questions; and, the methodology.

iii) **Scope, objective and methods** presenting the evaluation's purpose, the evaluation criteria used and questions to be addressed;

iv) **Project Performance and Impact** providing *factual evidence* relevant to the questions asked by the evaluator and interpretations of such evidence. This is the main substantive section of the report. The evaluator should provide a commentary and analysis on all eleven evaluation aspects (A − K above).

v) **Conclusions and rating** of project implementation success giving the evaluator's concluding assessments and ratings of the project against given evaluation criteria and standards of performance. The conclusions should provide answers to questions about whether the project is considered good or bad, and whether the results are considered positive or negative. The ratings should be provided with a brief narrative comment in a table (see *Annex 1* to this Appendix);

vi) **Lessons (to be) learned** presenting general conclusions from the standpoint of the design and implementation of the project, based on good practices and successes or problems and mistakes. Lessons should have the potential for wider application and use. All lessons should 'stand alone' and should:
   - Briefly describe the context from which they are derived
   - State or imply some prescriptive action;
   - Specify the contexts in which they may be applied (if possible, who when and where)

vii) **Recommendations** suggesting *actionable* proposals for improvement of the current project. In general, Terminal Evaluations are likely to have very few (perhaps two or three) actionable recommendations.

Prior to each recommendation, the issue(s) or problem(s) to be addressed by the recommendation should be clearly stated.

A high quality recommendation is an actionable proposal that is:

1. Feasible to implement within the timeframe and resources available
2. Commensurate with the available capacities of project team and partners
3. Specific in terms of who would do what and when
4. Contains results-based language (i.e. a measurable performance target)
5. Includes a trade-off analysis, when its implementation may require utilizing significant resources that would otherwise be used for other project purposes.

viii) Annexes may include additional material deemed relevant by the evaluator but must include:

1. The Evaluation Terms of Reference,
2. A list of interviewees, and evaluation timeline
3. A list of documents reviewed / consulted
4. Summary co-finance information and a statement of project expenditure by activity
5. The expertise of the evaluation team. (brief CV).

TE reports will also include any response / comments from the project management team and/or the country focal point regarding the evaluation findings or conclusions as an annex to the report, however, such will be appended to the report by UNEP EOU.

Examples of UNEP GEF Terminal Evaluation Reports are available at www.unep.org/eou

Review of the Draft Evaluation Report

Draft reports submitted to UNEP EOU are shared with the corresponding Programmeme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff are allowed to comment on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks feedback on the proposed recommendations. UNEP EOU collates all review comments and provides them to the evaluators for their consideration in preparing the final version of the report.

4. Submission of Final Terminal Evaluation Reports.

The final report shall be submitted in electronic form in MS Word format and should be sent to the following persons:

Segbedzi Norgbey, Chief,
UNEP Evaluation and Oversight Unit
P.O. Box 30552-00100
Nairobi, Kenya
Tel.: +(254-20)762-4181
Fax: +(254-20)762-3158
Email: Segbedzi.Norgbey@unep.org

With a copy to:

Maryam Niamir-Fuller,

Director
UNEP/Division of GEF Coordination
P.O. Box 30552-00100
Nairobi, Kenya
Tel: +(254-20)762-4166
Fax: +(254-20)762-4041/2
Email: Maryam.Niamir-Fuller@unep.org

{Name}
Task Manager
{Contact details}

The Final evaluation will also be copied to the following GEF National Focal Points.
{Insert contact details here}

The final evaluation report will be published on the Evaluation and Oversight Unit's web-site www.unep.org/eou and may be printed in hard copy. Subsequently, the report will be sent to the GEF Office of Evaluation for their review, appraisal and inclusion on the GEF website.

5. Resources and schedule of the evaluation

This final evaluation will be undertaken by an international evaluator contracted by the Evaluation and Oversight Unit, UNEP. The contract for the evaluator will begin on ddmmyyy and end on ddmmyyyy (# days) spread over # weeks (# days of travel, to {country(ies)}, and # days desk study). The evaluator will submit a draft report on ddmmyyyy to UNEP/EOU, the UNEP/DGEF Task Manager, and key representatives of the executing agencies. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary revisions. Comments to the final draft report will be sent to the consultant by ddmmyyyy after which, the consultant will submit the final report no later than ddmmyyyy.

The evaluator will after an initial telephone briefing with EOU and UNEP/GEF conduct initial desk review work and later travel to Costa Rica and meet with project staff at the beginning of the evaluation. Furthermore, the evaluator is expected to travel to Costa Rica and meet with representatives of the project executing agencies and the intended users of project's outputs.
In accordance with UNEP/GEF policy, all GEF projects are evaluated by independent evaluators contracted as consultants by the EOU. The evaluator should have the following qualifications:

The evaluator should not have been associated with the design and implementation of the project in a paid capacity. The evaluator will work under the overall supervision of the Chief, Evaluation and Oversight Unit, UNEP. The evaluator should be an international expert in { } with a sound understanding of { } issues. The consultant should have the following minimum qualifications: (i) experience in {} issues; (ii) experience with management and implementation of { } projects and in particular with { } targeted at policy-influence and decision-making; (iii) experience with project evaluation. Knowledge of UNEP programmemes and GEF activities is desirable. Knowledge of {specify language(s)} is an advantage. Fluency in oral and written English is a must.

6. Schedule Of Payment

The consultant shall select one of the following two contract options:

Lump-Sum Option
The evaluator will receive an initial payment of 30% of the total amount due upon signature of the contract. A further 30% will be paid upon submission of the draft report. A final payment of 40% will be made upon satisfactory completion of work. The fee is payable under the individual Special Service Agreement (SSA) of the evaluator and **is inclusive** of all expenses such as travel, accommodation and incidental expenses.

Fee-only Option
The evaluator will receive an initial payment of 40% of the total amount due upon signature of the contract. Final payment of 60% will be made upon satisfactory completion of work. The fee is payable under the individual SSAs of the evaluator and is **NOT** inclusive of all expenses such as travel, accommodation and incidental expenses. Ticket and DSA will be paid separately.

