PROJECT DOCUMENT

SECTION 1: PROJECT IDENTIFICATION

1.1 Project title: Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region

1.2 Project number: GFL/
PMS: GEF ID: #2967 (fused with #3735)

1.3 Project type: FSP

1.4 Trust Fund: GEF

1.5 Strategic objectives:

GEF strategic long-term objective: BD3

Strategic programme for GEF IV: SP6 Biosafety

1.6 UNEP priority: Environmental Governance

1.7 Geographical scope: Regional - 12 Caribbean countries (*)

1.8 Mode of execution: External

1.9 Project executing organization: University of West Indies (UWI)

1.10 Duration of project: 48 months: Commencing: Jun 2011
Completion: Jun 2015

1.11 Cost of project	**US$**	**%**
Cost to the GEF Trust Fund	(**) **5,972,493**	**46%**
Co-financing	**6,897,582**	**54%**
In-kind/Cash: CARICOM	2,000,000	29.0 % of co-finance
In-kind: UWI/UG	1,000,000	14.5 % of co-finance
In-kind: IICA	200,000	2.9 % of co-finance
In-kind/Cash: Participating Countries (12)	3,697,582	53.6 % of co-finance
Total	**US$ 12,870,075**	**100%**

(*) Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, St. Kitts & Nevis, St. Lucia, Suriname, Trinidad & Tobago, St. Vincent & the Grenadines. At the time of project approval, Jamaica had not yet gained CPB Party status; it will join this project under GEF-V through an MSP.

(**) This funding brings together the approved budget for two separate PIFs (GEF ID #2967 and #3735)

1.12. Project summary

1. The participating Caribbean governments have signed the Convention on Biological Diversity (CBD) followed by ratification or accession to the Cartagena Protocol on Biosafety (CPB). Each country participated in the global UNEP/GEF Development of National Biosafety Frameworks (NBF) project that was technically completed in the Caribbean by 2009. The current project is therefore a continuation from previous biosafety capacity building efforts, including those of the global UNEP/GEF Biosafety Clearing House project (phase I) in which some Caribbean countries participated. Countries included in the current project are: Antigua & Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, St. Kitts & Nevis, St. Lucia, Suriname, Trinidad & Tobago, and St. Vincent & the Grenadines.

2. The project here presented comprises national and regional aspects. National component activities will support the establishment of the necessary legal and institutional frameworks, public education programs and training necessary for effective and sustained implementation of the CPB. Country-specific outcomes expected include establishment and consolidation of the following: 1) fully functional and responsive NBFs in line with the CPB and national and regional needs and priorities; 2) functional national systems and availability of services for handling requests, performing risk assessment, detecting living modified organisms (LMOs), decision-making and for performing administrative tasks; 3) functional systems for monitoring environmental effects and enforcement; 4) functional national systems for biosafety information management and stimulating public awareness, biosafety education, and participation in the decision-making process.

3. The regional aspects of the project will support: (a) the establishment and/or strengthening of region-wide processes and mechanisms for cooperative coordination to support countries in biosafety management; (b) region-wide training on biosafety risk assessment and risk management, and other specific CPB-related topics; (c) evaluations of existing and required capacity for risk management and LMO detection; (d) the creation of a Regional Node for the Biosafety Clearing House (BCH) to support and coordinate information exchange and access to information on biosafety; and (e) project management structures and processes, and monitoring and evaluation of project performance. In relation to (a), under the regional component, countries will determine whether the development of CARICOM-wide standards, protocols and procedures for biosafety risk assessment /management, LMO authorization (permit issuance) and identification are warranted and how such regional mechanism may be operated and maintained cost-effectively.

4. Outputs expected from the project's regional level work are: 1) technical guidance documents and training procedures for risk assessment, risk management, inspection, monitoring, enforcement, evaluation and measurement of environmental impacts, and if possible, common or harmonized approaches to these tasks; 2) strengthened institutional capacities and human resource base in participating Caribbean countries for implementing NBFs and for the safe use and application of modern biotechnology; 3) strengthened networks and information sharing in partnership with the BCH Central Portal and regional institutions; 4) strengthened stakeholder participation and political support mechanisms in biosafety policy-making and decision-making; 5) assessment and/or establishment of regional support mechanisms for participating countries,

potentially through CARICOM, to provide overall sustainability of NBFs. In considering such supporting mechanisms, countries will resolve the designation of an entity or entities to function as a node for biosafety information exchange, carry out training, provide access to appropriate technical and human resource capability, and/or eventually serve as a "gatekeeper" of regional biosafety applications and permits, ensuring adequate public access to information on the processing of such applications, and facilitating public input into the risk assessment process.

5. Given the need to seek cost-effective ways to sustain NBFs and biosafety levels over time, the founding of mechanisms for region-wide technical support in biosafety, as well financial sustainability and political contextualization for better CPB implementation have been built into the project. This project will involve key regional partners with mandates or capacities in biosafety, able to guide regional processes and policy definitions and make the most of opportunities related to promoting biosafety education, information availability, technical assistance (especially in agriculture) and linkages with trade-related issues. Exploiting such opportunities will be particularly important in the context of the impending creation of the Caribbean Single Markey and Economy, and the need to couple the benefits of free trade with an overall increase in biosecurity (including biosafety) management standards.

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ACRONYMS AND ABBREVIATIONS

BCH	Biosafety Clearing House
BEST	Bahamas Environment, Science and Technology
BPOA	Barbados Program of Action
CABI	Commonwealth Agricultural Bureaux International
CAHFSA	Caribbean Agricultural Health and Food Safety Agency
CARDI	Caribbean Agriculture and Development Institution
CARICOM	Caribbean Community
CARIRI	Caribbean Industrial Research Institute
CBD	Convention on Biological Diversity
COTED	Council for Trade and Economic Development
CPB	Cartagena Protocol on Biosafety
CROSQ	Caribbean Regional Organization for Standards and Quality
CSME	Caribbean Single Market and Economy
DGEF	UNEP's Division of GEF Coordination
ECLAC	Economic Commission for Latin America and the Caribbean
ECU	Environmental Coordinating Unit
EMA	Environmental Management Authority
EOU	Evaluation and Oversight Unit
FAO	Food and Agriculture Organisation of the United Nations
FSP	Full Sized Project
GEF	Global Environment Facility
GM	Genetically Modified
I3N	Invasives Information Network of IABIN
IA	Implementing Agency
IABIN	Inter-American Biodiversity Information Network
IAS	Invasive Alien Species
IC	Project Manager/International Coordinator
ICGEB	International Centre for Genetic Engineering and Biotechnology
IICA	Inter-American Institute for Cooperation On Agriculture
ISO	International Organization for Standardization
IT	Information Technology
LEA	Lead Executing Agency
LMOs	Living Modified Organisms
M&E	Monitoring And Evaluation
MEA	Multi-Lateral Environmental Agreement
MTR	Mid-Term Review
NARI	National Agricultural Research Institute
NBF	National Biosafety Framework
NBII	United States National Biological Information Infrastructure
NBSAP	National Biodiversity Strategy and Action Plan
NCA	National Competent Authority
NEA	National Executing Agency
NEPA	National Environment and Planning Agency
NPFP	National Project Focal Point
NSC	National Steering Committee
OECS	Organisation of Eastern Caribbean States

PCR	Polymerase Chain Reaction
PEO	Public Education and Outreach
PIF	Project Identification Form
PIR	Project Implementation Review
PPG	Project Preparation Grant
PMU	Project Management Unit
PROCICARIBE	Program for Cooperation of Institutes of Agricultural Science and Technology in the Caribbean
R&D	Research and Development
RA	Risk Assessment
RAF	Resource Allocation Framework
RCHM	Regional Clearing House Mechanism
RM	Risk Management
ROLAC	UNEP's Regional Office for Latin America and the Caribbean
RPM	Regional Project Manager
SIDS	Small Island Developing States
SPS	Sanitary and Phyto-Sanitary measures
SRC	Scientific Research Council
STAP	Scientific and Technical Advisory Panel
TOR	Terms of Reference
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNIDO	United Nations Industrial Development Organization
USGS	United States Geological Survey
UG	University of Guyana
UWI	University of West Indies
WTO	World Trade Organization

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

2.1. Background and context

1. The objective of the *Cartagena Protocol on Biosafety,* which derives from the Convention on Biological Diversity (CBD), is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movement." As of September 2010, 160 countries, including 17 from the Caribbean region (Antigua and Barbuda, The Bahamas, Barbados, Belize, Cuba, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Honduras, Jamaica, Saint Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago) have ratified or acceded to the Cartagena Protocol on Biosafety (CPB). As the financial mechanism of the CBD, the Global Environment Facility (GEF) is called upon to serve as the financial mechanism of the Protocol.

2. Articles 1 and 2 of the Protocol require Parties to: "*ensure an adequate level of protection in the field of the safe transfer, handling and use of these LMOs*", and to ensure that *"the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health"*. Each Party is required to "*take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol*". Accordingly, in order to meet these requirements, Caribbean countries that are Parties to the CPB need to develop comprehensive frameworks for biosafety, and to put in place appropriate legal and regulatory systems to assess any possible impact on their environment. The capacity-building initiatives must take into account procedures for risk assessment and risk management as identified in the Protocol, including any scientific skills that might be required. This would allow participating Caribbean countries to:
   - Regulate, manage and control risks and potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, including risks to human health;
   - Ensure adequate protection of the environment;
   - Minimize the risks posed to their ability to trade with other countries; and
   - Provide mechanisms for technology transfer and biotechnology benefit sharing.

3. Modern biotechnology promises remarkable advances in medicine, agriculture, and other fields, and includes new medical treatments and vaccines, new industrial products, and improved fibres and fuels. Well managed application of modern biotechnology has the potential to lead to increases in food security, decreased pressure on land use, sustainable yield increase in marginal lands or inhospitable environments and reduced use of water and agrochemicals in agriculture. However, for participating Caribbean countries modern biotechnology is a very new field, and much about the interaction of living modified organisms (LMOs) with various ecosystems is not yet known.

4. Within the Caribbean region, research in biotechnology is being carried out in several institutions in Barbados, Belize, Grenada, Jamaica, St. Kitts and Nevis, St. Lucia and Trinidad and Tobago. The status of modern biotechnology advances (incipient and applied) is shown in the table below.

Table 1: Status of biotechnology processes and approval for release

Biotechnology Processes Applied	Country	Research	Validation	Pre-commercial	Commercial	Approval of LMO
Transgenic Papaya	Jamaica	yes	yes	Yes	no	no
Transgenic Sea Island Cotton	Jamaica	yes	no	No	no	no
Transgenic citrus	Jamaica	yes	no	No	no	no
Transgenic hot pepper	Jamaica	yes	no	No	no	no
Somatic embryogenesis Ackee	Jamaica	yes	yes	No	no	no
Shoot-tip Grafting - Citrus	Jamaica	yes	yes	No	no	no
Plant Tissue Culture	Jamaica	yes	yes	Yes	Yes	no
Bio-inoculants - Plant Growth Promoting Bacteria	Jamaica	yes	yes	No	no	no
Transgenic anthuriums	Trinidad & Tobago	yes	yes	Yes	no	no
Soil bioremediation	Guyana	yes	yes	No	no	no
Plant Tissue Culture	St. Vincent & Grenadines	yes	yes	Yes	Yes	no
Plant Tissue Culture	St Kitts & Nevis	yes	yes	Yes	Yes	no
Plant Tissue culture	Barbados	yes	yes	Yes		no

5. There is potential for Caribbean countries, particularly Jamaica and Trinidad & Tobago, to release their own LMOs. In the short- and mid-term, Caribbean countries will largely continue to import LMOs foods, including food components used for research and contained use, while expanding the region's bourgeoning biotechnology industry.

6. New initiatives in biotechnology have provided opportunities for Caribbean countries to manage their natural resources while seeking to obtain maximum benefits from the sustainable use of these resources for economic and social development. It is critical that modern biotechnology products, including LMOs, are managed so that all concerns with respect to negative impacts to human, animal and plant health and environmental safety be addressed and plans are put in place to minimize such risks should they occur.

7. While not all Caribbean countries concur over the magnitude and consequences of the potential threats of modern biotechnology, it is fair to say that all coincide over the relevance of biosafety systems. Having the necessary safeguards in place and requiring explicit decisions to precede the importation and release of an LMO are means to allow the responsible use of these products. As a precautionary instrument, the *Cartagena Protocol on Biosafety* places information, coordination and transparency at the heart of any biosafety system, and presumes that LMOs and other applications of modern biotechnology can be used alongside other productive systems (in agriculture, this is

known as a *co-existence* approach) to bring benefits to society and where possible, to the environment. It also places the decision-making capacity in the hands of institutions that need to have the necessary competencies over LMOs but that may not share the same vision or mandates. Hence, even within a country and especially between countries, views on the risks and benefits of using LMOs, and how they should be treated, tend to differ.

8. Whether more or less in favor of the use of modern biotechnology products, the majority of countries and competent institutions acknowledge the need for biosafety regulatory frameworks -with a primary emphasis on agricultural systems- and the advantage of "regulatory certainty" for users and developers of modern biotechnology alike. Many also call for more information, capacities and control over the LMOs that reach national territories, and for biosafety frameworks to be ranked higher on the scale of sustainable development priorities. Some recognize the extensive use of LMOs and case-by-case evaluations and authorizations issued by other regions and countries as a knowledge base from which the Caribbean region can draw; others wish to develop such a knowledge base locally, preferring a "learn as you do" approach to build a reserve of local biosafety data and skills. Whatever the case, national biosafety frameworks need to be put in place and functionally tested if Caribbean States are to reap the benefits from LMOs, manage the risks, and comply with their international environmental obligations.

9. It is with this recognition that the countries of the Caribbean Community participated in the UNEP/GEF global project on "Development of National Biosafety Frameworks". By early 2009, 12 countries of the region had completed draft versions of their National Biosafety Frameworks (NBF), with some taking a step further and adopting official policy and legal instruments for biosafety, and developing technical and administrative guidelines, while others formulated recommendations for implementing their biosafety frameworks and proposed specific actions, time frames, and follow-up activities. These draft NBFs can be viewed on: http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx.

10. The participation of the Caribbean States in this first global biosafety project was coordinated through the UNEP/GEF Biosafety office in Barbados up until 30 June 2009, as was the conceptualization of a follow-up UNEP/GEF project, intended to take participating countries onto implementation. The "implementation project" as it became known was conceived as a regional project for NBF implementation, for which a concept (PIF) was presented to the GEF. At the time, a group of countries was deemed ineligible to receive GEF funding support for implementing their NBF on the basis that these countries either were not yet Parties to the CPB or had not yet communicated their endorsement of the above mentioned PIF. Consequently the project was initially presented for approval as two separate project concepts (PIF) with the same objective and design but comprising two country groups. The first PIF included Trinidad & Tobago, St. Vincent & the Grenadines, St. Lucia, Barbados, Dominica, Antigua & Barbuda and St. Kitts & Nevis and was approved under the April 2008 GEF Council Work Program, while the second PIF brought on board Bahamas, Belize, Grenada, Guyana and Suriname as new Parties to the *Cartagena Protocol*, and was approved under the November 2008 Work Program. The intention was always to join both project concepts into a single Full Size Project proposal, with a GEF project budget that summed over US$ 5.9 million, giving rise to the project here presented.

11. After the UNEP/GEF Biosafety office closed, continuing with project work in biosafety was taken up by UNEP's Caribbean SIDS Programme which is based in Panama at UNEP's Regional Office for Latin America and the Caribbean (ROLAC). This Programme was formally adopted by the Forum of Ministers for Latin America and the Caribbean in 2003 as a framework for assisting the Caribbean SIDS in implementing the Barbados Programme of Action and the Multilateral Environmental Agreements (MEAs) supportive of the programme areas addressed in the BPOA. It is within this context that the SIDS Programme took on the responsibility of executing the Project Preparation Grant (PPG) and coordinating the consultation process for this project.

12. Project preparation was supported by means of a PPG associated to only one of the two approved PIFs and by co-finance from CARICOM to cover the cost of participation of those countries not covered under the PPG. Project preparation was coordinated by UNEP's SIDS Programme and the Consulting group of the University of West Indies (UWI) that was subcontracted to run the process. In addition to all project countries, Jamaica also took part as well as several regional and international partners; the consultations process included a first regional discussion workshop held in July 2009 in Barbados, and a second and final encounter in June 2010, also in Barbados.

13. The 12 Caribbean countries officially participating in the current project are: **Antigua & Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, St. Kitts & Nevis, St. Lucia, Suriname, Trinidad & Tobago,** and **St. Vincent & the Grenadines**. At the time of the CEO Endorsement request, Jamaica had not yet gained Party status and hence was not eligible to use GEF-4 funding for this project. Jamaica will join this project through an add-on MSP under GEF-5.

14. This project is intended to level countries in their implementation of the CPB by strengthening individual NBFs and setting them on an evolutionary path towards more harmonized biosafety systems that make best use of existing national and regional capacities, create new capacities where needed, have ensured their financial sustainability, take advantage of economies of scale and regional support mechanisms where convenient, and fit with the regional objectives of establishing a Caribbean Single Market and Economy (CSME) and with CARICOM's initiative of promoting biotechnology and biosafety by means of a regional strategy. While the project maintains a national focus, homing in on institutional capacity and management needs, at the same time it looks to take advantage of regional options and solutions in support of biosafety, should these prove cost-effective and politically viable. The national and regional components comprised in the project are linked by issues of trade, infrastructure and scientific capacity.