In case, the evaluator cannot provide the products in accordance with the TORs, the timeframe agreed, or his products are substandard, the payment to the evaluator could be withheld, until such a time the products are modified to meet UNEP's standard. In case the evaluator fails to submit a satisfactory final product to UNEP, the product prepared by the evaluator may not constitute the evaluation report.

Annex 1 to Appendix 9: OVERALL RATINGS TABLE

Criterion	Evaluator's Summary Comments	Evaluator's Rating
A. Attainment of project objectives and results (overall rating) **Sub criteria (below)**		
A. 1. Effectiveness		
A. 2. Relevance		
A. 3. Efficiency		
B. Sustainability of Project outcomes (overall rating) **Sub criteria (below)**		
B. 1. Financial		
B. 2. Socio Political		
B. 3. Institutional framework and governance		
B. 4. Ecological		
C. Achievement of outputs and activities		
D. Monitoring and Evaluation (overall rating) **Sub criteria (below)**		
D. 1. M&E Design		
D. 2. M&E Plan Implementation (use for adaptive management)		
D. 3. Budgeting and Funding for M&E activities		
E. Catalytic Role		
F. Preparation and readiness		
G. Country ownership / drivenness		
H. Stakeholders involvement		
I. Financial planning		
J. Implementation approach		
K. UNEP Supervision and backstopping		

RATING OF PROJECT OBJECTIVES AND RESULTS

Highly Satisfactory (HS): The project had no shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Satisfactory (S): The project had minor shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Satisfactory (MS): The project had moderate shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Unsatisfactory (MU): The project had significant shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Unsatisfactory (U) The project had major shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Highly Unsatisfactory (HU): The project had severe shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Please note: Relevance and effectiveness will be considered as critical criteria. The overall rating of the project for achievement of objectives and results **may not be higher** than the lowest rating on either of these two criteria. Thus, to have an overall satisfactory rating for outcomes a project must have at least satisfactory ratings on both relevance and effectiveness.

RATINGS ON SUSTAINABILITY

A. Sustainability will be understood as the probability of continued long-term outcomes and impacts after the GEF project funding ends. The Terminal evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, i.e. stronger institutional capacities, legal frameworks, socio-economic incentives /or public awareness. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes.

Rating system for sustainability sub-criteria

On each of the dimensions of sustainability of the project outcomes will be rated as follows.

Likely (L): There are no risks affecting this dimension of sustainability.

Moderately Likely (ML). There are moderate risks that affect this dimension of sustainability.

Moderately Unlikely (MU): There are significant risks that affect this dimension of sustainability

Unlikely (U): There are severe risks that affect this dimension of sustainability.

According to the GEF Office of Evaluation, all the risk dimensions of sustainability are deemed critical. Therefore, overall rating for sustainability will not be higher than the rating of the dimension with lowest ratings. For example, if a project has an Unlikely rating in any of the dimensions then its overall rating cannot be higher than Unlikely, regardless of whether higher ratings in other dimensions of sustainability produce a higher average.

RATINGS OF PROJECT M&E

Monitoring is a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing project with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds. Evaluation is the systematic and objective assessment of an on-going or completed project, its design, implementation and results. Project evaluation may involve the definition of appropriate standards, the examination of performance against those standards, and an assessment of actual and expected results.

The Project monitoring and evaluation system will be rated on 'M&E Design', 'M&E Plan Implementation' and 'Budgeting and Funding for M&E activities' as follows:

Highly Satisfactory (HS): There were no shortcomings in the project M&E system. Satisfactory(S): There were minor shortcomings in the project M&E system.

Moderately Satisfactory (MS): There were moderate shortcomings in the project M&E system.

Moderately Unsatisfactory (MU): There were significant shortcomings in the project M&E system.

Unsatisfactory (U): There were major shortcomings in the project M&E system.

Highly Unsatisfactory (HU): The Project had no M&E system.

"M&E plan implementation" will be considered a critical parameter for the overall assessment of the M&E system. The overall rating for the M&E systems will not be higher than the rating on "M&E plan implementation."

All other ratings will be on the GEF six point scale.

GEF Performance Description		Alternative description on the same scale
HS	= Highly Satisfactory	Excellent
S	= Satisfactory	Well above average
MS	= Moderately Satisfactory	Average
MU	= Moderately Unsatisfactory	Below Average
U	= Unsatisfactory	Poor
HU	= Highly Unsatisfactory	Very poor (Appalling)

Annex 2 to Appendix 9: Co-financing and Leveraged Resources

Co-financing (basic data to be supplied to the consultant for verification)

* Other is referred to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

Co financing (Type/Source)	IA own Financing (mill US$)		Government (mill US$)		Other* (mill US$)		Total (mill US$)		Total Disbursement (mill US$)	
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
– Grants										
– Loans/Concessional (compared to market rate)										
– Credits										
– Equity investments										
– In-kind support										
– Other (*) - - - -										
Totals										

Leveraged Resources

Leveraged resources are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector. Please briefly describe the resources the project has leveraged since inception and indicate how these resources are contributing to the project's ultimate objective.

Table showing final actual project expenditure by activity to be supplied by the UNEP Fund management Officer. (insert here)

Annex 3 to Appendix 9
Review of the Draft Report

Draft reports submitted to UNEP EOU are shared with the corresponding Programme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff provide comments on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks agreement on the findings and recommendations. UNEP EOU collates the review comments and provides them to the evaluators for their consideration in preparing the final version of the report. General comments on the draft report with respect to compliance with these TOR are shared with the reviewer.

Quality Assessment of the Evaluation Report

All UNEP GEF Mid Term Reports are subject to quality assessments by UNEP EOU. These apply GEF Office of Evaluation quality assessment and are used as a tool for providing structured feedback to the evaluator.

The quality of the draft evaluation report is assessed and rated against the following criteria:

GEF Report Quality Criteria	**UNEP EOU Assessment**	**Rating**
A. Did the report present an assessment of relevant outcomes and achievement of project objectives in the context of the focal area programme indicators if applicable?		
B. Was the report consistent and the evidence complete and convincing and were the ratings substantiated when used?		
C. Did the report present a sound assessment of sustainability of outcomes?		
D. Were the lessons and recommendations supported by the evidence presented?		
E. Did the report include the actual project costs (total and per activity) and actual co-financing used?		
F. Did the report include an assessment of the quality of the project M&E system and its use for project management?		
UNEP EOU additional Report Quality Criteria	**UNEP EOU Assessment**	**Rating**
G. Quality of the lessons: Were lessons readily applicable in other contexts? Did they suggest prescriptive action?		
H. Quality of the recommendations: Did recommendations specify the actions necessary to correct existing conditions or improve operations ('who?' 'what?' 'where?' 'when?)'. Can they be implemented? Did the recommendations specify a goal and an associated performance indicator?		
I. Was the report well written? (clear English language and grammar)		
J. Did the report structure follow EOU guidelines, were all requested Annexes included?		
K. Were all evaluation aspects specified in the TORs adequately addressed?		
L. Was the report delivered in a timely manner		

GEF Quality of the MTE report = 0.3*(A + B) + 0.1*(C+D+E+F)

EOU assessment of MTE report = 0.3*(G + H) + 0.1*(I+J+K+L)

Combined quality Rating = (2* 'GEF EO' rating + EOU rating)/3

The Totals are rounded and converted to the scale of HS to HU

Rating system for quality of terminal evaluation reports

A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1, and unable to assess = 0.

Annex 4 to Appendix 9
GEF Minimum requirements for M&E

Minimum Requirement 1: Project Design of M&E3
All projects must include a concrete and fully budgeted monitoring and evaluation plan by the time of Work Programme entry (full-sized projects) or CEO approval (medium-sized projects). This plan must contain at a minimum:

- SMART (see below) indicators for project implementation, or, if no indicators are identified, an alternative plan for monitoring that will deliver reliable and valid information to management
- SMART indicators for results (outcomes and, if applicable, impacts), and, where appropriate, corporate-level indicators
- A project baseline, with:
  - a description of the problem to address
  - indicator data
  - or, if major baseline indicators are not identified, an alternative plan for addressing this within one year of implementation
- An M&E Plan with identification of reviews and evaluations which will be undertaken, such as mid-term reviews or evaluations of activities
- An organizational setup and budgets for monitoring and evaluation.

Minimum Requirement 2: Application of Project M&E

- Project monitoring and supervision will include implementation of the M&E plan, comprising:
- Use of SMART indicators for implementation (or provision of a reasonable explanation if not used)
- Use of SMART indicators for results (or provision of a reasonable explanation if not used)
- Fully established baseline for the project and data compiled to review progress
- Evaluations are undertaken as planned
- Operational organizational setup for M&E and budgets spent as planned.

SMART INDICATORS GEF projects and programmes should monitor using relevant performance indicators. The monitoring system should be "SMART":

1. **Specific**: The system captures the essence of the desired result by clearly and directly relating to achieving an objective, and only that objective.

[3] http://gefweb.org/MonitoringandEvaluation/MEPoliciesProcedures/MEPTools/meptstandards.html

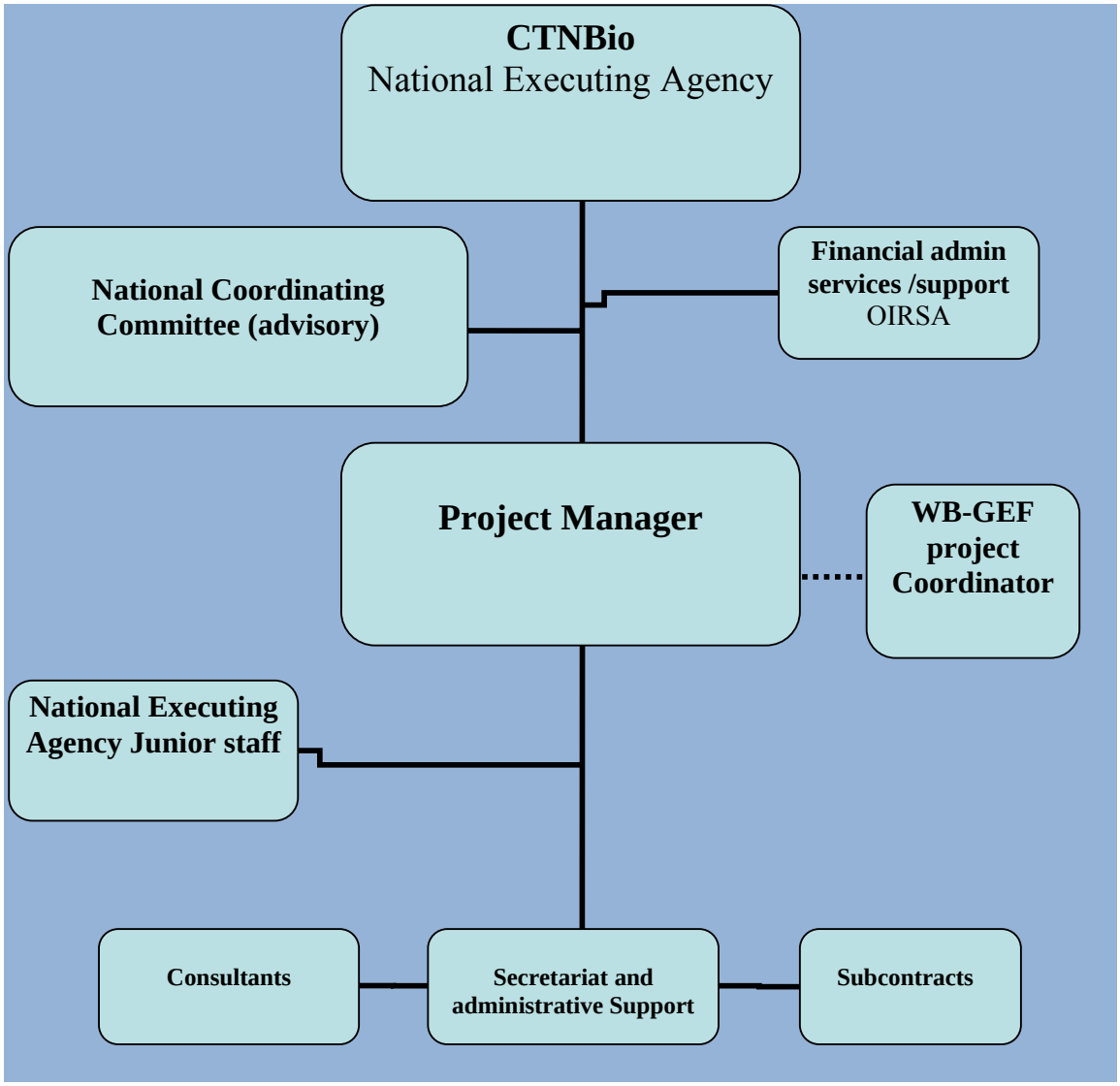
2. **Measurable:** The monitoring system and its indicators are unambiguously specified so that all parties agree on what the system covers and there are practical ways to measure the indicators and results.
3. **Achievable and Attributable:** The system identifies what changes are anticipated as a result of the intervention and whether the result(s) are realistic. Attribution requires that changes in the targeted developmental issue can be linked to the intervention.
4. **Relevant and Realistic:** The system establishes levels of performance that are likely to be achieved in a practical manner, and that reflect the expectations of stakeholders.
5. **Time-bound, Timely, Trackable, and Targeted:** The system allows progress to be tracked in a cost-effective manner at desired frequency for a set period, with clear identification of the particular stakeholder group to be impacted by the project or programme.