15. While trade between islands is generally low, and LMOs entering one Caribbean nation may or may not be subject to further transboundary movements across to other Caribbean States, transshipments occur frequently in Caribbean waters which raises the issue of LMOs in transit that are not subject to the "Advanced Informed Agreement" procedures of the *Cartagena Protocol*. Thus, upholding the Protocol, maintaining an adequate level of biosafety and defining how to handle transit cases and first-time imports is a common interest to all Caribbean SIDS. This will require for similar minimum standards to be applied across all countries that conform the CSME. Likewise, collaboration with Haiti and Montserrat as the only CARICOM Member States that have not joined this project will also be determinant.

16. As was noted by the GEF's Scientific and Technical Advisory Panel (STAP) "*the threats associated with IAs [Invasive Alien Species] and LMOs in the Caribbean are characterized by a weakest-link technology: if most of the nations take the optimal actions but a few fail to do so, the level of global environmental benefits will determined by the nations who invest the least."* Hence, this project is housed on the premise that, in recognition of potential risks to the common environment, all participating countries are able to guarantee a minimum level of biosafety protection, as required by the Cartagena Protocol; this, despite differing technical capacities, dependencies on imported products and views on the convenience of "regionalizing" aspects of biosafety management - an issue that needs further analysis. This project aims to align national and in part regional investments to prompt concomitant capacity building and an across-the-board increment in biosafety management standards in all participating countries, and to mobilize regional support mechanisms that can enable long-term incentives and sustainability to the capacities being built.

17. Modern biotechnology and the trade in LMOs may present an undetermined level of risk to the biodiversity and human health of fragile small island and coastal developing States in the Caribbean region. In order for the introduction of new organisms -specially those intended for the environment- to bring about benefits, precaution and safeguards are required. The potential risks pivot around the regional political and economic agenda, the high prevalence of vulnerable small-island ecosystems and the all-round low capacity in the individual eligible countries, and the remainder of the Caribbean sub-region as a whole, to implement and operate National Biosafety Frameworks (NBFs) to effectively manage the possible risks associated with biotechnology and the introduction of invasive alien species.

18. The Caribbean's regional political and economic agenda is currently focused on the effective establishment of the Caribbean Single Market and Economy (CSME) of CARICOM. CSME is the legal foundation permitting trade without barriers among CARICOM member states, including the participating countries. In this free-trade environment, LMOs cleared for entry in one member state may end up in another even if they are unsuited for the receiving environment. This would also be the case for potentially-invasive alien species, making foreign organisms as a whole a regional concern.

19. Participation of CARICOM countries in the CSME requires a significant degree of cooperative coordination of their NBFs and those of the remaining countries of the Caribbean sub-region in order to minimize the possibility for unintentional and or accidental release of LMOs into the environment in CARICOM member states. This requirement has been recognized by CARICOM, specifically by CARICOM's Council for Trade and Economic Development (COTED), which established and mandated a Technical Working Group to formulate a "Regional Biotechnology and Biosafety Policy" and prepare the cooperative coordination process for biosafety and biosecurity[1].

20. The well acknowledged fragility of small-island ecosystems, represented by the participating countries, makes them especially vulnerable to threats to biodiversity.

[1] Biosecurity is understood to be wider than biosafety, and can be defined as a set of preventive measures designed to reduce the potential risk of transmission of infectious diseases, quarantined pests, invasive alien species, and living modified organisms. Biosecurity regimes are often applied in the context of traded products.

Contributing to this vulnerability are large scale frequent encroachments into areas of rich forest biodiversity by commercial agriculture, mainly through the use of external inputs, notably crop species of which LMO-types are commercially available and which could be introduced unintentionally and or accidently. In the context of agriculture several concerns feature frequently. There is concern that some LMOs if released in the environment may become invasive species and cause damage to ecosystems. There are also concerns about what is referred to as "gene flow". Gene flow is the (naturally occurring) possibility of transferring genes between individuals, which in the case of LMOs could mean transgenes passing from a genetically modified (GM) crop to other species or unintended parts of the environment.

21. The following are the main gene flow concerns in the Caribbean region:
    - spreading of transgenes through hybridization of LMOs with closely related domesticated or wild species or unintended;
    - unintended spreading of transgenes through horizontal transfer from LMOs to unrelated species (eg. from plants to microbes); and
    - development of herbicide resistant weeds (if a GM plant is resistant to herbicides and the resistance is transferred to weeds);

    Additional concerns relating to the presence of LMOs in the environment are:
    - development of Bt-resistant pests; and
    - damage to non-target organisms interacting with LMOs intended for specific species.

22. In the case of the LMOs used for food or feed, there exists within the Caribbean region a number of public and animal health concerns, including the following:
    - persistence and uptake of LMO-derived DNA and proteins in the mammalian gastro-intestinal tract;
    - presence of toxicants, allergens, anti-nutrients and potential carcinogens associated with transgenes; and
    - presence of unwanted and potentially harmful substances in food and feed through hybridization of LMOs producing pharmaceuticals (known as pharma-crops or second generation LMOs) and closely related domesticated species or unintended mixture of these LMOs and conventional crops.

23. Although participating countries have initiated measures to address these risks, capacity to comply with the CPB in the areas of risk assessment and risk management is seriously lacking in CARICOM. The participating countries and the remainder of the Caribbean sub-region have compiled rosters of experts of relevance to biosafety related to modern biotechnology and for each country there is a significant shortfall in the skills base required to implement, operate and sustain biosafety. Institutional coordination at both regional and national levels is of paramount importance if countries are to deal effectively with transboundary movements of LMOs, as with alien invasive species, that require detection, prior evaluation, consent and follow-up mechanisms. Consequently, potential risks from modern biotechnology will not be significantly lowered, nor the full array of benefits enjoyed, unless biosafety capacity is improved.

24. Since the risks highlighted above are generally common to all participating countries and the remainder of the Caribbean sub-region, the regional project encourages the development of country-driven national components and seeks to promote cooperative

coordination of NBFs in the context of the CSME to avoid duplication of efforts and to enhance efficiency and cost-effectiveness in their implementation. The interests in fostering a common market and promoting the protection of the environment, biodiversity and human health are equally represented in project development and execution.

25. Based on the "NBF Development" projects and posterior gap analyses, several countries have generated Results Frameworks (or logframes) to guide their national efforts. Some have also developed workplans and a costed breakdown of activities, though they may still have to submit these elements to consultation, or refine budgetary estimations. These countries include Antigua & Barbuda, Barbados, Jamaica, St. Kitts & Nevis, St. Lucia, Suriname and Trinidad & Tobago. The remainder will finalize these tasks once the regional project has enabled the contracting of NBF Coordinators. Preliminary elements of the national project components are therefore available but require completion and fine-tuning, with each country still to present implementation plans and specific mid-term and end-of-term targets for each expected national outcome.

26. In regard of regional efforts, the extent to which biosafety responsibilities and tasks should be pooled, giving rise to regional processes for managing biosafety, requires further analysis and debate. The political and financial implications of such a strategic decision must first be clarified and sanctioned. This discussion was initiated during the project preparation and consultation process, shedding light on the main concerns of countries over "biosafety going regional". Even though there is general agreement that regional harmonization and coordination are necessary, the degree to which harmonized processes or standards should be integrated and "institutionalized" has not been agreed. Whether or not the creation of a Regional Biosafety Authority or Centre is warranted and cost-effective is still being discussed and has raised questions over the creation of a new entity *versus* mandating an existing entity, the cost implications as well as the legal, infrastructural and personnel obligations. Broadly, options range from a coordination mechanism that relies on national capacities and services, and on regional information exchange to support the harmonization or alignment of NBFs, to a legally-backed and financially-sustainable regional biosafety authority that functions under the auspices of CARICOM to oversee biosafety management.

27. The cooperative effort will begin with the participating countries defining, after a concerted assessment, which areas -if any- would gain from a pooling of financial and other relevant resources to create a larger and more adequate common capacity for all participating countries to implement their NBFs successfully. Countries need to determine whether (and which) biosafety functions or responsibilities can be cost-effectively delegated from individual countries to a common institutionalized regional mechanism (consisting in a Centre, for example) in a manner that can heighten coordination between NBFs and support their sustainability. Alternatively, specific biosafety services could be offered regionally by institutions that have basal capacities intended to be strengthened through the current project, and requested on a country-by-country basis.

28. On another front, experts have noted opportunities in linking NBF implementation with other related areas of biosecurity, in particular with certain aspects of invasive species management, and have recommended their exploration. Although the organisms involved and their potential impacts differ, dealing with LMOs and invasive alien

species (IAS) both require risk decision tools, biodiversity information and capacities to undertake monitoring and rapid responses, giving rise to commonalities that may be relevant to this capacity-building project. This potential was highlighted during project preparation and consultations, with several institutions pointing to the lessons learnt to be had from the management of invasive alien species, and the benefits of creating formal relations and access to ongoing regional programs on this topic. These included the GEF-funded regional project Mitigating the Threats of Invasive Alien Species in the Insular Caribbean (GEFSEC Project ID 3183) with the Bahamas, Dominican Republic, Jamaica, St. Lucia and Trinidad & Tobago, and the Inter-American Biodiversity Information Network (IABIN) upon which national and regional biosafety risk assessment and management institutional frameworks could be expanded, access facilitated to databases and risk decision support tools, and joint training supported on early detection (surveillance) and rapid (emergency) response.

29. There are also other UNEP/GEF biosafety projects in the region and in Latin America with which synergies can be sought, including the Cuban "Implementation of the National Biosafety Framework" project and a second phase of the global BCH project currently under development ("Global BCH-II: Continued Enhancement of Capacity Building for Effective Participation in the BCH").

30. The project's national component will cater for country-specific activities in the implementation of NBFs, while the other components will provide services owned by all participating countries. Both regional and country-level project activities will be tailored to produce the expected project outcomes and outputs mentioned earlier. The project has been developed and will be executed in close cooperation with Ministries for Agriculture and for Environment in each participating country to ensure a sound balance of interests since both arms of government have biosafety responsibilities and competence in Caribbean countries.

2.2. Global significance

31. In the global context, being an importer in excess of 80% of its food and largely economically reliant on trade in agricultural products, the Caribbean region's rich biodiversity and human health are highly vulnerable to potential risks from modern biotechnology. The region's vulnerability is measured both by way of its exposure and its capacity to respond to eventual risks from modern biotechnology. In the case of the former, uncontrolled and unregulated introduction of LMOs pose a significant threat to the Caribbean region's significant biodiversity. The Caribbean, designated as one of the world's biodiversity hotspots, supports extremely diverse ecosystems (marine, freshwater and terrestrial) of global ecological and economic importance. The terrestrial and aquatic ecosystems of the Caribbean also boast exceptionally high levels of species endemism, as shown in Table 2. Jamaica has been ranked fifth among islands of the world in terms of endemic plants.

Table 2: Species diversity and Endemism in the Insular Caribbean

Taxonomic Group	# Species	# Endemic Species	% Endemism
Plants	13,000	6,550	50
Mammals	89	41	46
Birds	604	163	27
Reptiles	502	469	93
Amphibians	170	170	100
Freshwater Fishes	161	65	40

32. The Caribbean islands have 41 endemic mammalian species, including two endemic rodent families: *Solenodontidae* and *Capromyidae*. Over 600 species of birds have been recorded in the Caribbean, 163 of which are endemic. Of these regional endemics, 105 species are confined to single islands. More than 120 bird species migrate from their breeding grounds in North America to winter in the Caribbean. The Caribbean is the most important (and sometimes the exclusive) wintering ground for a number of North American species such as the declining Cape May warbler, Northern parula, black-throated blue warbler, palm warbler and prairie warbler. It is also the only wintering ground for globally threatened migrants such as Kirtland's warbler, Bicknell's thrush and (the possibly extinct) Bachman's warbler. In Trinidad and Tobago, 467 bird species have been recorded. These include six globally threatened species. Saint Lucia's avifauna totals 177 species, of which seven are endemic and seven are globally threatened.

33. The insular Caribbean is also particularly rich in reptile diversity, with 502 species, of which 469 (93%) are endemic. The diversity includes several large evolutionary radiations of lizards, such as the anoles (*Anolis*; 154 species, 150 endemic) with their colourful dewlaps used in displays; dwarf geckos (*Sphaerodactylus*; 86 species, 82 endemic); and curly tails (*Leiocephalus*; 23 species, all endemic) that hold their tails in a coil as they run. Also included in the reptile fauna are nine species of rock iguana, all threatened, from the genus *Cyclura* including some that are over one metre long. The Jamaican iguana (*Cyclura collei*, CR) was thought to be extinct until a small population of about 200 individuals was rediscovered in 1990 in the Hellshire Hills.

34. Island systems are unique with respect to their biodiversity and the fragility of their ecosystems. Their biodiversity is unique because islands are physically isolated from each other and from continents by water. This water functions as a barrier to plant and animal dispersal. Because of their isolation, islands often produce highly adaptive species. Isolation also means that there is little or no dispersal of species. For this reason island ecosystems tend to contain species of narrow genetic diversity. This usually means that island species have reduced competitive ability, small populations and narrow distribution range relative to continental systems. Island species tend to become concentrated in small areas on account of the generally limited size of islands. For this reason islands make a contribution to global biodiversity in disproportion to their land area. It is also for this reason that island ecosystems are regarded as biodiversity hot spots that concentrate most of the world's biodiversity. Even though islands are only three percent of the land surface of the earth, 1 in 6 of the known plant species are endemic to islands. Islands therefore represent a vast pool of genetic information. It is for this reason and the high adaptive nature of their biodiversity that island ecosystems are unique.

35. There are two main reasons for the fragile nature of small island ecosystems. First, the entire land mass and the marine ecosystems are in close proximity to each other. Because of this, the effect of natural or man-made disturbances on land can impact coastal marine biodiversity quickly. Another reason for the fragility is that small islands possess limited capacity to buffer natural hazards or man-made disturbances. The unique features of island biodiversity, previously characterized by the narrow genetic base, reduced competitive ability, small populations and narrow distribution ranges also make island ecosystems vulnerable in the face of threats to biodiversity.

36. The threat to the Caribbean region's significant biodiversity from LMOs that could be introduced, either intentionally or by accident, is exacerbated by a limited capacity to identify, assess or manage such risks, as highlighted in the inventory and assessment work carried out by countries in preparing their NBFs and an assessment of national biosafety capacities that was undertaken as part of project preparation activities.

2.3. Threats, root causes and barrier analysis

37. Ever increasing trade in the Caribbean region and efforts to reduce trade barriers under the CSME presents a significant threat to the biodiversity of the region, principally in the form of undetected gene flow. Undetected and unregulated entry of LMOs into the region is likely to continue in the absence of a common transboundary control system, insufficient information to inform decision-making and risk management measures, weak public awareness of the risks created by modern biotechnology, and weak legal and institutional frameworks for effective management of such risks.

38. There is low but growing appreciation for modern biotechnology and biosafety in participating Caribbean countries, and limited understanding of the need to establish an effective risk management framework as embodied in each country's NBF. Additionally, national and regional political agendas are largely focused on addressing the current global economic downturn. Consequently, effective and timely implementation of NBFs could be undermined. The highest risks to the success of NBF implementation are the lack of awareness among key agencies, poor institutional coordination, and lack of human resources and infrastructure for biosafety management. These risks are compounded by the absence of a biosafety coordination mechanism at the regional level.

39. There is little information available to participating countries concerning the state of modern biotechnology in the region, or the nature and scope of LMOs that may be transported or in trade. Where regionally relevant information does exist, it is not adequately shared between countries and territories. The lack of relevant data to inform politicians, the public and decision-makers provides a serious impediment to the successful implementation of the NBFs since there is insufficient relevant material upon which to base education, training and awareness programs at the national and regional level. There is insufficient understanding of the pathways by which LMOs can be introduced into participating countries. As such, the absence of a database on LMOs in transit through the Caribbean region is a serious impediment to timely detection that is a key element of biosafety risk management.

40. While the project aims to build national and regional capacity in various fields of biosafety management and create rigorous biosafety risk management frameworks, there

is a real risk that successful outcomes will not be sustained beyond the life of the GEF project. This risk needs to be addressed both through increased awareness of the economics of modern biotechnology products, and through the establishment of a self-financing mechanism to sustain regional and national biosafety activities. The project needs to overcome important barriers if adequate support mechanisms are to be put in place for sustaining NBFs and reducing the regulatory burden of biosafety management through regional harmonization. These barriers are both financial and political and will require careful consideration of the options and in depth consultations with project country authorities and CARICOM as the main regional governance body.

2.4. Institutional, sectoral and policy context

41. All of the participating countries of the Caribbean sub-region have produced National Biosafety Frameworks (NBFs) to address national needs and priorities and common sets of concerns and to fulfill their obligations to the CPB. These NBFs were produced in the context of the global UNEP/GEF Project for the "Development of National Biosafety Frameworks" and were complemented with an additional global UNEP/GEF project for the "Effective Participation in the Biosafety Clearing House (BCH)", in which the majority of Caribbean States participated. These capacity building projects assisted each participating country in the establishment of a National Competent Authority (NCA) and supporting committee structures, the initial creation of national nodes of the Cartagena Protocol's BCH (known as nBCH) and designation of BCH Focal Points, the commencement of data collection and storage on respective nBCHs, the development of biosafety regulatory frameworks, the preparation of the 1st National Report on the Biosafety Protocol and the submission of these reports to the CBD. Very few Caribbean countries however have updated or comprehensive records on the Central Portal of the BCH.