Annex 5 to Appendix 9

List of intended additional recipients for the Terminal Evaluation (to be completed by the IA Task Manager)

Name	Affiliation	Email
Aaron Zazuetta	GEF Evaluation Office	azazueta@thegef.org
Government Officials		
GEF Focal Point(s)		
Executing Agency		
Implementing Agency		
Carmen Tavera	UNEP DGEF Quality Assurance Officer	

Appendix 10: Decision-making flowchart and organizational chart



Appendix 11: Terms of Reference

TERMS OF REFERENCE, PROFILE AND RESPONSIBILITIES OF THE UNEP-GEF PROJECT MANAGER

GENERAL RESPONSIBILITIES
To Manage project management, especially in the support, logistics, human resources, procurement, contracting and financial management.

SPECIFIC DUTIES: The Project Manager will have the following specific duties:
Logistical and administrative

i. Compose routine correspondence in the languages of Spanish and English.
ii. Prepare correspondence, financial reports, tables, graphs, tables, etc., when required.
iii. Establish and maintain working files on all activities of the project (technical, financial, shopping, etc.).
iv. Assist in preparing presentations and reports related to the Project.
v. Make travel arrangements, appointments and meetings, when required.
vi. Maintain records of project files and other documents support, both printed and electronic.
vii. Prepare budget revisions and obtain other financial information, as necessary.
viii. Maintain appropriate records and process the cancellation of unliquidated obligations.
ix. Ensure that the recruitment of project personnel, the purchase of goods and services and disbursement of funds is carried out in accordance with policies and procedures of UNEP for the Project.

Human resources management

i. Managing human resource issues related to the Project consultants (payments, assist in preparation of TORs, recruiting process, engagement of consultants and contractors, subcontracts and other project-related transactions, ensuring updated records and information).
ii. Review invoices from subcontractors and verify supporting documentation to ensure that the services rendered and claimed comply with the terms of the contract.
iii. Considering the availability of funds, verify and submit the Certification of Payments / invoices from consultants / firms to UNEP and to follow up outstanding issues to ensure the taking of appropriate action.

Financial management

i. Manage budget funds and the loan fund financed by the GEF (preparation, revisions, amendments, reports of the budget).
ii. Ensure conformity of project disbursement requests with the procedures, work plans and availability of resources for expenditure.
iii. Prepare and maintain monthly financial reports through knowledge and use of the tools of UNEP/OIRSA financial information, indicating the approved budget, disbursements and commitments to identify the remaining balance of the project budget.
iv. Ensure that all financial reports specified in the approved project document be prepared and submitted in a timely manner to the UNEP.
v. Reviewing the quarterly financial reports meet the expected results based on the agreed work plan and correlate the financial report with the report of the program.
vi. Advise and propose corrective actions, as necessary, including the reallocation of budgets to different activities and phases.

vii. Monitor the financial status of the project and analyze the transactions to ensure compliance with the outcomes, outputs, work plan, objectives and budget agreed for the Project.

Procurements and Purchases

i. Assist in preparing all necessary documentation for the purchase of goods and services through requests for quotations and invitations to quote or any other appropriate means in accordance with the rules and regulations of OIRSA and UNEP
ii. Assist with preparation of purchase orders and contracts.
iii. Keep records of the procurement process to ensure full transparency and accountability.

REQUIRED SKILLS AND KNOWLEDGE

The following skills are required:

i. Ability to draft written communications in both Spanish and English.
ii. Excellent organizational skills and proven diplomacy.
iii. Conscious and efficient in meeting deadlines.
iv. Focused on results.
v. Ability to organize and use time efficiently and effectively.
vi. Ability to work in a team environment and to exercise tact and discretion in dealing with internal and external partners.

ACADEMIC QUALIFICATIONS AND EXPERIENCE

a) Postgraduate degree (Master's or Doctor's) in a discipline relevant to the project (natural sciences)
b) Experience in managing projects and administering work teams.
c) Experience in working on coordinating projects with responsibility for supervising personnel and controlling budgets.
d) Experience in directing and supervising multi-disciplinary plans where different actors and authorities intervene. Experience required includes organization, implementation, follow-up of project execution, and evaluation of progress and results.
e) Capacity and experience in leading multi-disciplinary work teams. Capacity and experience include: planning the use of human resources, encouraging innovation and co-operation in team work, inspiring confidence, resolving conflicts and settling differences.
f) In-depth knowledge of the problem of agricultural freeing of LMO's into the atmosphere, national and international biosafety policies and legal framework.

PERIOD OF CONSULTANCY

Hired for an initial period of one year, three month trial, and with the possibility of annual extensions, subject to compliance with the project's annual workplan and clearance from UNEP.
Available immediately.

CONDITIONS OF CONTRACT

Project Manager (a) work under a flexible time scheme and respond to the NEA President.
The payments are made monthly.

APPLICATION REQUIREMENTS

Those candidates should not be officials of the Costa Rican Government, effective, in activity, on leave or licensed, and may not have acted or be contracted as staff of the Costa Rica Government in the last 6 months.

Appendix 12: Co-financing commitment letters from project partners

Ministerio de Agricultura y Ganadería
Servicio Nacional de Salud Animal
Tel.: (506) 2262-0221Fax: (506) 2262-0221
www.senasa.go.cr
San José, Costa Rica

Heredia, 21 de julio del 2009
SENASA-DG-928-2009

Global Environment Facility
1818 H Street NW
Washington, D.C
USA.

Estimados señores:

El Servicio Nacional de Salud Animal (SENASA), adscrito al Ministerio de Agricultura y Ganadería (MAG) de la República de Costa Rica y cuya misión es: *"….brindar servicios de calidad que permitan al sector pecuario integrarse al plan de desarrollo del país, facilitar el comercio de animales, productos y subproductos pecuarios en los mercados internacionales; vigilar, operar y negociar políticas en materia de su competencia, en la importación y comercio nacional; mediante una organización armonizada y equivalente, que asegure que las medidas veterinarias se basan en evaluación de riesgos para la salud animal y la salud pública veterinaria; gozando así del respeto y confianza de la comunidad nacional e internacional"* , se place informar a las autoridades del Global Environment Facility (GEF), su interés y compromiso en participar en el proyecto **"Implementación de un Marco Nacional de Bioseguridad para Costa Rica"**.

La ley de SENASA 8495, ha designado a la Comisión Técnica Nacional de Bioseguridad como órgano de consulta en el tema de los OVMs de origen animal, y por tanto es de sumo interés en que se estructure un Marco Nacional de Bioseguridad que dé sustento jurídico y administrativo a las actividades del Servicio Nacional de Salud Animal.

Asimismo, manifestamos nuestra disposición en participar con recurso humano especializado, infraestructura y apoyo administrativo para que se realicen las acciones y actividades programadas en el ámbito del proyecto.

Con las muestras de mi más alta estima

SERVICIO NACIONAL DE SALUD ANIMAL - COSTA RICA - DIRECCION GENERAL

Dr. Yayo Vicente S.
Director General

C: Archivo

Ministerio de Agricultura y Ganadería
Servicio Fitosanitario del Estado
DIRECCION

27 Julio, 2009
DSFE 575 2009

Global Environment Facility
1818 H Street NW
Washington, D.C
USA.

Estimados Señores:

El Servicio Fitosanitario del Estado (SFE) del Ministerio de Agricultura y Ganadería, (MAG) de la República de Costa Rica, comunica a las autoridades del Global Environment Facility (GEF), su disposición e interés en participar en la **"Implementación de un Marco Nacional de Bioseguridad para Costa Rica"**.

De acuerdo con la ley de Protección Fitosanitaria No. 7664 y su reglamento, las actividades agrícolas que tienen que ver con el uso de OVMs son regulados por el SFE, por lo que la implementación del Marco Nacional de Bioseguridad y las actividades conexas derivados de su implementación, son de sumo interés para esta dependencia.

Dado lo anterior, y al igual que lo hemos hecho con los otros proyectos relacionados con Bioseguridad y que han sido auspiciados por el GEF, estamos en la mejor disposición de brindar el apoyo político y técnico-financiero necesario, y a aportar recurso humano especializado, infraestructura y apoyo administrativo para que se realicen las acciones y actividades programadas.