42. In developing each NBF, obligatory public consultations were mounted to provide the primary stakeholders and the general public with opportunities to influence the biosafety regime. In addition, an obligatory project management committee (known as National Coordination Committee) was set up to oversee implementation of the project as well as development of each biosafety framework. These committees comprised representatives from respective government agencies, parastatal bodies, regional inter-governmental organizations and civil society organizations, thus allowing for expression and accommodation of different interests. These prior UNEP/GEF project have therefore set important institutional bases that will aid the current work, both in terms of products and processes.

43. At the regional level, CARICOM Heads of Governments have recognized the strategic importance of addressing LMO risks within the context of promoting biotechnology R&D as a key element of ongoing support for the region's agricultural sector development. CARICOM leadership has called for the establishment of a cooperative biosafety process among CARICOM member states and has appointed a Working Group on Biosafety and Biotechnology for this purpose. The Inter-American Institute for Cooperation on Agriculture (IICA), through a broad-base panel of experts (that included the UNEP/GEF Biosafety office staff for the Caribbean) was also mandated by CARICOM Heads of Government to formulate a regional policy on biotechnology and biosafety.

44. Following consultations with the CARICOM Secretariat, a concept paper on a proposed regional project for implementing NBFs in the Caribbean sub-region was also presented to CARICOM Heads of Governments for consideration for endorsement and support. Recently, CARICOM Heads of Governments, on the recommendation of the CARICOM Secretariat, endorsed the commissioned biotechnology and biosafety policy and the planned regional biosafety implementation project (which is inclusive of the proposal contained here but is intended for all CARICOM member states). A decision was also taken to adopt a broader regional biosafety programme that could cater for all Caribbean countries into the work programme of the CARICOM Secretariat. These decisions were reinforced recently by the backing given to the current proposal by the CARICOM Council for Trade and Economic Development (September 2010).

41. Within the CARICOM region, biotechnology research and applications are still in the early stages of development and is mostly limited to cell biology and diagnostic techniques and as a consequence the requisite frameworks to enable both R&D and utilization are not in place. There is however a growing understanding and appreciation of the wide scope of modern biotechnology and its potential economic benefits to the development of the region's industries especially in agriculture and food, healthcare, energy, environmental management, conservation and bio-prospecting. There is also a growing awareness that the development and use of biotechnology must occur within a framework which supports innovation, effective technology exploitation, overall public awareness and an appropriate legal and regulatory framework for biosafety, protection of biodiversity, and protection of human health.

42. Biotechnology initiatives within the CARICOM region are spearheaded by a number of institutions within various countries. Notable is the work undertaken within the framework of The University of the West Indies (UWI) and other tertiary institutions as well as other regional institutions which have an R&D thrust. The programmes undertaken by these institutions are varied and cover a range of biotechnology applications including agriculture (UWI, the Caribbean Agriculture and Development Institution (CARDI) and research arms of the ministries of agriculture, food, forestry and fisheries in participating countries); food technologies (Caribbean Industrial Research Institute (CARIRI) in Trinidad and Tobago, the Scientific Research Council (SRC) in Jamaica); and networking and technical assistance (IICA, the National Agricultural Research Institute (NARI) in Guyana, and PROCICARIBE).

43. Research initiatives undertaken by regional institutions have yielded a number of successes such as the development of new disease-resistant *Anthurium* varieties and transgenic papaya varieties resistant to devastating papaya ringspot virus; molecular characterization of animal breeds and plant species; micropropagation protocols for a variety of tropical plants; new biochemical compounds suitable for use as bio-pesticides; and the development of biosensors using enzyme technologies.

44. Recognizing the importance of biotechnology for economic development and the need for countries to effectively manage any potential risks posed by trade in products of biotechnology and the domestic use of such products, the CARICOM Council for Trade and Economic Development (COTED) mandated the establishment of a CARICOM Working Group on Biotechnology/GM Organisms with representation from prominent biotechnology experts of the region. The Working Group, chaired by CARDI, has been given a mandate to mobilize information, analyze technical information and to develop a

regional policy and strategic framework to place the region in a position to articulate and implement a regulatory framework to enhance the development of the region while protecting the region's biodiversity. The CARICOM "Regional Biotechnology and Biosafety Policy", which is currently undergoing consultations among Member States, is framed within four main thematic areas with the potential to cross-fertilize and substantiate national efforts:

i. Expanding applications of biotechnology in CARICOM Member States
ii. Development of appropriate legal, regulatory and institutional biosafety frameworks
iii. Human capital development
iv. Education, training and public awareness

The draft Policy promotes a more regionalized approach to biosafety management, identifying priority areas for the establishment and maintenance of regionally harmonized biosafety systems:

a) The coordination of regional biotechnology and biosafety initiatives from a central 'coordinating unit' for more efficient management and utilization of scarce human and financial resources. This central entity should be housed at the CARICOM level and be supported by regional governments and institutions, external funding and monies from the provision of services.
b) The upgrade of laboratory systems to meet international standards and to deal with testing with respect to LMOs. The CARICOM regional laboratory network should consist of at least two state-of-the-art laboratory facilities which will be equipped to conduct detailed tests and analyses.
c) Building human resource capacity with respect to risk assessment and management and monitoring and evaluation systems and other relevant areas.
d) Fostering greater participation of regional experts in international biotechnology and biosafety fora related to the development of standards, certification and best practices.
e) The recognition of test results and decisions made in relation to request for trade in LMOs in one Member State by other CARICOM Member States. This will require the development of harmonized legislation, forms and administrative procedures.

45. Importantly, in March 2010, the agency upon which CARICOM Member States will depend to strengthen agricultural health and food safety and ensure high standards for trade in agricultural products was launched. The newly created Caribbean Agricultural Health and Food Safety Agency (CAHFSA) is mandated to lead the establishment of an effective Sanitary and Phyto-Sanitary (SPS) regime and the harmonization of laws, administrative practices and procedures in respect of agriculture. It will be faced with the task of developing technical measures and protocols required to achieve SPS certification for agricultural trade, and will be critical in respect to the operations of the CSME. A new regional player has therefore come on scene, offering the project both opportunities for convergence and additional coordination requirements to ensure coherence between project actions and the CARICOM agenda. Also relevant in terms of regional policy and instruments is the work of the Caribbean Regional Organization for Standards and Quality (CROSQ) in promoting efficiency and competitive production through the process of standardization and the verification of quality. Both CROSQ and CAHSFA will likely interact closely if the expansion of intra-regional and extra-regional trade in goods and services, including LMOs, is to be successful under the CSME.

46. In conclusion, Caribbean Governments have recognized that there is a need to protect rich national and regional biodiversity in order to put the region on a course towards sustainable development of its natural resources. Caribbean governments are committed to achieving this goal through innovative, decentralized and participatory approaches in which communities take part in biodiversity management decision-making and the economic benefits that are subsequently generated. In this context, risk management for competitive food safety and agricultural health recently took centre stage. Caribbean governments have also undertaken several initiatives linking sustainable development and use of natural resources to economic, social and cultural development. These initiatives are elucidated in key policy and strategy documents developed over the past ten (10) years and include areas such as science and technology, agriculture, biodiversity management, environmental policies and strategies, and strategic plans for agriculture health, food safety and standards.

2.5. Stakeholder mapping and analysis

51. The range of stakeholders involved in biosafety is ample; its association with the complexities of genetic engineering often leads to questions over the purpose of modern biotechnology that can distract from the purpose of biosafety itself. More often than not, those against LMOs are against biosafety not because it is inherently faulty but because implicit in any biosafety system is the "acceptance" of LMO use - albeit regulated and responsible acceptance. Hence, biosafety stakeholders at the national level can include those with an interest due to their convictions over environmental protection and health concerns as well as those with direct "stakes" in biosafety. The latter group includes affected parties whose interest stems from the impact that new requirements may have on their daily business (the regulated), and those with public responsibilities who are charged with developing and applying those regulations (the regulators).

52. In CARICOM countries, biosafety is deemed a specialist topic and is therefore less mainstream than other environmental or health causes; it nevertheless awakens a low level of interest from civil society organizations, such as consumer or activist groups, and a medium level of interest from the research sector given its direct role biotechnology development and the interest that some scientists have in seeing this technology flourish in the region.

53. Within the group of direct stakeholders (the regulated), farmers and food producers, importers and exporters, scientists and researchers are amongst those who stand to gain from the capacity building efforts of this project. The benefits to these users and developers of modern biotechnology will come in the form of better understanding of the issues at stake, greater transparency in regulatory processes, and opportunities to participate in policy making and decision making, and contribute to technically-sound State actions. Optimally, key stakeholders can also act as project partners.

54. Should project countries decide in favour of a consolidated application process for LMOs that are to be introduced into the region, and the consequent development of harmonised risk management standards and protocols, not only will agencies and institutions involved in biosafety R&D, including universities and technical colleges in the region, be key constituents in this work, but so will other project beneficiaries such as the private sector and LMO importers/exporters and their agents. Similarly, the need to mobilize and systematize biosafety information will require consulting and working closely with potential users of the "biosafety clearing houses" to be developed by this

project, including biosafety regulators and inspectors, biosafety advocates and opponents, and the biosafety R&D community. It is therefore in the interest of each national project to involve these stakeholder groups at different stages and for different purposes during NBF implementation. Once on board, NBF Coordinators are expected to prepare a stakeholder analysis and participation plan to delimit which non-public sectors need to be targeted by each national project and why, and determine the best means to motivate and sustain their involvement.

55. From the public sector, institutions traditionally involved in biosafety include the Ministries of Environment, Agriculture, Health, Science and Technology, and in some instances, Foreign Affairs and Commerce. Customs offices have not historically had much involvement but this tendency is shifting, as their role as biosafety "front-liners" and important providers of information is being recognized. Likewise, public research institutions and Universities, usually affiliated to a specific Ministry and where much of the Government's technical, technological and scientific capacity resides, are also being increasingly deployed in either a regulatory or advisory capacity, as work in biosafety evolves from policy-making into the more applied fields of biosafety.

56. To conduct project activities at the national level, the project will rely on committed partner institutions that include CPB Focal Points and BCH Focal Points, as well as GEF Focal Points and other agencies responsible for biosafety who will undertake key aspects of project implementation. These institutions will be led by a single National Executing Agency (NEA) that in turn will count on a NBF Coordinator to manage all project operations at the national level. The NEAs that have been designated for the current project are as follows:

- Antigua and Barbuda - The Environment Division currently within the Ministry of Agriculture;
- The Bahamas - The Bahamas Environment, Science and Technology (BEST), Ministry of Environment;
- Barbados - The Ministry of Environment, Water Resources, and Drainage in collaboration with the Ministry of Agriculture;
- Belize - Belize Agriculture and Health Authority, Ministry of Agriculture;
- Dominica - The Environmental Coordinating Unit within the Ministry of Health and Environment;
- Grenada - The Ministry of Agriculture, Lands, Forestry and Fisheries;
- Guyana - The Environmental Protection Agency;
- St. Kitts and Nevis - The Ministry of Sustainable Development;
- Saint Lucia - The Ministry of Agriculture, Lands, Fisheries and Forestry;
- St. Vincent and the Grenadines - The Ministry of Health and the Environment;
- Suriname - The Ministry of Labour, Technological Development and Environment;
- Trinidad and Tobago - The Environment Management Authority (EMA).

57. By explicit request from the GEF Council, in the implementation of the current project, irrespective of the choice of main NEA all countries will be requested to ensure the involvement of both the Ministry of Environment and the Ministry of Agriculture, in light of their combined competencies in biosafety and the importance of their coordinated actions. This "bridging" will take place at the level of the project's National Steering Committees.

58. At the regional level, several stakeholders have been identified as key players in biosafety. Paramount among them is CARICOM represented by its Secretariat, and supported by the CAHFSA, CARDI and CROSQ as more technical arms. CARICOM has a crucial political role given its hosting of the COTED, and the imminent rolling out of the CSME as well as the regional biotechnology/biosafety policy. Though the list is by no means exhaustive, institutions of technical character able to provide biosafety technical support to the project include:

a) the Inter-American Institute for Cooperation on Agriculture (IICA);
b) the Caribbean Agricultural Research and Development Institute (CARDI);
c) the United Nations Food and Agriculture Organization (FAO);
d) the United Nations Economic Commission for Latin America and the Caribbean (ECLAC);
e) the United States Geological Survey (USGS) through the IABIN initiative;
f) the University of West Indies (UWI); and
g) the University of Guyana (UG)

59. The extent to which these institutions become involved in the current project will in part depend on the level to which biosafety management is "regionalized" as a result of country consensus, but even without a fully regionalized biosafety system, many are crucial capacity providers and have much to offer national biosafety systems in the way of technical know-how and resources. All have indicated their willingness to support project activities. The Universities in particular will play an essential role in forming human resources and facilitating training activities, in guiding the development of risk assessment protocols and processes, and in providing biosafety services for LMO monitoring and detection.

60. During the project preparation phase, a scoping exercise with the above mentioned institutions identified potential roles and responsibilities in the context of regional biosafety operations and capacity building. These roles translate into services and technical support that can be provided across the board, or upon request by countries. Listed below are the potential roles of IICA, CARDI, FAO, ECLAC and USGS/IABIN based on inputs from each agency and considering actions that benefit either the project, or national biosafety systems, or both:

IICA could support the capacity/needs assessment for regional biosafety laboratories and the upgrading of biosafety equipment, skills and risk management tools, and the establishment of a select number of detection facilities to service the needs of nearby participating countries. IICA could also support the development and implementation of biosafety risk management standards, protocols and labelling/identification and a single biosafety permitting process for the region, should this be agreed to.

CARDI has been spearheading the provision of technical assistance and policy definitions for the region, and could prove instrumental in accessing technical support to countries and for the project, and for keeping in synch with regional agricultural development.

FAO implements its overall mandate, including its mandate in biotechnology, in four ways, by providing: a) Advice to governments; b) Technical assistance; c) Information; and d) Support for meetings, training and workshops. In furthering its objectives, and as the United Nations lead agency committed to the promotion of food and agriculture, FAO has a key role to play in assisting its member countries to harness the potential of science and technology to improve agriculture and people's access to food, while ensuring that the implications and risks in doing so are adequately addressed.

FAO has been actively involved in recent years in a number of key activities focusing on biotechnologies, such as promoting international standard-setting bodies (such as the Codex Alimentarius Commission, that has, for example, developed guidelines covering the safety of foods derived from LMOs); building capacity through technical assistance and training; and providing objective, science-based information on agricultural biotechnologies. FAO recently completed the *Draft Strategic Plan 2010-2017 For The Implementation Of The Multi-Year Programme Of Work Of The Commission On Genetic Resources For Food And Agriculture.*

The FAO offices in the Caribbean can provide support to the participating countries through its technical assistance program, should countries request it. FAO can facilitate capacity building and training in furtherance of key component areas, and make available copies of relevant work items[2] for dissemination and training purposes.

ECLAC can support countries providing studies relating to the impact of invasive species, and evaluations of pathways and associated biosafety implications to enhance baseline data on regional risks from modern biotechnology, and assist in the development of risk management tools which will take into consideration alien invasive species from the point of view of transgenic species.

IABIN/USGS in association with CABI can provide to participating countries access to a suite of existing biodiversity informatics tools, including a regional IAS database template (known as I3N); a Web template through which to access the database on-line; a risk management tool; and a pathways analysis tool. They can also provide existing training materials and documentation that have been used successfully in over 20 regional invasive species data management training sessions. The IABIN/USGS can also collaborate on the development of regional recommendations for a common risk assessment framework and on training in risk assessment.

61. Institutions for higher learning within the region will collectively be responsible for developing and presenting training programs on biosafety risk management in collaboration with regional agencies responsible for agricultural development. This effort will be spearheaded by UWI, a regional entity recognized as an engine for the economic, social, political and cultural development of West Indian society through teaching, research, innovation, advisory and community services and intellectual leadership. In this task, UWI will be supported by the University of Guyana. Agencies

[2] These include: (i) the report of the 37th Session of the Codex Committee on Food Labelling that took place on 4-8 May 2009 in Calgary, Canada. Agenda Item 6 was dedicated to "Labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering" and is covered in paragraphs 88-105 of the report; (ii) the report of the 30th Session of the Codex Committee on Methods of Analysis and Sampling that took place on 9-13 March 2009 in Balatonalmadi, Hungary. Agenda Item 7 was dedicated to "Proposed draft guidelines on criteria for methods for the detection and identification of foods derived from biotechnology" and is covered in paragraphs 93-108 of the report; (iii) "The State of the World's Animal Genetic Resources for Food and Agriculture" (September 2007), a comprehensive 511-page publication drawing on 169 Country Reports and a range of other sources to provide the first global assessment of animal genetic resources and their management. It also contains many sections indirectly or directly relevant to biotechnology, such as applications of molecular markers and reproductive technologies; and (iv) FAO's Fisheries and Aquaculture Department recently published "Understanding and applying risk analysis in aquaculture", The 304-page publication contains a number of relevant papers, including 'Application of risk analysis to genetic issues in aquaculture', that covers GM organisms.

and institutions involved in biosafety R&D including universities and technical colleges in the region are also expected to assist counties to develop standards and protocols for biosafety risk assessment, identification documentation, labelling and placarding, which could also be harmonised should this be defined as a regional need.

62. In the fields of biotechnology and biosafety, the UWI has the largest cadre of researchers in the Caribbean as well as modern biotechnology facilities. Its researchers have been instrumental in guiding the development of national and regional policies and strategies in biotechnology and biosafety, and have also represented the countries in international fora and conferences. UWI has the capacity to galvanize this expertise to meet the needs of the CARICOM member states. As a member of the International Centre for Genetic Engineering and Biotechnology (ICGEB), UWI is able to access personnel from the ICGEB system and the United Nations Industrial Development Organization (UNIDO) to mount courses in biotechnology and biosafety. In fact, UWI has already approached UNIDO towards developing a diploma in biosafety.