Sin otro particular, se suscribe

Atentamente,

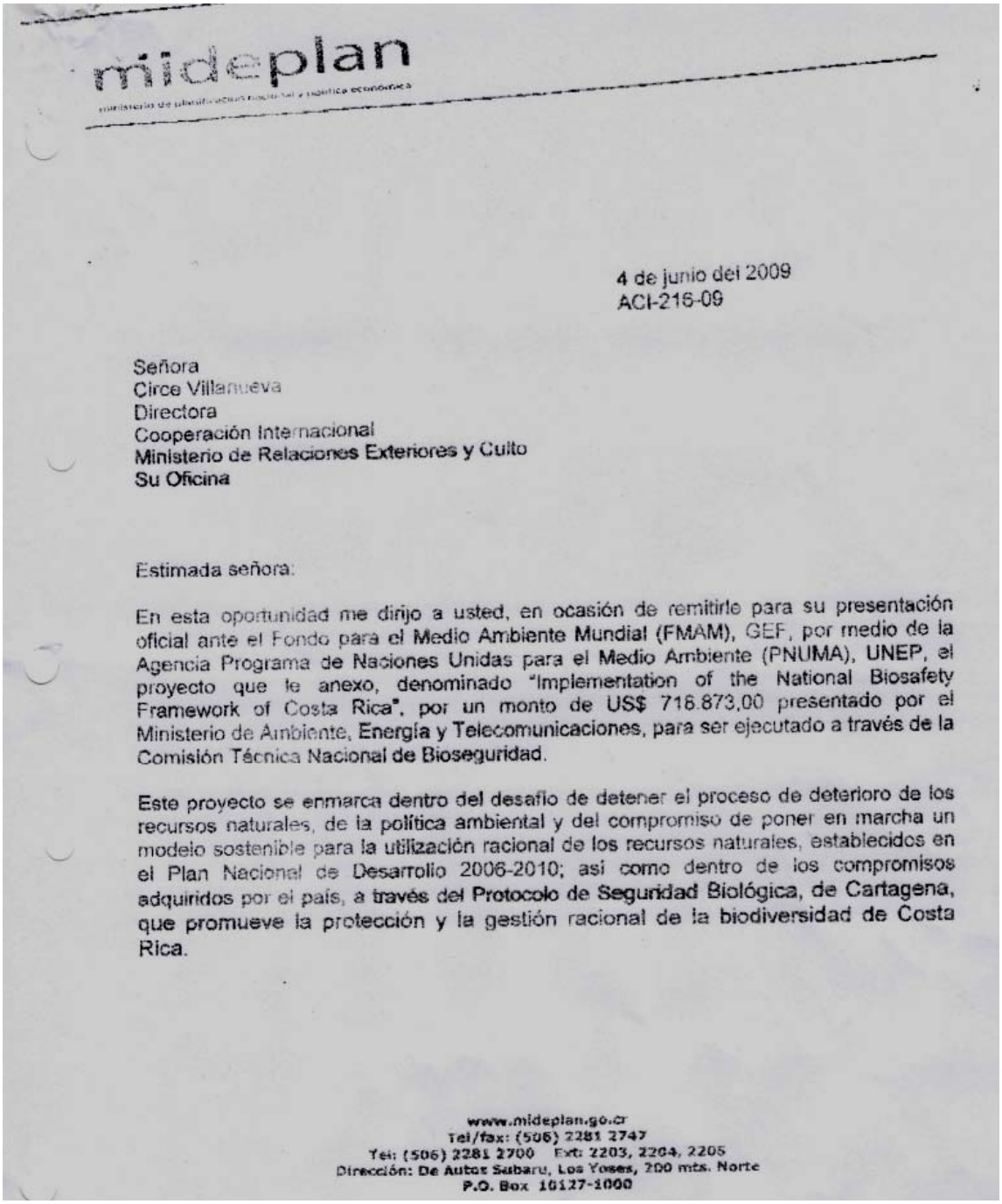
Ing. Ana Gabriela Zúñiga V.
Directora

SERVICIO FITOSANITARIO DEL ESTADO
MAG - COSTA RICA

Ing. German Carranza C. Jefe Depto. Programas Especiales
Ing. Alex May Montero. Jefe Programa Biotecnología
Archivo

Tels: (506) 2260-6190 - (506) 2260-8300 · Fax: (506) 2260-8301
Apdo. 70-3006 Barreal Heredia
www.protecnet.go.cr

Appendix 13: Endorsement letters of GEF National Focal Points



mideplan

ministerio de planificación nacional y política económica

4 de junio del 2009
ACI-216-09

Señora
Circe Villanueva
Directora
Cooperación Internacional
Ministerio de Relaciones Exteriores y Culto
Su Oficina

Estimada señora:

En esta oportunidad me dirijo a usted, en ocasión de remitirle para su presentación oficial ante el Fondo para el Medio Ambiente Mundial (FMAM), GEF, por medio de la Agencia Programa de Naciones Unidas para el Medio Ambiente (PNUMA), UNEP, el proyecto que le anexo, denominado "Implementation of the National Biosafety Framework of Costa Rica", por un monto de US$ 716.873,00 presentado por el Ministerio de Ambiente, Energía y Telecomunicaciones, para ser ejecutado a través de la Comisión Técnica Nacional de Bioseguridad.

Este proyecto se enmarca dentro del desafío de detener el proceso de deterioro de los recursos naturales, de la política ambiental y del compromiso de poner en marcha un modelo sostenible para la utilización racional de los recursos naturales, establecidos en el Plan Nacional de Desarrollo 2006-2010; así como dentro de los compromisos adquiridos por el país, a través del Protocolo de Seguridad Biológica, de Cartagena, que promueve la protección y la gestión racional de la biodiversidad de Costa Rica.

www.mideplan.go.cr
Tel/fax: (506) 2281 2747
Tel: (506) 2281 2700 Ext: 2203, 2204, 2205
Dirección: De Autos Subaru, Los Yoses, 200 mts. Norte
P.O. Box 10127-1000

4 de junio del 2009
ACI-216-09

Agradecemos su valiosa gestión en beneficio de la articulación y armonización del proceso de gestión de la Cooperación Internacional para Costa Rica.

Estamos en la mejor disposición de apoyar el proceso de negociación de los recursos para su ejecución.

Cordialmente,

Saskia Rodríguez Steichen
Coordinadora
Área de Cooperación Internacional

MINAET

DIRECCION GENERAL DE COOPERACION Y RELACIONES INTERNACIONALES - COSTA RICA

San José, 27 de mayo de 2009
DGCRI-291-09

Señora
Saskia Rodriguez
Coordinadora
Dirección de Cooperación Internacional
MIDEPLAN

Estimados señora:

Le solicito por este medio la no objeción al Proyecto Regional a financiar con recursos del GEF/ UNEP " **Implementation of the National Biosafety Framework of Costa Rica**".

El mismo será ejecutado por la Comisión Técnica Nacional de Bioseguridad.

Atentamente,

Rubén Muñoz Robles
Director

MINISTERIO DEL AMBIENTE, ENERGIA Y TELECOMUNICACIONES
DIRECCION COOPERACION INTERNACIONAL
COSTA RICA

c: Marta Liana Jiménez CONAGEBIO
Archivo Bioseguridad-MAG

Appendix 14: Draft procurement plan

Expendable equipment	Acquisition date	Cost (US$)	Responsible	Location
Consumables and office supplies	First quarter of each year of the project.	18,500	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
Software and security system of CBI information.	First quarter of the second year of the project	10,000	PMU	To be defined by the NEA
Non-expendable equipment				
One laptop computer	First quarter of the first year of the project	1,500	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
One fax	First quarter of the first year of the project	180	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
Two printer-scanners	First quarter of the first year of the project	1,360	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
One multimedia projector	First quarter of the first year of the project	2,332	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
1 colour laser printer	First quarter of the first year of the project	1,757	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.
Computer system: Servers, computers, terminals, internet, cable, etc. Condition Air.	First quarter of the second year of the project	15,000	PMU	To be defined by the NEA
Digital Archive with backup	First quarter of the second year of the project	5,000	PMU	To be defined by the NEA
Two GPSs equipment	First quarter of the second year of the project	4,460	PMU	Biotechnology Programme, Ministry of agriculture and Livestock and PMU.

Appendix 15: Tracking Tools

Applying the GEF Tracking Tools in GEF-4

Objective: To measure progress in achieving the impacts and outcomes established at the portfolio level under the biodiversity focal area. The following targets and indicators are being tracked for all GEF-4 projects submitted under Strategic Objective Three and the associated Strategic Programs.