63. In a partnership with the University of Guyana, UWI-UG will specifically provide support to participating countries in the following areas:

    a. training of scientific and non-scientific personnel in certificate programmes in biosafety- related areas;
    b. workshops /short courses in LMO detection for technicians;
    c. training for customs officers, inspectors in biotechnology and biosafety related areas;
    d. workshops/short courses in risk assessment and management;
    e. development of protocols for –
        - risk assessment and management;
        - laboratory–based testing for LMOs;
        - quality assurance and standardisation across laboratories;
        - labelling;
    f. assessment of laboratory capacities in terms of personnel and equipment; and
    g. possible development of postgraduate programmes in biosafety.

2.6. Baseline analysis and gaps

61. Section 3.6 further describes progress made by countries during the preparation of their NBFs and outlines how biosafety, modern biotechnology and the CPB link to each country's development path.

62. An analysis was undertaken during project preparation of national and regional agencies and organizations involved in biosafety and biotechnology related activities. The aim of the evaluation was: (a) to identify gaps and needs in biosafety requirements of participating CARICOM countries as they seek to implement NBFs; and (b) to identify gaps in the current capacities and capabilities of regional institutions to undertake biosafety activities. The full evaluation, including the ensuing recommendations on risk assessment /management and information management, are provided as *Appendix 16*.

63. The analysis determined that although most of the participating countries were Parties to the CBD and the CPB, and recognized the importance of managing possible risks associated with modern biotechnology, neither biotechnology nor biosafety policies nor laws had been enacted in any of the participating countries, the majority of which were

at the draft stage. Biosafety regulatory frameworks had been established to some extent (eg. through the preparation of biosafety policies) and National Competent Authorities designated in some participating countries. However, only half of the countries had established a National Biosafety Committee and only one had convened a Scientific Advisory Panel. Most Caribbean countries participated in the UNEP/GEF project for Effective Participation in the BCH (phase I), and received hardware, software, and training on the use of the BCH. However, of those countries that had not established a BCH or discontinued the work on their nBCH, lack of a sustained source of funding and inadequate infrastructure were cited as the cause.

64. Most participating countries had no capability to deal with LMOs with nearly all saying that they had however never received any such requests. Only three countries had institutions capable of risk management, although no harmonized risk assessment protocols had been developed. Funding for biosafety activities was limited with most coming from external sources. Half of the participating countries reported a lack of local experts with a limited number of persons having been trained in biosafety-related areas, mostly in workshops with training facilitated through prior UNEP/GEF projects. Although several BCH Regional Advisors are Caribbean and were trained are trainers under the first global BCH project, few recognized these experts as resource persons that are still available to the region.

65. **Summary of Baseline Analysis** - Legislation, infrastructure, policy and funding were considered the major factors that have impeded adoption of the Biosafety Protocol and the implementation of an effective National Biosafety Framework. Five countries reported that they had received requests for handling LMOs with only four countries indicating that they were capable of handling such requests. Three countries indicated that they had institutions capable of carrying out risk assessment and management at this time. Of these, two were based at the Mona and St. Augustine campuses of the UWI in Jamaica and Trinidad and Tobago respectively. Copies of their management protocols were not generally available.

66. Fifty percent (6 of 12) of the participating countries reported that biotechnology was considered a medium priority matter, only one reported high priority and 33.3% low priority (**Fig.1a**). Jamaica was the only country with a national policy on biotechnology. Research in biotechnology was being carried out in several institutions in Barbados, Belize, Grenada, Jamaica, St. Kitts and Nevis, Saint Lucia and Trinidad and Tobago. In terms of biosafety, 75% (9 of 12) of the countries reported that it was considered important and 25% very important. (**Fig 1b**). The majority (11 of 13) had prepared National Policies on biosafety but of these 90% had only reached the draft stage and one reported that no action had been taken as yet. The majority of the countries had signed, ratified, or acceded to the CBD and the CPB while several were unsure of the situation with the International Treaty on Plant Resources for Food and Agriculture, Trade Related Aspects of Intellectual Property Rights and the Sanitary and Phytosanitary Agreement of the WTO. Jamaica is a party to the CBD and has signed the CPB but to date has not ratified the Protocol.

Fig. 1a.

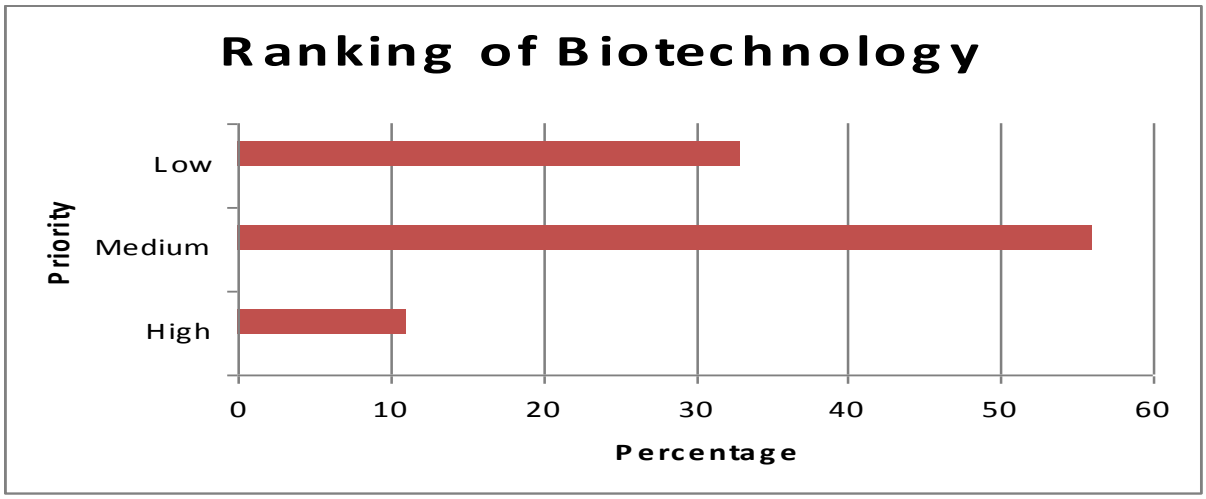
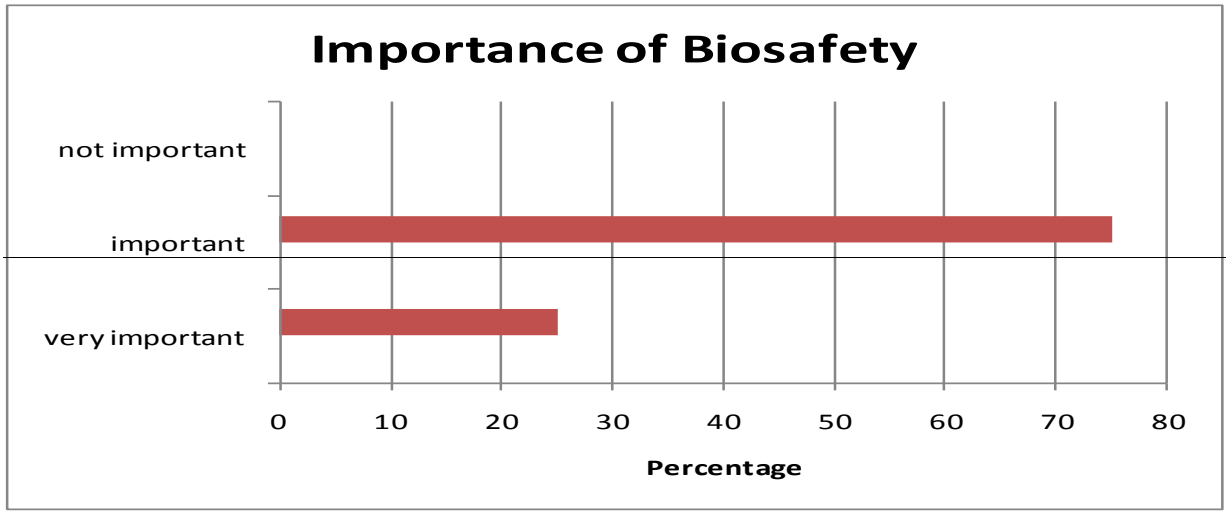


Fig.1b.



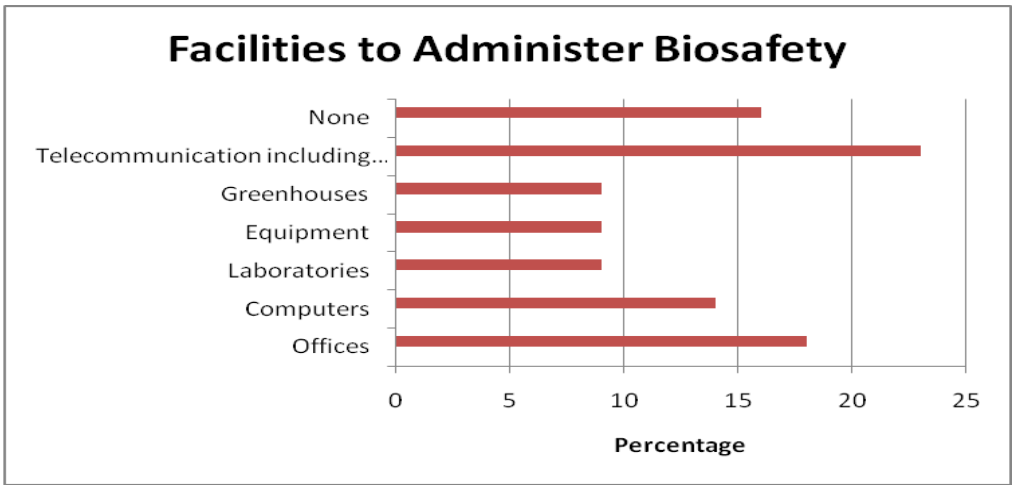
67. **Institutional Capacity** - The majority of the countries reported that there were no institutional mechanisms for administrating biosafety in their countries and that biosafety frameworks, including policies, laws and regulations for the effective implementation of the biosafety protocol, had not been fully established. National Competent Authorities (NCA) had been appointed in eight countries but just over half (54%) had established a National Biosafety Committee (NBC). Some countries wondered at the need for such a committee, since other national committees such as the Biodiversity and National Coordinating Committees were already in existence. Most NCAs were located in the Agriculture and Health Ministries which often had an environmental portfolio. A Scientific Advisory Panel (SAP) to advise the NCA had been appointed only in Jamaica and The Bahamas. National portals for the Biosafety Clearing House (nBCH) had been established in five of the thirteen countries. Of those who had not established a nBCH, lack of funding and inadequate infrastructure, such as a malfunctioning computer, were cited as the cause.

68. **Human Resources – development and training** - Four countries reported that adequate local expertise was available and that this expertise had been used extensively in the development of the NBF. In terms of training in biosafety-related areas, locals were trained in regulatory systems and risk assessment and management. Of these, 50% received their training at workshops while 20% trained through international biosafety courses with training facilitated via UNEP/GEF biosafety projects.

69. **Public education and awareness** - Exposure of the public to biosafety issues was carried out by workshops as well as by electronic and print media. The majority felt that the public had been sensitized to some extent. Mechanisms for public deliberations to include their views were in place for 75% of the countries. St. Vincent and the Grenadines reported that as much as 91.3% think that food containing genetically modified (GM) ingredients should be labeled as such and 56 % revealed that they look at labels to see if GM ingredients are listed.

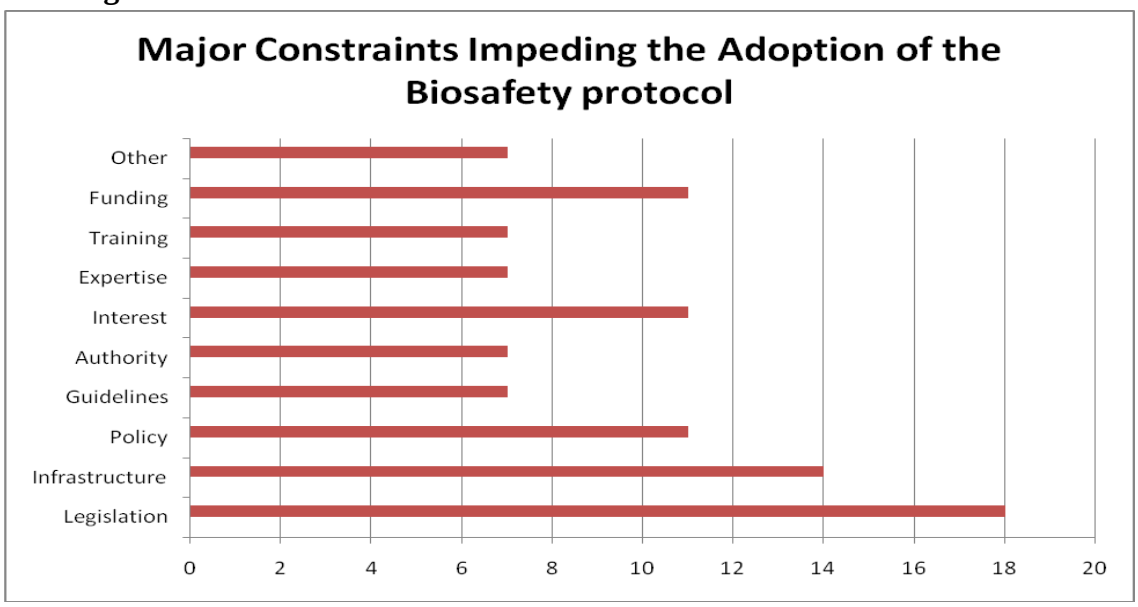
70. **Funding** - Funding for biosafety activities was reported to be limited. The principal sources of funding were international agencies (e.g. UNEP/GEF) while five countries cited their Governments had also provided some funding. **Fig. 2** shows the responses from ten countries when asked if they had the facilities in place to reliably administrate biosafety.

Fig. 2.



71. **Constraints** - Fig 3 shows what were considered to be some of the major obstacles to the adoption of the biosafety framework. They include legislation, policy, infrastructure, interest and funding, all cited as impediments to the adoption of the biosafety framework.

Fig. 3.



72. **Identified Gaps –** Participating countries identified the following gaps in their National Biosafety Framework to implement the Cartagena Protocol:
    - Institutional mechanisms;
    - Policies, laws, regulations;
    - Infrastructure;
    - Expertise;
    - LMO handling capabilities at national level; and
    - Continued public education and outreach.

73. The analysis of capacities within **regional organizations** that was undertaken during project preparation activities also highlighted several deficiencies in biosafety risk management capacities. The study determined that there were significant gaps/needs in current biosafety capabilities and capacities particularly in infrastructure and equipment that are required for the testing of LMOs. There is urgent need for training particularly in the areas of legal, administrative, regulatory and policy guidelines for LMO laboratory, research, green house and field testing and risk assessment and risk management. Only two institutions within the Caribbean region (specifically at the Mona and St. Augustine campuses of UWI) have in place real-time PCR equipment and expertise to undertake quantitative PCR. Several institutions in the region do have the necessary training and have greenhouse and contained field facilities for testing to undertake biosafety risk assessment (RA) and risk management (RM). A copy of the report on the evaluation is attached as *Appendix 16*.