Outcome Indicators for Strategic Objective Three and Associated Strategic Programs

Strategic Objective	**Expected Long-Term Impacts**	**Indicators**
To safeguard biodiversity	Potential risks posed to biodiversity from living modified organisms are avoided or mitigated	Biosafety: • Each request for intentional transboundary movement or domestic use is processed through a regulatory and administrative framework aligned with the CPB • For each request for intentional transboundary movement or domestic use risk assessments carried out in accordance with the CPB • For each request for intentional transboundary movement or domestic use, measures and strategies to manage risks established
	Potential risks posed to biodiversity from invasive alien species are avoided or mitigated	Invasive Alien Species: • Number of point-of-entry detections • Number of early eradications • Number of successful prevention and control programs
Strategic Programs for GEF-4	**Expected Outcomes**	**Indicators**
6. Building capacity for the implementation of the Cartagena Protocol on Biosafety	• Operational national biosafety decision-making systems that contribute to the safe use of biotechnology in conformity with the provisions and decisions of the CPB	• Percentage of participating countries with regulatory and policy framework in place • Percentage of participating countries that have established a National Coordination Mechanism • Percentage of participating countries with administrative frameworks in place • Percentage of participating countries with risk assessment and risk management strategies for the safe transfer, handling and use of living modified organisms (LMOs), specifically focused on transboundary movements • Percentage of participating countries that have carried out risk assessments • Percentage of participating countries that fully participate

		and share information on the Biosafety Clearing House (BCH)
Strategic Programs for GEF-4	**Expected Outcomes**	**Indicators**
7. Prevention, control, and management of invasive alien species (IAS)	• Operational IAS management frameworks that mitigate impact of IAS on biodiversity and ecosystem services	• National coordination mechanisms to assist with the design and implementation of national strategies for IAS • National strategies that inform policies, legislation, regulations, and management • Regulatory and policy frameworks for IAS in place • Point of detection mechanisms in place • Incorporation of environmental considerations with regards to IAS into existing risk assessment procedures • Identification and management of priority pathways for invasions

Rationale: Project data from the GEF-4 project cohort will be aggregated for analysis of directional trends and patterns at a portfolio-wide level to inform the development of future GEF strategies and to report to GEF Council on portfolio-level performance in the biodiversity focal area.

Structure of Tracking Tool: Each tracking tool requests background and coverage information on the project and specific information required to track the indicator sets listed above.

Guidance in Applying GEF Tracking Tools: GEF tracking tools are applied three times: at CEO endorsement[4], at project mid-term, and at project completion.

In GEF-4, we expect that projects will be fully aligned with specific Strategic Objectives and support Strategic Programs under each Strategic Objective hence only one tracking tool will need to be completed.

On *very rare occasions*, projects make substantive contributions to more than one strategic objective. In these instances, the tracking tools for the relevant strategic objectives should be applied. It is important to keep in mind that the objective is to capture the full range of a project's contributions to delivering on the targets set for each of the strategic priorities. The GEF Implementing Agency/Executing Agency will guide the project teams in the choice of the tracking tools. Please submit all information on a single project as one package (even where more than one tracking tool is applied).

Multi-country projects may face unique circumstances in applying the tracking tools. The GEF requests that multi-country projects complete one tracking tool per country involved in the project, based on the project circumstances and activities in each respective country. The completed forms for each country should then be submitted as one package to the GEF. Global projects which do not have a country focus, but for which the tracking tool is applicable, should complete the tracking tool as comprehensively as possible.

The tracking tool does not substitute or replace project level M&E processes, or GEF Implementing Agencies'/Executing Agencies' own monitoring processes. Project managers,

[4] For Medium Sized Projects when they are submitted for CEO approval.

consultants and project evaluators will likely be the most appropriate individuals to complete the Tracking Tool, in collaboration with other members of the project team, since they would be most knowledgeable about the project.

Submission: The finalized tracking tool will be cleared by the GEF Implementing Agencies and Executing Agencies before submission. The tracking tool is to be submitted to the GEF Secretariat at three points:

1.) With the project document at CEO endorsement[5];
2.) Within 3 months of completion of the project's mid-term evaluation or report; and
3.) With the project's terminal evaluation or final completion report, and no later than 6 months after project closure.

I. Project General Information

1. Project Name: *Implementation of the National Biosafety Framework of Costa Rica*
2. Project Type (MSP or FSP): *MSP*
3. Project ID (GEF): *3629*
4. Project ID (IA):
5. Implementing Agency: *UNEP*
6. Country(ies): *Costa Rica*

Name of reviewers completing tracking tool and completion dates:

	Name	**Title**	**Agency/Institution**
CEO Approval	Dr. Alex May	President of CTNBio	CTNBio (Executing Agency)
Project Mid-term			
Final Evaluation/project completion			

7. Project duration: ***Planned***___3__ years ***Actual*** _____ years

8. Lead Project Executing Agency (ies): *The National Technical Commission for Biosafety (CTNBio)*

9. GEF Strategic Program: *SP-6*

✓ Building capacity for the implementation of the Cartagena Protocol on Biosafety (SP6)

□ Prevention, control, and management of invasive alien species (IAS) (SP7)

[5] For Medium Sized Projects when they are submitted for CEO approval.

Strategic Program 6: Building capacity for the implementation of the Cartagena Protocol on Biosafety Tracking Tool

Issue	Scoring Criteria	Score: Tick only one box /question	Comment/Explanation	Next Steps
Biosafety Policy *1) Has a biosafety policy been developed and is it being fully implemented?*	A stand alone biosafety policy does not exist	0	Costa Rica does not have an integrated policy in Biosafety, as indicated in documents resulting from the first UNEP-GEF project.	The current project will be looking to obtain political commitment, prepare a policy and its action plan for biotechnology and biosafety in feed, food, environment, as well as human and animal health.
	A stand alone biosafety policy has been produced	1		
	A stand alone biosafety policy has been produced and has been formally adopted by the government	2		
	A legally approved biosafety strategy has been incorporated into broader sectoral policies (e.g. agriculture, biotechnology, science and technology, health, etc) and is being enforced	3		
	A biosafety policy is implemented through a multi-year Action Plan that involves more than one sector of Government or society.	4		
Biosafety Regulatory Regime	A regulatory regime has not been developed	0		
2) Has a regulatory regime been developed and does it have full legal force?	Interim measures for biosafety decision making, including some modification of existing regulations, have been put in place.	1	Costa Rica has not specific regulations on biotechnology or biosafety decision making processes for LMOs intended for human or animal consumption and processing LMOs.	The required processes, procedures, guidelines and actions will be created and standardized for incorporation into the national legal regime.
	A regulatory regime has been developed and adopted but does not yet have full legal force	2		
	The regulatory regime has full legal force, is operational and linked to the administrative system -i.e. used for decisions	3		