74. Additionally, a consolidated gap analysis was undertaken and developed by participating countries during a regional consultative meeting held in Barbados in late July 2009 as part of project preparation activities. The consolidated analysis is presented in *Figure 4.*

Fig 4. – ***Capacity-Building needs to implement and operate NBFs in the Caribbean Region – Consolidated Table***

NBF COMPONENTS	CAPACITY-BUILDING NEEDS
Biosafety Policy ▪ **Integration of biosafety and biotechnology into all national plans and policies**	• Review draft policy to ensure integration of biotechnology, bio-security and invasive species where appropriate at the national level. • Support to public consultations on draft policies. • Develop a strategy for providing national inputs on biosafety to the work programme on the CARICOM working group on LMOs. • Strengthen and enforce the National Biosafety Policy as the basis for an efficient national regulatory regime and institutional framework - consistent with the Cartagena Protocol and other international agreements. • Organize meetings, biannually, with authorities to reflect the biosafety plans and policies in important strategic documents. • Harmonize biosafety and biotechnology, plans and policies into agricultural, environmental, health, educational, and other national development plans.
▪ **Strengthen public and political support for Biosafety policy and implementation**	• Training and sensitisation on biosafety policy for decision makers, National Coordination Committee (NCC) members, parliamentarians, public, etc. • A 2-day training on the consultative process to establish dialogue and receive feedback for improvement of the strategy. • Strengthened public and political support for biosafety policy implementation and activities through the Internet, media campaigns, materials, public outreach
▪ **Training**	• Increase knowledge of policies and procedures in respect to biosafety and biotechnology • Emphasise the capacity building of a *team* rather than an individual at the national level to ensure continuous biosafety implementation. • Organise a 5 day training workshop on Risk assessment for decision-makers, researchers, experts and relevant personnel.
Administrative System ▪ **Socio-economic and environmental impact**	• Establish a national competent authority and provide training to undertake their administrative functions • Human resource capacity to perform the administrative day to day operations of the administrative system with respect to the processing of applications, and ensure coordination within the existing administrative functions of the line ministries and at regional level. • Guidance on undertaking socio-economic and environmental impact assessments while recognizing local and cultural sensitivities
▪ **Coordination of research, assessment and monitoring of biosafety**	• Guidelines for lab-based research and development and for bio-ethics • Scientific and technical training in : - administrative practices(including handling of requests for LMOs, import/export and other types of applications such as releases); - the development and use of manuals and guidelines on procedures for handling LMO requests (regional activity); - the development of simple user guides on application procedures for use by notifiers, importers , researchers, etc (regional activity); - the development of procedures for handling and protection of confidential information provided by the applicant (regional activity); and - preparation and presentation of LMO export or release applications/dossiers (regional activity).
▪ **Training**	• Scientific and technical training in the use of risk assessment for biosafety - Scientific and technical training in development /use of technical manuals & guidelines for risk assessment (regional activity) • Scientific and technical training in decision-making and risk management procedures (regional activity)

	• Training in: socio-economic impact assessment in the context of LMOs (regional activity) • Establish linkages with locally based regional institutions (e.g. UWI, CARDI etc.) to make resources available for risk assessment and evaluation (regional activity) • Biosafety communication (regional activity). • Harmonized application form (regional activity). • Exchange programmes for administrative system training on biosafety management (regional activity).
<u>**Regulatory Regime**</u> ▪ **Access to information and confidentiality** ▪ **Legislation** ▪ **Standardization including labelling and placarding** ▪ **Protocols for risk assessment** ▪ **Training**	• Development of a password restricted Database • Review existing legislation to ensure (i) biotechnology is addressed, (ii) harmonization at the regional level, (iii) addressing of foreign invasive species where determined appropriate at the national level, (iv) intellectual property rights, (v) traditional knowledge, (vi) inclusion of self-financing scheme to cover administration costs, and costs associated with implementation of NBF at the national and regional levels beyond the project. • Reaffirmed in the CARICOM policy • Develop legislation through a process of consultation • Include access to information and confidentiality provisions • Agreement on prior informed consent at the regional level • Include liability and redress provisions • Develop a standard identification and placarding mechanism at regional level for adoption at each country • Development of standards and protocols for risk assessment at the regional level for incorporation into national regulations • Training for authorities relevant authorities in use of manual
<u>**Public Awareness and Participation**</u> ▪ **Database and BCH at national and regional level** ▪ **Access to information**	• Establish a functioning BCH with adequate equipment, infrastructure, and properly trained staff to assist in public awareness and education programmes. • Collaborate with regional organizations and support their activities in the upkeep of a BCH regional node (regional activity). • Having experts to provide their knowledge to the database (writing scientific papers and public information materials) • Conducting research • Having facilities to conduct research • Having qualified personnel to maintain the BCH and sharing national information • Undertake pathway analysis to establish mechanisms to facilitate public involvement/participation in the decision-making process including access to the relevant information • Train nationals at a regional level to undertake pathway analysis • Training in mechanisms to facilitate public involvement in decision-making (regional activity). • Information sharing and communication network among national and regional biosafety stakeholders (community practice). • Development of baseline for risk assessment to be included on the BCH. • Develop a regional public awareness strategy on biosafety, biotechnology, bio-security and invasive species where applicable. • Development and sharing of public awareness material • Regarding biotechnology – consider development and enactment of patent legislation (Suriname).

▪ **Training**	• Hold workshop /stakeholders consultation • A national awareness strategy with the focus not only on government but also students, scientific community, communities, general public • Organize discussions on identified problems with experts and stakeholders. • For government officials (awareness officials) and the media. • Development of curricula at all levels for biosafety (regional activity). • Hold workshops on the use of the BCH on the use and procedures and processes for import, export, transport, storage, handling of LMOs • Train relevant staff on identification, placarding, handling, storage and transport of LMOs • Hold training on the procedures for the proper disposal of LMOs and their by-products • Inform and sensitize the public through extensive media campaigns on the goals and development of biosafety and related issues (interviews, newspapers, magazines, radio).
<u>Monitoring and Enforcement System</u> ▪ **Risk Management** ▪ **Management of bio-waste** ▪ **Compensation and redress** ▪ **Facilities for LMO identification, handling and containment** ▪ **Early warning and detection: tools and database** ▪ **Training**	• Development of strategies and procedures with clearly identified roles for risk assessment, risk management and monitoring • Support for the establishment of testing facilities to monitor the status of imports (national and regional activity). • Enhance capabilities of institutions to carry out risk assessment and management procedures • Conduct analyses to determine the most effective and efficient institutional arrangements at the national and regional levels for conducting tests and research in support of the risk management process • Development of emergency response plans and procedures with clearly articulated lines of communication and command, with associated training. • Develop procedures for the management of bio-waste and evaluate a need for a regional bio-waste disposal facility (regional activity). • Training at national and regional level to determine most effective institutional arrangement to conduct tests and research in support of risk management process • Train personnel to develop manuals for handling of LMOs • Train persons to conduct needs assessment in RA & RM to identify gaps • Training for biosafety offices, judiciary, laboratory staff, police, prosecutors in the presentation of scientific analysis of evidence (including protocols and training on chain of custody). • Training of port-of-entry/exit officials in detection, monitoring and secure containment. • Conduct a needs assessment of key institutions responsible for risk assessment, risk management and monitoring of LMOs of biosafety and biotechnology, to identify gaps and weaknesses (and implement the recommendation to strengthen the necessary regional capacity)
<u>Risk Management (import, export, transport, handling, storage & contained use)</u> ▪ **Risk assessment** ▪ **Early warning, detection and**	• Situation analysis to evaluate exposure and risk to the Caribbean from LMOs and evaluation of pathways to identify the source of the risk (regional activity) • Development of a baseline and database of LMOs to which the region is likely to be exposed (regional activity) • Strengthen capacity at national capacity to conduct risk assessment specifically for LMOs. • Establish roster of regional experts to support risk assessment at the national and regional level.

response	• Import application forms need to be modified to request information on LMO. Laboratory capacity for detection of LMOs needs to be established.
▪ **Contingency planning** ▪ **Management of accidental discharges and containment** ▪ **Management of bio-waste** ▪ **Laboratories for LMO detection** ▪ **Tools, guidance documents, standards/protocols for risk assessment and applied research** ▪ **Training** **<u>Project Management</u>** ▪ **National Level** ▪ **Regional Level** ▪ **Training**	• National capacity needs to be developed to respond to accidental discharges and establish containment procedures. • National capacity to manage bio-waste needs to be developed. • Establish laboratory capacity for detection of LMOs (infrastructure, equipment, procedural manuals etc.) • Materials and equipment to facilitate risk assessment needs to be provided. • Development of manuals, protocols and procedures for all areas of risk management (regional activity). • Support for development and implementation of guidelines and internal safety procedures for public and private institutions engaged in modern biotechnology research for the use, transportation or storage of LMOs. • Training in: Risk assessment procedures for LMOs. Laboratory procedures for detection of LMOs. Bio-waste handling and disposal. Containment procedures. • Develop implementation plan Include stakeholders NFPs PFPs donor • Recruit consultants/staff: develop ToRs, contractual arrangements monitoring of activities evaluation of activities • Convene meetings Determine target audience, concept note, programme, presenters, reporting, logistics • Establish a steering committee Vet reports/outputs • Project evaluation: (mid term and final) • Dissemination of results • Reporting to donors

2.7. Linkages with other GEF and non-GEF interventions

75. The national biosafety frameworks, when implemented, are expected to contribute to the protection of the environment and for this reason they are complementary to projects under the CBD, UNFCCC and UNCCD, in particular. The overall aim of these

conventions is to improve environmental conservation and sustainable development programmes and to meet global environment management obligations.

76. If interest is confirmed at project inception, the current FSP will work closely with the GEF-funded regional project (Bahamas, Dominica Republic, Jamaica, Saint Lucia, Trinidad and Tobago) "Mitigating the Threats of Invasive Alien Species in the Insular Caribbean" (GEFSEC Project IS 3183) which aims to broaden the approach to dealing with invasive alien species (IAS), both by strengthening existing national measures and by fostering regional cooperation frameworks through which Caribbean-wide strategies can be developed. In parallel with participation in the development of national and regional strategies, each country will also address its own most pressing IAS problems through a total of twelve pilot projects, relating to prevention, early detection and rapid response, management and eradication of the most problematic. Recognizing that participating Caribbean countries have limited human resources to undertake early detection and risk assessment/management, and that key agencies involved in inspection for LMOs are also involved in inspections for IAS, the projects will seek to harmonize detection and risk assessment protocols and standards, and detection/surveillance training. This harmonized approach is in keeping with the holistic approach adopted by The Bahamas in its NBF whereby biosafety, biotechnology, biosecurity and the early detection and management of IAS are undertaken within a coordinated national framework supported by national legislation and institutional structures.

77. The current project can also seek collaboration with the Inter-American Biodiversity Information Network (IABIN) in order to expand national and regional biosafety risk assessment and risk management institutional frameworks, and facilitate access to databases and risk decision support tools, and joint training supported on early detection (surveillance) and rapid (emergency) response.

78. IICA in collaboration its partners such as CARDI will continue to support national and regional programs in capacity building and provide technical support to regional networks in biotechnology/biosafety. Through its hemispheric network IICA will facilitate access to lessons learned and share relevant experiences from the Central and South American regions. With its partners IICA will continue to cost-share in joint training initiatives and support exchange visit among regional biotechnology/biosafety scientists.

79. There are opportunities to be had in linking with the capacity building efforts of other UNEP/GEF biosafety projects in the region, especially with Cuba, a country recognized as a biosafety pioneer with growing training capacities and biotechnology developments, and operations that cost-effectively link LMO and IAS management. UNEP will therefore promote and facilitate coordination with other UNEP/GEF NBF implementation projects in Latin America and Caribbean, including those of Cuba and Central America (Costa Rica, Guatemala, El Salvador, and Panama) and the global BCH Phase II project in which a number of Caribbean countries will be involved. All NBF implementation projects led by UNEP will be closely linked to the BCH-II Project, which is developing mechanisms for gathering, sharing and disseminating information of relevance to the CPB, will be enhanced by concomitant execution phases, and is being led by UNEP-DELC.

80. Moreover, the World Bank is also implementing a regional biosafety project with the International Centre for Tropical Agriculture (consisting in a FSP "Multi-country Capacity-building for Compliance with the Cartagena Protocol on Biosafety" plus a complementary MSP focusing on Communication) for Brazil, Colombia, Costa Rica and Peru, with which the current project will seek coordination mechanisms, through UNEP and relevant regional and national organizations and experts, in areas where links are considered relevant and cost-effective. UNEP will also work closely with the GEF Secretariat in the context of the forthcoming GEF knowledge management effort to ensure uptake and dissemination of good practice and lessons learned from this and other biosafety projects in the region.

SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)

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

81. The project aims to build capacity for the implementation of the Cartagena Protocol on Biosafety in participating Caribbean countries. The project belongs to the Biodiversity Focal Area and is consistent with the GEF's *Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1)* approved in December 2006 and 2007 and with GEF's new *Focal Area Strategies and Strategic Programming for GEF-4.* The project is especially relevant to Strategic Programme 6, which has as its objective, the building of capacity for implementation of the Cartagena Protocol on Biosafety (CPB), and to the Biodiversity Strategic Objective No. 3. It also conforms to key elements of the *Updated Action Plan for Building Capacity for the Effective Implementation of the Cartagena Protocol on Biosafety,* agreed at COP/MOP 3 of CBD.

82. At the national level, the Caribbean sub-region countries, as Parties to the CPB, will fulfill their obligations by implementing and operating NBFs consistent with the Protocol and national needs and priorities. At the regional level, the proposed project will support implementation and operation of NBFs through a cooperative coordination mechanism, which in as far as possible will be inclusive of all CARICOM Member States, and aim to provide common biosafety services, including infrastructure, and relevant skilled manpower, and possibly operational methods or approaches. Project design is based on the recommendations and discussions that resulted from the consultation processes carried out between 2009 and 2010, as part of project preparation, and accommodates outstanding definitions that require regional consensus.

83. The project seeks to facilitate the establishment of an effective NBF in each participating country in order to address possible risks to national and regional biodiversity from unregulated exposure to LMOs. The project also is founded on the strongly-held belief amongst the participating countries that effective management of the risks associated with modern biotechnology can be aided through improved regional coordination and collaboration. A coherent biosafety risk management system requires an effective and operational NBF in each participating Caribbean country supported by regional services and mechanisms. Working simultaneously to instate NBFs and build regional operative capacity, which may go as far as having common control mechanisms and risk management standards, will enable all Caribbean states to apply a similar level of biosafety protection, by the end of the project.

84. It is an assumption that bridging the capacity gap will act as an incentive firstly for CP implementation and secondly for the uptake of modern biotechnology. If the region is thus able to tap into the potential benefits of modern biotechnology without compromising its natural resource base or the confidence of their citizens, it will have gained global environmental benefits by achieving the CP objectives in a biodiversity-rich, vulnerable and unique region, and in a manner that is compatible with its own development goals.

85. Mainstreaming biosafety into wider biosecurity-related efforts, by linking its operations to other areas such as zoo- and phyto-sanitary requirements, certification programmes, and IAS control, is believed to be the best means to accrue global environmental benefits while contributing to the sustainability of biosafety systems. With the impending onset of the CSME and the recent creation of the CAHFSA, the conditions are ripe within the region to bring environmental considerations into trade-related operations.

3.2. Project goal and objective

86. The overall goal of the project is to implement effective, operable, transparent and sustainable National Biosafety Frameworks which cater for national and regional needs, deliver global benefits and are compliant with the *Cartagena Protocol on Biosafety* in the Caribbean sub-region countries of Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago to ensure that their biodiversity will be less vulnerable to any potential risks from introduced LMOs.

87. More specifically the project aims:

i. To establish institutional (policy /legal) frameworks for biosafety at both the national and regional levels that will allow Parties to the CPB to utilize modern biotechnology in compliance with this Protocol;

ii. To facilitate the establishment, enhancement and operationalization of institutional capacities as well as technical and technological resources among the participating Caribbean Member States for the detection, assessment and management of potential risks from modern biotechnology (in combination with IAS where appropriate) at the national and regional levels;

iii. To develop and strengthen the human resource base and level of expertise in biosafety on a national and regional scale, in support of biosafety management and national biosafety systems in the Caribbean;

iv. To improve and consolidate biosafety information management within Caribbean project countries in a way that can promote transparency, raise public awareness and facilitate biosafety decision-making, and be upscaled to provide broader regional information services as needed, and if possible, establish links to IAS information sources.

3.3 Project components and expected results

88. The project comprises five components which will be implemented in a complementary manner at both the national and regional levels. The expected outcomes and outputs are outlined here, as well as in *Appendix 4* (Results Framework), and will be further refined to include country-specific targets following project inception. Monitoring for progress

towards achieving outcome indicators and targets, accruing global environmental benefits and leveraging co-funding will be included in Project Implementation Reviews and in other reports contemplated within the Monitoring and Evaluation (M&E) plan (*Appendix 7*) and evaluated at project mid-term and project completion by means of independent evaluations.

89. Country-level ***outcomes*** expected include the establishment and consolidation of the following: **a)** fully functional and responsive NBFs in line with the CPB and national and regional needs and priorities; **b)** functional national systems and availability of services for handling requests, performing risk assessment, detecting living modified organisms (LMOs), decision-making and for performing administrative tasks; **c)** functional systems for monitoring environmental effects and enforcement; **d)** functional national systems for biosafety information management and stimulating public awareness, biosafety education, and participation in the decision-making process.

90. Project expected ***outputs*** are: **a)** standards and protocols, technical documents, training procedures, and where possible, common approaches, for biosafety risk assessment, risk management, inspection, monitoring, enforcement, evaluation and measurement of environmental impacts; **b)** strengthened institutional capacities and human resource base in the participating Caribbean sub-region countries for implementing NBFs and for safe use and application of modern biotechnology; **c)** strengthened networks and means for information sharing and information management in partnership with the Central Portal of the BCH and regional institutions; **d)** strengthened stakeholder participation and political support mechanisms in biosafety policy-making and decision-making; and **e)** creation of regional support mechanisms for participating countries, potentially through CARICOM, to provide overall sustainability of NBFs.

91. Extensive discussions took place during the project preparation phase (2009/2010) on the supporting mechanisms required to aid NBF implementation. Many countries agreed that such mechanisms would need to be region-driven, and not project-driven, which underscored the importance of financial sustenance beyond the GEF. To what extent (and with what cost-savings) biosafety responsibilities should be devolved regionally could not be defined; but it was generally agreed that: (i) countries would face strong limitations if technical assistance for NBF implementation is not regionally available; (ii) the nature of an eventual regional biosafety regime requires in depth study, especially in terms of costs and benefits, and political will; (iii) cost-efficiency factors such as linkages with other programmes for biosecurity should be exploited; and (iv) the leadership role of the project's executing agency will be paramount in promoting biosafety coordination at the regional level and resolving the eventual designation of an entity or entities to function as a biosafety hub for the region.

92. This project therefore has the task of seeking agreement amongst participating countries on how best to establish sustainable operations of institutional mechanisms and strategies for cooperative coordination and execution of common and delegated biosafety functions. The first output will be a viability assessment for putting in place and operating regional support mechanism(s) for participating countries, potentially through CARICOM, that contribute to the overall sustainability of NBFs, and can in addition function as a node for biosafety information exchange, provide and coordinate training and access to appropriate technical and human resource capability, serve as a "gatekeeper" (i.e. "one-stop-shop") for regional biosafety applications and their electronic tracking, and ensure adequate public access to information on the processing

of such applications, while facilitating public input into the risk assessment process. This assessment will be followed by a political decision which will determine the scope and final outcomes of the project's regional component (component 5).

93. The project is structured into 5 components, the first of which focuses solely on national-level tasks for NBF implementation, the following 3 technical components have mixed national and regional aspects, and the fifth is exclusively of regional scope. The delivery of these components will be led by the project's Lead Executing Agency but will follow a partnership model where more than one regional institution will participate in each component, in line with their own capacities, interests and areas of work.

Component 1. Establishment of National Legal Frameworks for Biosafety /Biotechnology: This component will be country-driven and will rely on coordinated actions between the Lead Executing Agency and 12 National Executing Agencies. Each participating country will enact a functional legal and administrative framework for regulating genetically engineered organisms created, used, released, imported, exported or transported in participating Caribbean countries. The legislative framework will make provisions for: the formulation/implementation of a national biosafety and biotechnology management policy with the associated biosafety/biotechnology legislation; the establishment and effective operations of National Competent Authority(ies); coordination mechanisms and support structures for scientific assessments and monitoring of biosafety/biotechnology issues, and if relevant, biosafety research; and legislative procedures to ensure the right of the public to participate in decision-making in biosafety management (within biosafety legislative framework). The full list of Component 1 activities is provided in the preliminary project workplan (*Appendix 5*); key activities are summarized here:

i. support for review of proposed biosafety legislation (where necessary) to ensure: (a) consistency with the CPB and other biosecurity risk management frameworks to meet current national needs and circumstances, including, where appropriate, IAS and trade requirements; (b) right of the public to participate in decision making in biosafety management, access to information and confidentiality provisions included; (c) standardized risk management processes (use of standards for identification documents, biosafety measures, laboratory analytical protocols, etc); and (d) potential for regional harmonization contemplated.

ii. work with respective Office of the Attorney General and NCA in each participating country to prepare (where necessary) draft legislation for submission to Cabinet and Parliament, including public sensitization program to support enactment of biosafety law;

iii. finalization, updating and/or adoption of a national biosafety policy (where necessary), including a public outreach program in support of development and adoption of national biosafety policy; and

iv. training programs (with links to Components 2 and 3) to support effective operation of the national biosafety competent authority, and coordinating mechanisms for research, assessment and monitoring of biosafety issues.

94. **Component 2: Establishment and Upgrading of Resource Base and Institutional Capacities for Biosafety Decision-Making and Management:** This component will be executed concurrently at both the national and regional level, for which the involvement of IICA and CARICOM-affiliated institutions will be paramount. How this component

will cross-fertilize with the other project components is shown in *Appendix 5,* together with a full list of activities. Activities to be undertaken include:

i. completing overall capacity/needs assessment of key institutions (national and regional) that have or could have responsibility for detection, risk assessment, management and monitoring LMOs/IAS/biosecurity issues at the national (and regional) level;

ii. designing training programs and manuals and conducting training workshops and providing short term attachments for scientists and technical personnel involved in detection and risk management of LMOs (to be undertaken in harmonization with Component 3);

iii. development of validated standards and protocols for biosafety risk assessment and risk management, and if relevant, identification of LMO shipments; and strengthening of Bureau of Standards of each participating country to improve their capacity to provide monitoring services as far as standards for biosafety management, and to coordinate national (and eventually regional) accreditation scheme for biosafety laboratories;

iv. procurement of laboratory equipment, supplies and reagents required for establishing and or equipping and operationalizing national reference laboratories for LMO testing.

95. As part of this component, countries will look into potentially establishing a region-wide harmonized risk management system as a pioneer model for regional harmonization on biosafety standards and protocols and LMO identification and pooling of risk management laboratories and capacities. The characteristics of such a system and steps leading to its operationalization, which are outlined in the Box below, were discussed during project preparation but were not sanctioned by all participating countries. Achieving such a harmonized system is contingent on political support and evident cost-efficiency savings, as well as on first fulfilling national capacity gaps.

Regional Option:
Establishment and Upgrading the Risk Management Capability of the Region

With the view of establishing a regional *Harmonized Risk Management System,* a regional network for risk assessment and LMO testing would be established to build, where appropriate, on existing laboratory facilities in the participating countries. It would consist of a Central Regional Biosafety Facility (*Tier 1*) supported by a network of *Tier 2* and *Tier 3* biosafety laboratory facilities.

To ensure the sustainability of the *Tier 1* Central Regional Biosafety Facility, one of the more advanced of the participating countries or a regional institution would be approached to house this facility and to commit the recurring costs for operating such a facility until it becomes self-financing. Existing biosafety laboratories (*Tier 2*) in the participating Member States (including those within the University systems in the region) would be upgraded to complement and support the capabilities of the Central Regional Biosafety Facility. *Tier 3* laboratories would be established in select participating countries to serve the LMO detection needs of neighbouring members countries.

The Caribbean Agricultural Research and Development Institute (CARDI), in collaboration with the IICA, would play a key role in ensuring that the *Harmonized Risk Management System* meets the needs of regional agricultural development.

The following specific activities would be undertaken in support of this component:

i. a detailed analysis of the existing laboratory facilities to determine the most efficient institutional arrangements (national, regional) for conducting tests and research in support of the risk management process and institute recommendations;

ii. the establishment of linkages between national and regional laboratories and agencies to conduct coordinated biosafety risk assessments;

iii. as a next step to national procurements, an upgrade of laboratory equipment, supplies and reagents required for establishing and/or equipping and operationalizing laboratories for LMO testing, for these to become reference laboratories for the region or to offer services and undertake detection analyses for neighbouring countries;

iv. the adoption of harmonized biosafety standards and protocols, and identification of LMO shipments, for unified risk management. This would include support to the Bureau of Standards of each participating country to enable their participation in a regional accreditation scheme for biosafety laboratories and to CARICOM at the Caribbean Regional Organization for Standards and Quality (CROSQ) in developing a harmonized regional biosafety risk framework and risk assessment standard through a collaborative approach with regional experts, stakeholders, and project proponents. The guidelines being developed by the *Ad Hoc Technical Expert Group on Risk Assessment and Risk Management Under the Cartagena Protocol on Biosafety* and the International Organization for Standardization's ISO 31000: *Risk Management - Principles and Guideline* would serve as the foundation for the development of the harmonized regional biosafety risk framework, while the Canadian Standards Association's CAN/CSA-Q850-09: *Risk Management: Implementation to CSA-ISO-31000* would serve as the foundation for the biosafety risk assessment process;

v. a detailed analysis to determine the most efficient institutional arrangement at the regional level for coordinating biosafety risk assessments within existing regional agencies and optimizing access to laboratory services for LMO testing, and implement ensuing recommendations.

96. **Component 3: Human Resources Development in Support of Biosafety Management throughout CARICOM Member States:** This component will support the production of biosafety procedural and training manuals and the delivery of human resource training at the national and regional levels. A significant amount of the biosafety training will targeted, and orientated towards the development of national capacity, and on a secondary level, to the formation of biosafety specialists able to serve the region. This component will be coordinated and undertaken at the regional level to ensure consistency across the participating countries. The University of the West Indies (UWI) in collaboration, where appropriate, with other universities (i.e. University of Guyana *et al*) based in the region, will play a leading role in both designing and delivering this training component. An integral part of the human resources development strategy will be the development of biosafety training programmes and manuals, the convening of training workshops, short term attachments for scientific and technical personnel involved in coaching and risk management of LMOs, and ensuring sustainability for biosafety training programs for these to remain ongoing beyond GEF support. All activities to be undertaken under this component can be seen in Appendix 5; key activities include:

i. Development of biosafety training programmes and manuals for personnel involved in: (a) administrative system management; (b) legislative, monitoring and enforcement system management; (c) public education and participation system management; and (d) LMO risk management (including risk communication) at the national and regional levels;
ii. Ensuring continuity in biosafety training with succession planning and continuous training to ensure the development of a cadre of trained personnel in which relevant expertise is always available at the national and regional levels;
iii. Training workshops for scientific and technical personnel involved in risk assessment of LMOs;
iv. Facilitating short-term attachments for scientific and technical personnel involved in risk assessment or risk management of LMOs;
v. Training of scientific and non-scientific personnel in certificate programmes in biosafety-related areas, including:
    - Workshops and short courses in LMO detection for technicians and supervisors;
    - Training for customs officers, inspectors in biotechnology and biosafety related areas;
    - Workshops and short courses in risk assessment and management;
    - Seminars and workshops for policy makers and senior executives.

97. **Component 4: Strengthening biosafety information management in the Caribbean sub-region:** Together with NEAs, the CARICOM Secretariat and eventually CAHFSA are expected to be key players in this component, which aims to boost the quality and availability of relevant biosafety information in the region to benefit both the general public and decision-makers. A regional node for the BCH with a data management system will be established, for which an essential element will be the establishment of national nodes (nBCH) in each of the participating countries. The Regional Node also has the potential to house IAS and biosecurity data and will be hosted by an institution that possesses adequate technical and infrastructural capacities, and access to scientific data providers and regional networks. Integral to the Regional Node's functions will be the creation of an enabling environment to support public awareness and participation in biosafety management, including the design and implementation of a public education and outreach (PEO) strategy to promote awareness and communication with various target audiences and outreach to key stakeholders (including interest groups) in biosafety issues relevant to decision-making.

98. Under this component a communication strategy of the results of the project will also be developed for communicating the results of the project to other projects and to distribute information. The elements of the strategy include the development of a regional BCH node, upgrading of a host website, the development of a monthly electronic and printed newsletter on biosafety, and the publication of lessons learned in appropriate technical journals. Key project activities to be undertaken under this component, as listed in Appendix 5, include:

i. Conduct needs assessment to determine the level of resources (physical, human and financial) required to establish and maintain the regional and national biosafety clearing house mechanisms and data base;

ii. Based upon outcomes from (i) above, design, procure equipment/software and establish effective regional and national biosafety clearing house mechanisms and database system;

iii. Establish collaborative regional/national network for information exchange especially with regards to the biosafety decision making and notification process;

iv. Generate and compile biosafety data (and to the extent possible, combine with IAS data) and populate regional and national biosafety clearing house mechanisms and database system;

v. Development of monthly electronic and printed newsletter on biosafety;

vi. Undertake assessment of effectiveness and usefulness of regional and national biosafety and IAS clearing house mechanisms and a database system adapted from the IABIN database on IAS (I3N) to derive lessons learnt;

vii. Develop, design and implement comprehensive PEO strategy at national and regional levels to promote awareness and communication with various target audiences and outreach to key stakeholders (including interest groups) in biosafety issues relevant to decision making. In developing the PEO strategy, emphasis should be placed on non web-based information mechanisms to reach the non-technically literate and non-reading public, including mass media and town hall meetings.

99. **Component 5: Regional processes in support of the project and NBF sustainability in the Caribbean: (5.1) Building regional support mechanisms for biosafety; (5.2) Regional project management; (5.3) Regional project M&E.** This component is of a fully regional nature and considers those all-embracing activities needed to build regional support mechanisms for NBF implementation, those required for region-wide technical coordination of project activities (including its administration and financial management) and those required for overall monitoring and evaluation of project performance and impact. Operational expenditures directly related to the execution, management and monitoring of the project (which would not have been incurred in the absence of the project), consisting of equipment procurement and maintenance, utilities, office and scientific supplies and equipment, communications, bank charges, travel and per diem for project staff, and salaries of core project staff, will be covered through this component. A breakdown of Component 5 activities is provided in *Appendix 5*. The project management structure, institutional and implementation arrangements are further outlined in section 4 of this project document, and in *Appendices 10* and *11*.

100. This fifth component will determine the most appropriate means to maintain the Regional Node for biosafety information exchange, and deliver targeted training and access to appropriate technical and human resource capability. Coordination and communication flow between countries and to-and-from regional organizations will be at the heart of this regional component. Through adaptive management, and with the aim of seeking overall sustainability for the NBFs, this component may be revised by project mid-term, with a view to foster the establishment of a regional support mechanism for participating countries, potentially through CARICOM. An initial viability assessment will look into options such as centralizing biosafety applications, with a single entity serving as a "gatekeeper" (i.e. "one-stop-shop") and able to electronically track and ensure timely processing of applications and permits, ensure adequate public access to information on the processing of such applications, and facilitate public input into the risk assessment process. This assessment will also include an evaluation of self-

financing mechanisms and the implementation of a self-financing strategy in search of adequate resources to sustain project outcomes at the national and regional levels after project completion.

101. Having to cater for individual biosafety regimes and at the same time build consensus over which -if any- biosafety responsibilities can be devolved at the regional level and which biosafety services countries wish to access regionally has resulted in a project that requires differential implementation strategies for its national and regional components.

102. For project components with core national elements (components 1-4), each country will develop within the first 6 months of the project a roadmap for implementing its NBF over a 3-year period. For this, NBF Coordinators will be tasked with finalizing national capacity inventories and assessments, coordinating the definition of national targets, and generating costed workplans to achieve these targets. Individual implementation plans must be fully aligned with the overall Results Framework of the project. To substantiate this process, further consultations with national Ministries will lead to agreements on what will be delivered nationally and where to prioritize national investments. Thus, countries will finalize their national baselines and results frameworks and commit to individual NBF targets and performance indicators.

103. For this regional component (component 5), an agreement was reached with countries to destine no more than 10% of total GEF funding (and hence, of individual country allocations) to regional activities, with some countries amenable to raising this to 15%. Though at the time it was not decided what this "regional cap" would cover, the interpretation given concerns regional project management costs, which currently stand at 11% of all GEF funding. Activities that are necessary for the project to function as a regional intervention (hence, those not seen to directly benefit countries) sum 17% of the total GEF budget. Besides regional project management and M&E activities, the remainder of Component 5 consists of activities conducive to national biosafety regimes securing their place in the region's political and commercial agendas, and to ensuring that coordination across the region proves effective for successfully delivering the project, extracting lessons learnt, exchanging information and positions, and evaluating outcomes as they unfold.

104. This regional component thus includes: project management services to be provided by the Lead Executing Agency; coordination, oversight and validation activities at the regional level, including meetings of the Regional Steering Committee; monitoring and evaluation responsibilities; and a viability assessment and scoping exercise that will take place within the first 6-months of the project. The latter, which will be part of setting the project's regional baseline, will provide a full evaluation of the legal, financial and technical benefits to be had from a regional mechanism for biosafety, weighing up the various options that are available and determining which has majority support and could be sanctioned by both national and regional authorities. The long-term financial viability of any option will be a critical factor to consider, as well as biosafety operations in the context of the CSME.

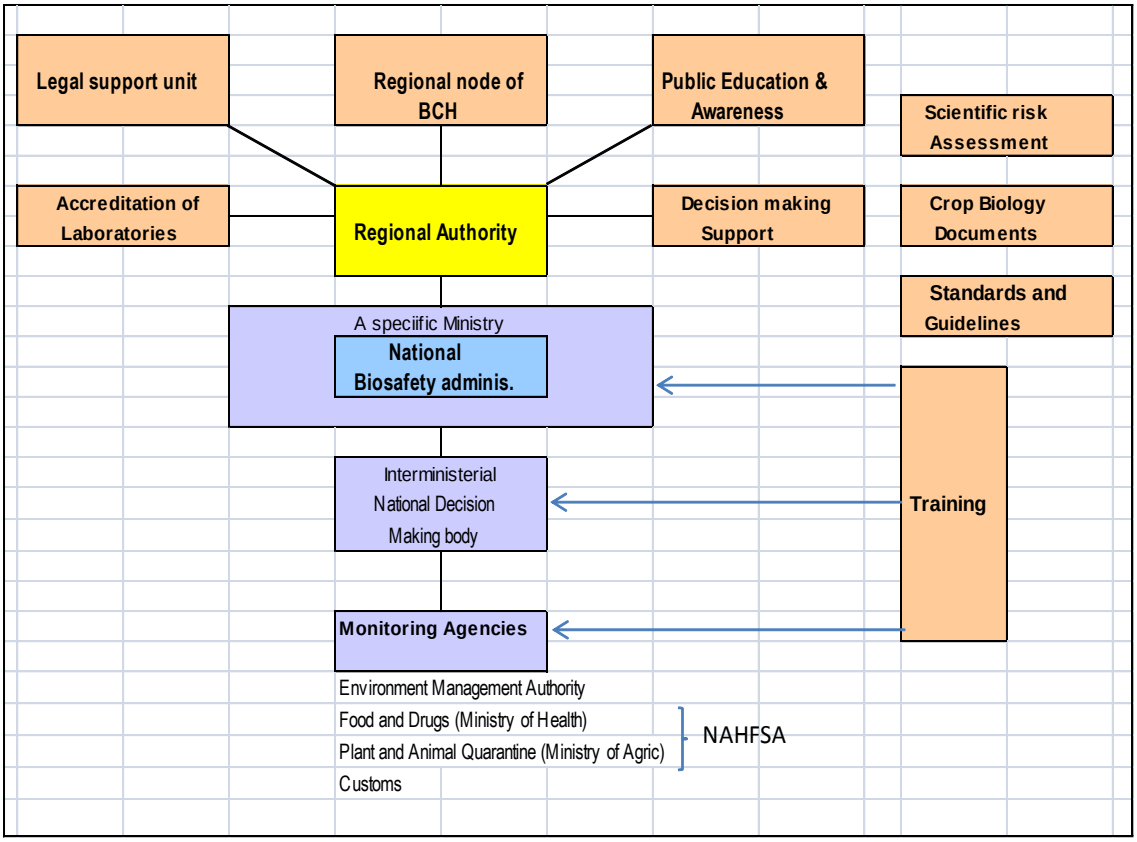
105. Some of the key questions to be answered by this exercise and as the project progresses surfaced during the project preparation phase, and are summarized here:

- How should a regional biosafety system be developed to ensure that the aspirations of the CSME are not stifled by disharmonious biosafety regimes that could affect trade.