Issue	Scoring Criteria	Score: Tick only one box /question	Comment/Explanation	Next Steps
	The regulatory regime covers all the types of LMOs and transboundary movements referred to in the Cartagena Protocol, including agreements with Non-Parties	4		
Administrative System	Focal Points and National Competent Authorities not appointed nor available via BCH	0		
3) Is an administrative system in place and fully operational?	All Focal Points and National Competent Authorities appointed, and roles & responsibilities stated and available on BCH	1	Costa Rica has set up a nBCH system as well as appointed National Focal Points and National Competent Authorities. However, the roles and responsibilities of each National Competent Authority are not completely in place. Nor is there a coordinated or efficient administrative system. Some procedures and roles are not totally defined, or only partially adopted, or not publically known.	The project will be looking to develop a logical and harmonized inter-agency coordination system (approved by the ministries) to enable implementation of the administrative and operational system, including: financial, technical, operational, logistical and other aspects, in connection with CPB obligations and responsibilities. All procedures and information developed in the Project will be published on the nBCH.
	Procedures for handling requests have been designed, legally adopted, and made available to the public.	2		
	Requests have been received, processed, and decisions communicated to the BCH. Appeal procedures designed and operational.	3		
	Administrative system fully supported by national budget allocation or alternative (non-donor) system of revenue generation	4		
Risk Assessment and Decision-making	No risk assessment is applied to LMOs	0		
4) Are risk assessment procedures	Sectoral risk assessment dossiers are required to accompany LMO requests	1		

Issue	Scoring Criteria	Score: Tick only one box /question	Comment/Explanation	Next Steps
employed and contributing to decision-making?				
	Risk assessment/risk management system involves case-by-case analyses by scientific experts that provide recommendations to decision-making bodies. Composition and responsibilities of the decision-making bodies clearly stated and publicized.	2	The country is only able to make decisions concerning LMO crops (seed production) based on risk assessment and with risk management, but other sectors are precluded from using LMOs responsibly. CTNBio is the technical Government advisory body and has legal prerogative to recommend decisions on agricultural LMOs, but is not integrated by all the relevant NCAs.	The project will be looking to integrate representatives of SENASA and Ministry of Health into the CTNBio. Guidelines for decision making processes based on Risk Assessment and Management, for LMOs that are for food, feed or processing will be developed. Training of National Competent Authorities (NCAs) for evaluating and managing risks will also take place.
	Decisions on LMOs are integrated across sectors (e.g. take into account risks to human health)	3		
	Decision-making system allows for socio-economic considerations and for review of decisions based on new evidence	4		
Follow-up and Monitoring	No system for follow-up and monitoring exists	0		
5) Does an operational follow-up and monitoring system exist?	Institutional and human capacity in place to follow-up and monitor, including Risk Management for field-trials and post-release	1	In the specific case of agricultural LMOs, Costa Rica has an incipient monitoring system where Government and private auditors supervise field trials and LMO seed production.	Capacity building on follow up duties and monitoring is needed for Government inspectors, official auditors and civil observers.
	Compliance mechanisms for Risk Management established	2		
	Liability and redress mechanisms in place	3		
	Decisions, risk management plans, and reports on compliance and liability have been posted to the BCH	4		
Public awareness, education and	Little or no official information on LMOs available to the general public	0		

Issue	Scoring Criteria	Score: Tick only one box /question	Comment/Explanation	Next Steps
participation				
Awareness *6) Is information on LMOs made available to public?*	Information on LMOs generally available in at least one national language	1		
	Information on LMOs generally available in at least one national language and is kept updated	2	The BCH UNEP-GEF project resulted in a national web page having updated information on national decisions made on LMOs. The civil society doesn't have scientific information about risk and benefits of LMOs	The current project will prepare a training campaign and forums on access and use of the BCH. Information as well as databases, tools and training modules developed by the WB-GEF project will be used in the training forums.
	Information on LMOs is used for awareness-raising campaigns	3		
	Survey results on levels of public awareness available	4		
Education *7) Has coursework and training on biosafety been integrated into higher education?*	No modern biotechnology and biosafety available in the formal (i.e. technical, academic, extramural) education system.	0	The formal education system does not include biosafety and modern biotechnology issues	A formal primary and secondary "Education Strategy draft" on LMOs and biosafety (project TEACH: Training and Education in Agro biotechnology) and its Action Plan will be prepared, to enable long-term formal educational actions to disseminate biosafety to be carried out
	Basic modern biotechnology and biosafety information included in the curricula at technical and college levels.	1		
	Dedicated short-term courses on biosafety available for government staff at technical schools and higher education institutions.	2		
	National association for biosafety established	3		
	Undergraduate and graduate degree programs offering concentrations and/or degree programs on modern biotechnology, including	4		

Issue	Scoring Criteria	Score: Tick only one box /question	Comment/Explanation	Next Steps
	biosafety			
Participation	Little or no direct involvement of public in LMO decision-making	0		
8) Has the public been engaged in LMO decision-making?	Access to information includes other mechanisms in addition to the BCH (i.e. radio and television programs, newspapers columns, blogs, etc.).	1	A mechanism for participation of civil society is available for agricultural LMOs, but not for all LMOs described in the CPB. Newspaper and official journal edicts are published with information of agricultural LMO, requesting public positions.	The project will promote sharing of public information through greater access to biosafety information (BCH) BCH will be updated and linked with other important databases, and WB-GEF documents.
	Mechanism for public involvement in LMO decision-making established	2		
	Evidence of level of public involvement in LMO decision-making available via BCH or other means	3		
	Regular open consultation meetings held on biosafety	4		
TOTAL SCORE		**8**		
TOTAL POSSIBLE		**32**		