What is the minimum level of harmonization required? What models of harmonization can be adapted?

- Can model legislation be developed that can be adapted into national laws and regulations? Can this translate into common standards, guidelines and administrative systems to streamline activities in each country and also ensure that approvals in one country reduce the administrative burden on other counties and do not serve as technical barriers to trade in other countries within CARICOM?
- How can the regulatory burden on Member States be reduced? Can harmonization be performed by a regional authority or central biosafety facility so that (1) the cost of biosafety implementation is minimized for the region and (2) the scientific, technical and other capacities dispersed within the region can be best utilized
- Could a central biosafety facility take on the tasks of (i) coordinating and facilitating access to training programmes, (ii) developing and implementing public education and awareness programmes, and/or (iii) managing biosafety information? If not the central facility, should these tasks be devolved to several institutions, and if so, which?
- Which institution can take on the responsibility of systematizing biosafety information and making it available to the region using the IT technology to ensure transparency and coordination in decision making? How can a business case for the Regional Node of the Biosafety Clearing House be built?
- Assuming it can be done, who would be the authority for developing or adapting to the Caribbean context research documents on the biology of crops and other species subject to genetic modification?

106. There are numerous answers to the above questions, making the search for a majority decision a challenge. Nevertheless, by putting together an initial model (in schematic form below), a discussion on the range of direct and supporting functions that would be expected from a regional biosafety authority can ensue.



107. The strategy to come to a decision on what aspects of biosafety to regionalize is as follows:

- The viability assessment will take place with the NBF Coordinators on board, who will ensure that national authorities are kept abreast of the options being discussed and of the scope of their implications. The Project Steering Committee will also be closely involved in the assessment process.
- A technical regional workshop will first be convened in order to approve the viability assessment's Terms of Reference. The assessment's results will be widely shared among participating countries, after which will follow a high-level regional workshop with national authorities and political representatives to consider the outcomes and determine the most convenient option for the region.
- At project mid-term (ie. end of project year 2), countries will come to a decision on the scope and features of all regional biosafety mechanisms. If at that point, the consensus is that greater attention and funding should be channeled to regional efforts to lay the foundations for these regional mechanisms to start functioning, then the project's workplan, budget and targets for the regional component will be re-set accordingly.
- The CARICOM Secretariat will be consulted to achieve effective involvement of regional governance bodies such as the COTED (which normally meets every two years) in order that any decisions that affect CARICOM structures or mechanisms are duly presented and opportunely adopted.

3.4 Intervention logic and key assumptions

108. The absence of the proposed activities for the implementation and operation of NBFs will undermine national and regional efforts to protect fragile biodiversity in the Caribbean region. In the overall operation of NBFs, coordination and integration of national institutions with biosafety functions and the current levels of relevant human resource capacity present special challenges for each country. In each Caribbean country, statutory responsibilities for controlling and issuing import permits for several categories of goods including food, biopesticides, biological control agents, microbial soil inoculants, seeds and live plants and animals, are scattered amongst several government agencies. These goods will increasingly include biotechnology products and, for this reason, the permit-issuing agencies under whose remit they fall will be expected to play a role in biosafety regulation. Collective coordination of the potential biosafety functions of these institutions generally do not now exist. Each agency also generally lacks the administrative and technical skills base for executing its areas of responsibilities of the proposed biosafety regime. Without coordination and adequate human resource capacity, these institutions will create a fragmented, inefficient biosafety regime and will be ill-prepared to contribute to effective biosafety regulation. This situation will be compounded by the change in trade dynamics to be soon brought about by the CSME.

109. As was mentioned before, CARICOM has begun the creation of a single market and economy in which all goods and services will be traded freely in a single economic space. In this free-trade environment, safeguarding the common environment will require a significant degree of cooperative coordination of national biosafety systems

across the countries of the sub-region. Cooperation on biosafety will also be required to minimize the possibility of biotechnology products cleared for entry into one member state ending up in another, particularly if they are unsuitable for the unintended receiving environment.

110. If the problems mentioned above are not rectified, the participating Caribbean countries and the remainder of the Caribbean sub-region are likely to end up with ineffective frameworks and as a result, potential risks to biodiversity, agriculture and sustainable livelihoods in the face of biotechnology may not be lowered significantly, if at all. Given the acknowledged fragility of island ecosystems and their unique global contribution to biodiversity and the presence of biodiversity hot spots in the Caribbean region, the biosafety frameworks are notably relevant. Measures are therefore required to close the potential gaps mentioned above and these can be cost-effectively addressed by means of a regional biosafety implementation project.

111. A concern for the region beyond those of environmental or social character relate to the costs of sustaining NBF once they have become fully functional. The current regional project is therefore based on the notion that it is not convenient to "weave biosafety operations into the institutional fabric" in isolation, but rather in a manner integrated with wider biosecurity issues for which transboundary controls, prior evaluations, tracking systems and technical experts are also needed. Mainstreaming biosafety in this way, through linkages with other areas such as zoo- and phyto-sanitary requirements, certification programmes, and IAS control, especially if dealing with traded products, should serve to maximise effectiveness and coordination, while minimising the costs of sustaining biosafety systems.

112. Within the Caribbean region there is some degree of reliance on the private and research sectors wanting to introduce LMOs as another key factor in sustaining implementation of an effective biosafety system. The planned intervention's logic pivots on: (a) taking advantage of a capacity building continuum (that commenced with earlier UNEP/GEF projects support) and emerging political momentum within CARICOM; (b) designing a project that is responsive to country needs and regional realities; and (c) most importantly, setting up biosafety structures and mechanisms that can sustain themselves over time. A key assumption is that bridging the capacity gap will provide an incentive and a conducive environment for both CP implementation and safe uptake of modern biotechnology and its products with associated economic benefits, which in turn will further justify CP implementation.

113. There are also two main assumptions with respect to the project's regional outcomes and the strategy indicated in the section above vis-a-vis the regional component: (i) one is that, should consensus not be possible, the fallback option of having regionally accessible biosafety services to support individually functioning NBFs, can be equally effective (if not as efficient) in raising biosafety standards across the region as the ultimate aim of this project; (ii) the other is that for any regional biosafety mechanism to be long-lasting, and given sufficient political support, co-financing and sustained funding sources need to be (and can be) found beyond the "seed funds" that this project can provide.

3.5 Risk analysis and risk management measures

114. Many Caribbean sub-region countries intend to utilize modern biotechnology to enhance their economies and have sought to use their NBFs to create a conducive environment for modern biotechnology to flourish safely while ensuring adequate protection of vulnerable biodiversity. The potential of biotechnology together with appropriate risk management measures to address evolving challenges, including certain climate change factors (such as productive systems being affected by strong variance in the range and intensity of temperature and precipitation patterns), is highly relevant in the Caribbean sub-region. The key risk factors faced by the project in regards of successfully implementing NBFs and the CPB are summarized here, together with other risks that may affect the effective implementation of the project:

RISK THAT MAY ARISE	* RISK RATING	RISK MANAGEMENT MEASURES
Governments' commitment to addressing potential risks associated with modern biotechnology is reduced due to changes in the political environment and crisis presented by global economic downturn	H	▶ A multi-media public awareness campaign will be implemented at the national level in each participating country, including a focus on the potential economic and trade benefits of biosafety systems, to build a more receptive political audience with broad-based public support. ▶ CARICOM will continue to raise political awareness and mobilize political support through the development and implementation of the *CARICOM Policy on Biosafety and Biotechnology* which affirms environmental and economic benefits through biosafety application. Also the recent re-endorsement of the project by COTED is a clear sign of support.
CARICOM member states ineligible for the current project remain at the margins of biosafety capacity building efforts and compromise the extent to which biosafety standards can be upheld in the sub-region	M	▶ Jamaica has confirmed its intention to join this regional effort by presenting an "add-on" project as soon as it has laid its instrument of ratification with the CBD Secretariat, while Haiti, still in a slow process of recovery, has indicated its interest in acceding to the CPB. In as far as possible -subject to consensus and co-financing support- all efforts will be made in this project to be inclusive of the full CARICOM membership.
The lack of skills among staff within key national agencies to support biosafety management, coupled with existing weak institutional coordination and lack of human resources and infrastructure.	H	▶ A key element of the project is the establishment of a clearing house node and the necessary legal and inter-institutional coordination mechanisms for biosafety risk management that will function with or without regional support mechanisms to re-enforce and enhance national institutional

		frameworks. ▶ An extensive training program will be undertaken to strengthen biosafety risk management skills amongst existing staff in key national agencies.
Lost opportunities to cross-fertilize and coordinate between regional and national initiatives and seek common biosafety management approaches undermine: (a) national attempts to uphold effective biosafety levels; and (b) regional harmonization in support of CSME.	H	▶ The regional component of the project will scrutinize and resolve the adoption of harmonized biosafety risk management standards, protocols, tools and manuals for dissemination and use at the national level, and will ensure coordination and a majority decision on regional biosafety services and support mechanisms. ▶ The training component of the project will support an extensive training program on biosafety (risk assessment/management), including standards, protocols, tools and manuals, which will instill a more uniform approach to biosafety management across the region. ▶ National component activities will support a review of proposed legal and institutional NBFs to ensure, where possible, that opportunities for regional harmonization remain viable in the context of the CSME.
Absence of competent laboratory and trained staff (at national or regional level) to undertake biosafety testing and research or provide such services undermines effective implementation of the Cartagena Protocol	H	▶ The project offers opportunities for: (a) evaluation of national and regional biosafety laboratory capacity and needs, (b) procurement of minimum level of equipment for select detection laboratories which will serve the needs of host and adjoining project countries, (c) the establishment of validated analytical protocols, which can later be harmonized, and (d) the training of laboratory staff in LMO analysis. ▶ The project will strengthen the capacity of a critical mass of biosafety management staff within a coordinated network of national and regional laboratories.
Sustaining the effective implementation of the Cartagena Protocol after project completion will be a key challenge due to limited resources (human, technical, financial)	H	▶ The regional component of the project will support an evaluation of self-financing mechanisms and the implementation of a self-financing strategy to ensure that adequate resources are available to sustain project outcomes after project completion. ▶ Giving due political consideration to the establishment of self-sustaining regional support mechanisms for biosafety will

		increase the likelihood and ability of CARICOM Member States to maintain the biosafety regimes that are put in place by this project.
Enforcement of biosafety risk management protocols may be difficult due to a lack of awareness of potential risks from modern biotechnology at both the institutional and public level.	M	▶ Biosafety clearing houses will be established at the national and a coordinating node at regional level which will disseminate to the public information on LMOs (and possibly IAS) that may be introduced in the Caribbean, or that have been approved for use, and any products from modern biotechnology that may be undergoing a risk assessment prior to release.
Changes in CSME trade regime lead to actions that affect the status of biodiversity in the Caribbean region	M	▶ Through information exchange, public education, and training undertaken under the project it is unlikely that CARICOM countries will support trade rules that encourage or support the unrestrained trade in LMOs or IAS that may be harmful to national and regional biodiversity.
Absence of information on the risks to the Caribbean region's biodiversity and human health from LMOs (and possibly IAS) undermines public and political level support for effective NBF implementation	L	▶ Regional and national information exchange mechanisms (biosafety clearing houses) will be fully established under the project to develop a baseline of information on LMOs (and links to other biosecurity information sources) that present a possible risk to Caribbean biodiversity and human health.
The partitioning of GEF funds between country-level activities and the regional component of the project is not optimum for achieving project objectives and slows down NBF operationalization.	M	▶ Striking the right balance for countries to have sufficient resources to operationalize their NBFs may require additional fund raising efforts while the project is in execution. This task will require lobbying and active search for further donor support intended for national capacity development in areas relevant to biotechnology, biosafety and environment.

* Risk Rating: H = High, M = Medium, L = Low

3.6 Consistency with national priorities or plans

115. From a regional perspective, this project is very much in line with the regional drivers that favour modernization, stronger R&D, free commerce and environmental standards, as evidenced by the recent support given to the project by the COTED (September 2010). From a national perspective, this project is aligned with national agendas that aim to steer countries towards more sustainable development paths. In view of their fragile nature, the protection of national biodiversity through the implementation of appropriate

risk management measures forms a key pillar of the sustainable development policies and programs of the participating countries.

116. Antigua and Barbuda, like many other Caribbean Countries has an historic agricultural economy dependent on sugar and rum. These activities left a legacy of deforestation leading to erosion, watershed damage and species extinction. Under colonial rule, the island was virtually cleared of forests by the 1760's. Over the past three decades the economy has changed from a dependency on agriculture to that of a service-based economy, mainly tourism, which, although less environmentally damaging, has its own challenges and issues. Inventories of the vegetation of Antigua and Barbuda suggest that a large percentage of plant species is classified as rare and endangered. Many terrestrial animals have become rare, endangered or extinct due to the loss and/or fragmentation of natural habitats such as mangroves, sea-grass beds and coral reefs. Some water-birds and several species of reptiles have become extinct; sea-turtles that are endangered world-wide are declining in numbers; while over-fishing has resulted in a decline in the variety and number of reef species of fish. In addition, exotic species such as the mongoose have been introduced. The *Biodiversity Strategy & Action Plan for Antigua & Barbuda* (2001) highlights the need to identify current and future risks possibly associated with biotechnology and "develop the legal and institutional framework necessary to ensure the safety of biotechnology as well as to ensure that maximum benefits accrue to Antigua and Barbuda from the exploitation of its biological resources". An additional key objective highlighted in the Strategy and Action Plan is the adoption of a regional approach to establishing appropriate policies and legislation to ensure bio-safety and fair distribution of the benefits from modern biotechnology. The review of the status of biotechnology and LMOs in Antigua and Barbuda during the process of preparation of the country's National Biosafety Framework showed that generally, the twin island state was free of LMOs. However, concerns were expressed about the possibility of individuals importing genetically modified seeds as well as developments in certain ornamental plants such as genetically modified carnations, poinsettia, and chrysanthemums. Concerns were also expressed over a number of genetically modified animals, particularly pet fish which may be eventually imported into the country and which could inadvertently end up in the aquatic or marine environment. Much of the agricultural products that an open economy such as Antigua and Barbuda's import, is driven by multinational corporations which are increasingly resorting to modern biotechnology. While Antigua and Barbuda cannot and should not isolate itself from genetically modified products forever, it was generally agreed that care should be taken with adaptation of modern biotechnology while supporting requirements for labeling, traceability and compliance. There was a general consensus that the country should only selectively - that is, on a case by case basis and only after careful risk assessment - accept LMO products. The *Antigua and Barbuda Environmental Management Strategy and Action Plan 2004*-2009 includes as one of the Government's key strategies, the development, implementation and promotion of programs to ensure wise management of the environment and natural resources to provide maximum protection and economic benefits. This Strategy and Action also outlines as a key priority, the development of effective legal and institutional frameworks to implement obligations under various multi-lateral environmental agreements, including the Cartagena Protocol. The NBF for Antigua and Barbuda can be found at:
http://www.unep.org/biosafety/files/AGNBFrep.pdf

117. In The Bahamas, the NBF adopts a comprehensive and holistic approach that utilizes administrative and regulatory systems to address a myriad of environmental problems including potential risks from modern biotechnology and invasive alien species. The NBF builds upon and complements frameworks and enforcement mechanism established under its *National Biodiversity Strategy and Action Plan* (NBSAP), the *National Invasive Species Strategy*, and other biodiversity-related projects and programs. The NBF is closely linked with the *National Environmental Management and Action Plan* (2005) of The Bahamas and with existing biosecurity detection and enforcement systems operated by the Departments of Agriculture, Fisheries and Customs. The NBF for The Bahamas can be found at:

http://www.unep.org/biosafety/files/BSNBFrep.pdf

118. Barbados is a small island developing state that relies heavily on tourism and agricultural imports, it is concerned about the potential risk s to human health and the environment resulting from modern biotechnology. Barbados became a party to the Convention on Biodiversity in 1993 and signed on to the Cartagena Protocol in 2002. The practice of biotechnology has been taking place for many years in Barbados particularly with respect to sugar cane and breeding and selected agricultural crops. The government recognizes its heavy dependence on food and agricultural imports and the fact that its fragile ecosystems are vulnerable to natural disasters and invasive biological agents. Barbados' long-term biosafety policy vision is *''A society that safeguards human, plant and animal health and the environment, while optimizing the benefits of modern biotechnology'*. The main goal is to ensure the safe and sustainable utilization of biotechnology and its application in the development of science, agriculture and other disciplines and to improve the quality of life of Barbadians. Establishment of the NBF to implement the provisions of the Cartagena Protocol is a necessary component to the pursuit of these long-term aspirations. In addition, the Government of Barbados has recently adopted the National Strategic Plan of Barbados 2006-2025 which provides a blueprint for the realization of the country's vision of becoming a fully developed society. Although not making specific reference to biosafety and biotechnology, the Plan identifies the need to safeguard food and nutrition security given that the long term viability of the country rests upon the safety and health of the population. It further proposes among a range of strategies, the enhancement of the agricultural health and food safety programme through the rationalization, upgrade and international accreditation of government laboratories and related facilities in veterinary services, plant health, international food safety standards, pest and disease detection and control, and pesticide use. The NBF for Barbados can be found at:
http://www.unep.org/biosafety/files/BBNBFrep.pdf

119. In Belize, approximately 40% of its territory is in some form of protected area because of its fragile nature or the national needs to protect its flora and fauna. Examples include the preservation of mangroves in coastal and low lying area which serves as a natural barrier to protect the coastline from erosion. Mangroves also serve as a natural habitat for spawning and growth of fingerlings for many native fish species. Additionally, large tracts of interior forests are protected to serve as critical watershed and home to many native species of plants and animals. Belize boasts the largest barrier reef in the western hemisphere which is home to many species of coral, fin fish, lobster, conch, large marine mammals (dolphins, sea turtles, manatee) and many other marine species. The protection and preservation of this very importance resource is critical considering its importance in protecting the country's coastline, providing a means of food and income

for local fishermen and a means of recreation for Belizeans and tourists. Agriculture is a significant foreign exchange earner and provider of jobs and food for Belizeans. Hence, the protection of arable lands through effective land use planning and agricultural management practices is important in maintaining this industry. Indigenous groups such as the Maya and Garinagus have traditional lifestyles and cultures that rely heavily on the land and sea resources of Belize. The preservation of cultural lands also directly impacts the preservation of these cultures. Belize's tourism sector has experienced significant growth over the last 10 years. Noteworthy has been the marketing of Belize as an agro-eco-tourism destination which warrants the protection and preservation of these pristine resources. The unregulated introduction of LMO presents a serious threat, and the government has identified the effective implementation of its NBF as a significant component of the measures that have already been established to protect Belize's fragile biodiversity. The NBF for Belize can be found at: http://www.unep.org/biosafety/Documents/Belize%20-%20National%20Biosafety%20policy.pdf

120. Dominica is a small island state with one of the lowest population density rates in the Caribbean. It has the most intact forest cover in the Caribbean, with over 20% of Dominica's terrestrial area legally designated as a 'Protected Area'. It is geologically also the most active of the Caribbean islands with 6 active volcanoes. It has the only 'boiling lake' in the Western Hemisphere as well as one of the few terrestrial natural World Heritage Sites designated by UNESCO in the Caribbean. Dominica possesses tremendous terrestrial and marine biodiversity including some of the most vulnerable being, parrots, turtles, conch, lobster, reef fish and the white sea-urchin. Many of these species are threatened due to the impact of human activity and to natural causes to a lesser extent. The agricultural sector plays a major role in economic and rural development in the country. Dominica's economy continues to be led by outputs from the agricultural sector, contributing on average 18% of GDP. Within the agricultural sector, crop production is of greatest economic importance as it is the primary foreign exchange earner in the sector, accounting for 78.5% of all agricultural production. Dominica's economic conditions are on a downturn with the loss of the banana market. This has put even greater pressure on what is basically a subsistence agrarian society. Although a number of agricultural organizations in Dominica are involved in biotechnology research, development and commercial application in efforts to improve productivity within the agriculture sector, the country retains much of the older Caribbean agricultural practices and cultural botanic medicinal use. It is by any standard rich in agro- and plant bio-diversity and in cultural retention. However, it is also under assault on macro-economic and macro-cultural fronts - both of which threaten the retention and conservation and of its bio-diversity. There is a continuing commitment to retention of the natural state of Dominica, in part through the promotion of the island as 'The Nature Island of the Caribbean'. The country's tourism-master plan has highlighted the point that eco-tourism is viewed within Dominica as the basis of future economic development. To this end, a major Natural Indicative Program worth some 10 million Euros over 3 years has been agreed with the European Union to advance this concept. With the high retention of in-situ bio-diversity in Dominica and its clear importance to economic development, the development and implementation of a biosafety program - a key element of *Dominica's Biodiversity Strategy and Action Plan* - is an urgent national imperative. The NBF for Dominica can be found at: http://www.unep.org/biosafety/files/DMNBFrep.pdf

121. In Grenada, the Government's vision for the future is one in which the science of biotechnology and biosafety will contribute to the positive development of agriculture, health, and the environment in a manner which is both productive and safe, accruing to the well-being of its citizenry, its economy and the nation. The Government of Grenada, aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health and recognizing also that modern biotechnology has great potential for human well being if developed and used with adequate safety measures for the environment and human health, signed and ratified the Cartagena Protocol on Biosafety. Government believes that it is utmost importance that the provisions of the Protocol be fully implemented. Grenada's policy on biosafety would ensure that there is a strong technical infrastructure to carry out the necessary assessments and also that the necessary main infrastructure requirements are addressed. In this regard a component of the FAO project includes training and a plan for a new laboratory has been developed. The Sustainable Development Committee is also implementing a project by the UNEP/GEF, which focuses on national biosafety management. With regard to public involvement, the Government of Grenada also intends to safeguard the right to democratic participation of civil society and would therefore ensure that the mechanisms for the supply and exchange of information are so structure that it would be transparent and allows for the active participation of non-state actors. The NBF for Grenada can be found at: http://www.unep.org/biosafety/files/GDNBFrep.pdf

122. Guyana's, extensive but fragile forest ecosystems support a rich biodiversity and it is of prime importance to protect this natural wealth by implementing sound measures for biosafety and biosecurity. At the forefront of the advocacy for compensation for standing forests, it is of considerable national interest to implement biosafety measures to safeguard this resource and its potential for generating considerable revenue in return for sequestering carbon. As a largely agrarian economy Guyana must ensure the agricultural productivity required to sustain its economy and the livelihoods of its people; thus biosafety becomes critical. The growing biotechnology use in the national agriculture and food industry makes it necessary for the potential of this technology to be explored in a safe and secure manner. Additionally, as an open economy, Guyana is exposed to potential risks associated with biotechnology and needs to safeguard its citizens and food sources from likely negative impacts by having the relevant tools, human and institutional capacity to manage risks. The NBF for Guyana can be found at: http://www.unep.org/biosafety/files/GYNBFrep.pdf

123. Saint Lucia has a wide variety of flora and fauna, and is a leading proponent amongst small island developing States of an integrated approach to sustainable development which promotes the protection of the country's rich diversity of flora, fauna and associated ecosystems in order to achieve social and economic development as well as maintain cultural patrimony. The Government with the support of regional and national entities has undertaken several initiatives aimed at pursuing sustainable development through the management of the country's natural resources for economic, social and cultural development. Despite the absence of documented information on whether genetically modified organisms or their products are entering the country, evidence exists that genetically engineered substances may be entering the country as food, plants, animals, pharmaceuticals, veterinary medicines, micro-organisms or bio pesticides for processing or for planting. Further, recent and emerging developments related to modern biotechnology have highlighted the need for the nation to implement

effective biosafety management strategies, in order to benefit from the products of modern biotechnology, while safeguarding the country's biological resources and the health of its residents and the environment. Currently there are several national policies and legislation which relate to biodiversity management which have a bearing on the various issues associated with genetically modified organisms or their products. Biodiversity management currently underscores five of the seven objectives of the National Environmental Policy and National Environmental Management Strategy (NEP/NEMS) and it is mentioned in areas such as the draft National Policy and Strategic Plan for the Agriculture Sector and the draft policy on Science and Technology for Development. It is also one of the principles (#13) of the St. George's Declaration of Principles for Environmental Sustainability in the OECS. The country is also signatory to several MEAs which provide useful guidance with respect to some key issues in the national biosafety framework including provisions for notifications, treatment of confidential information, public participation and awareness, comparable data acceptability and data validation issues, and enforcement and compliance. The implementation of a Biosafety Policy and the Strategy and Action Plan will integrate the various national policies and initiatives related to food safety, health, environment, biological diversity, science and technology and consumer rights and protection. The NBF for Saint Lucia can be found at:
http://www.unep.org/biosafety/files/LCNBFrep.pdf

124. In St. Kitts and Nevis, the NBF policy provides the framework to protect the natural resources of the Federation of St. Kitts and Nevis and the health of the people living in the country from the adverse effects that may arise from the development and application of LMOs and its derived products including pharmaceuticals. As a small island developing state, St. Kitts and Nevis is particularly vulnerable to the potential adverse affects of LMOs. It has the potential for the development of niche markets for organic and fair-trade products and is aware that these markets will expressly forbid the use of or risk of contamination from LMOs or their derivatives. At the same time, the potential development gains from the use of modern biotechnology are recognized. However, it is important to strike a careful balance to ensure that the country's biodiversity, environment, health, and culture are not damaged in the process. St. Kitts and Nevis officially joined the UNEP-GEF Project for the Development of National Biosafety Frameworks (NBF) on July 15, 2005 to confirm its commitments under the Cartagena Protocol on Biosafety (CPB). In furtherance of its obligations, a National Biosafety Policy (NBP) to ensure an appropriate level of protection in the use of modern biotechnology has been developed. This policy is based on national priorities within the framework of sustainable development and in accordance with the "precautionary principle" for the benefit of present and future generations and the protection of all its citizens. Its goal: "*To ensure an appropriate level of protection of human, animal and plant health and life in the development and application of modern biotechnology, while ensuring the well-being of the Federation of St. Kitts and Nevis."* The NBF for St. Kitts and Nevis can be found at: http://www.unep.org/biosafety/files/KNNBFrep.pdf

125. Although limited by its small size, the biodiversity of St. Vincent and the Grenadines is still significant. It has 84 km. of coastline, with diverse ecosystems including bays, beaches, rocky shores, cays and coral reefs. The country also has significant stands of tropical rain forest, 13% of which is primary forest, that are critical wildlife habitat areas. There are 15 species of mammals, 111 species of birds, including the endemic St. Vincent Parrot (*Amazona guildingi),* 16 species of reptiles, and 4 species of amphibians.

This biodiversity is however under threat from deforestation, species introductions, emigrants, exotic pests/diseases, limited knowledge, agrochemical use, hunting, inadequate enforcement, and urban development. In the marine environment, threats include pollution, unsustainable fishing practices and the destruction of marine habitats such as mangroves and coral reefs. The Government of St. Vincent and the Grenadines is cognizant of the fact that environmental conservation and human health are inextricably linked. Therefore, the country's involvement in programmes that support both is critically important. To support this policy, the country became a signatory to the Biodiversity Convention in 1996 and to the Biosafety Protocol in 2002. The Government recognizes that biotechnology must be explored in a safe and secure manner. As such, it is imperative that safeguards and risk management processes be established to protect the environment, health of the general public and food sources from adverse impacts. The NBF for St. Vincent and the Grenadines can be found at: http://www.unep.org/biosafety/files/VCNBFrep.pdf

126. The Government of Suriname is committed to ensure the protection of the environment and specifically the pristine and rich biodiversity that comprises 80%-90% of the country's area. Over 80% of the land surface (165,940 squared km) of Suriname is covered by tropical rainforests, while the very small human population (approximately 400,000) is concentrated in and around the capital, Paramaribo, and along the coast. The biological diversity is high: 185 mammal species, 668 bird species, 152 retile species, 95 amphibian species, 452 fish species, 6,135 plant species, (of which 5,075 Spermatophyte species) and 1,750 invertebrate species, while large areas of the interior (the Guyana Shield) still remain unknown for their flora, fauna, ecosystems and ecological values. Suriname has about 14% of its land managed into protected areas, one of which is declared a World Heritage Site by UNESCO. Indigenous and rural communities use many of these resources for self-sufficient food production. In Suriname, the field of biotechnology is still at an early stage of development. There is no mechanism established to ensure protection from (potential) adverse impacts from products of biotechnology. The concentration of the biodiversity in a large and inaccessible area of the interior, the inadequate control on transboundary movements and the poor quarantine measures taken at borders corroborate to the need for safety measures. The Government of Suriname recognizes that the use of modern biotechnology can significantly contribute to improving agricultural- and industrial production. However, the use of modern biotechnology, if not properly managed, can also pose a potential risk to the environment and the conservation of biological diversity. When the Government of Suriname ratified the United Nations Convention on Biological Diversity in 1996, it recognized the need for care when using biotechnology in the conservation of biodiversity and the sustainable use of its components. The Government Declaration (Regeringsverklaring 2005-2010) mandates an efficient and effective approach to environmental management. The overall goal of the national environmental policy is defined as protection, conservation, improvement and rehabilitation of the quality of the environment and the establishment of sustainable development practices through:

- The development of a national environmental policy;
- The integration of the national environmental policy into the sectoral development policy;
- Formulation of laws and regulations and the incorporation of relevant aspects of ratified international environmental conventions and agreements including the Cartagena Protocol;
- Promotion of environmental awareness;

- Promotion of sustainable production; and
- Establishment of a policy for physical planning.

A key pillar of Suriname's ***National Biodiversity Strategy*** (March 2006) is to continue to develop a national biosafety policy and procedures and establish linkages with regional and international biotechnology committees to initiate a regional approach to the safe transfer, handling and use of living modified organisms resulting from modern biotechnology. The NBF for Suriname can be found at:

http://www.unep.org/biosafety/files/SRNBFrep.pdf

127. Trinidad and Tobago has identified biotechnology as an important technology option to address issues such as food security, development of the agricultural sector and environmental protection. The Government of Trinidad and Tobago remains committed to the effective implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. A draft National Biosafety Policy for Trinidad and Tobago was formulated in 2006 by the National Committee for the Development of a National Policy and Regulations on Biosafety, the objective of which was to guide:
    - development of an administrative, regulatory and legislative framework to govern the development and use of products of modern biotechnology;
    - establishment and maintenance of appropriate mechanisms to assess and manage risk;
    - development of an appropriate system for the labeling of products of modern biotechnology;
    - promotion and facilitation of public awareness and public education; and
    - development of a national biosafety capacity-building plan to effectively implement the Policy.

    Trinidad & Tobago has experienced delays in officially adopting its draft NBF, but the Government continues to be supportive of the draft National Biosafety Policy and its objectives and fully supports the Regional Project for Implementing NBFs in the Caribbean. Trinidad and Tobago is of the view that the realization of the objectives of these projects will provide the basis for ensuring that an adequate level of protection is afforded to the environment and human and animal health through the use and development of the products of modern biotechnology whilst at the same time ensuring that the country and the region derive the benefits to be gained from such technology.

3.7 Incremental cost reasoning

128. Caribbean livelihoods depend largely on trade, transport, tourism and agrarian economies which all provide pathways for LMO introduction at regional and national levels. Although there is a paucity of information available on the scope and range of LMOs in trade throughout the Caribbean, the region's continued reliance on the free-flow of food and agriculture sector imports/exports continues to present potential risks to vulnerable national and regional biodiversity and human health. This difficult baseline scenario is further complicated by the complexity and vulnerability of the insular Caribbean. The participating Caribbean countries are individually characterized by overall low biosafety capacity exacerbated by inadequate financial and human resources for implementing and operating effective and transparent NBFs which address national and regional needs and priorities, and are compliant with the CPB.

129. In the overall operation of national biosafety frameworks, coordination and integration of national institutions with biosafety functions and the current levels of relevant human resource capacity will present special challenges for each country. In each Caribbean participating country, statutory responsibilities for controlling and issuing import permits for several categories of goods including food, biopesticides, biological control agents, microbial soil inoculants, seeds and live plants and animals, are scattered amongst several government agencies. These goods will increasingly include products of modern biotechnology and, for this reason, the permit-issuing agencies under whose remit they fall will be expected to play a role in biosafety regulation. Collective coordination of the potential biosafety functions of these institutions generally do not now exist. Each agency also generally lacks the administrative and technical skills base for executing its areas of responsibilities of the proposed biosafety regime. Without coordination and adequate human resource capacity, these institutions will create a fragmented, inefficient biosafety regime and will be ill-prepared to contribute to effective biosafety regulation.

130. A key challenge for most countries has however been surpassed: the presentation to and in many cases approval by Congress /Cabinet /House of Assembly of legal frameworks that are specific to biosafety and the CPB. This was principally a result of the NBF Development projects, as was CPB ratification in some cases. Yet importantly, few countries have had the experience of approving LMOs and "testing" their biosafety frameworks. The various inputs required for biosafety management remain scattered; for instance: a few well-equipped laboratories exist but have not agreed on how to offer LMO testing services; separate institutions may have the mandates but do not coordinate in their acts or decisions; advisory structures are lacking even though national and even regional advisors may be available; and there is no scarcity of biosafety information but its compilation and screening for regional relevance is not happening. The creation of BCH systems, for which initial capacity building efforts through the BCH global project proved either insufficient or premature, is showing the same state of dispersal. Importantly, this project facilitated the training of a small cadre of trainers, known as BCH Regional Advisors, as biosafety resource persons that to this day remain available to the region.

131. At the regional level, CARICOM has begun the creation of a single market and economy in which all goods and services will be traded freely in a single economic space. In this free-trade environment, movement of biotechnology products will require a significant degree of cooperative coordination of national biosafety frameworks across the countries of the sub-region. Cooperation on biosafety will also be required to minimize the possibility of biotechnology products cleared for entry into one member state ending up in another, particularly if they are unsuitable for the unintended receiving environment.

132. If effective biosafety frameworks are not established at the national level and cost-effectively supported at the regional level, the participating countries in the Caribbean are likely to continue experiencing possible risks to biodiversity, agriculture and sustainable livelihoods in the face of an ever expanding global use of modern biotechnology. Given the acknowledged fragility of island ecosystems and their unique global contribution to biodiversity and the presence of biodiversity hot spots in the region, the establishment of effective biosafety frameworks and the narrowing of capacity gaps are notably relevant.

133. In the absence of GEF support, the participating Caribbean countries will be unable to make significant progress in the establishment of the enabling environment to adequately protect national biodiversity and human health from the eventual risks posed by modern biotechnology. More particularly, inadequate legal, administrative and institutional infrastructures as well as lack of coordination will persist without GEF support, making it impossible for effective implementation of the Cartagena Protocol at the national and regional level. The region's aspirations under the CSME to foster and promote the free and unencumbered flow of regional and international trade is likely to result in increased threat from LMOs and IAS unless effective frameworks for assessing and managing risks to biodiversity and human health associated with such organisms are developed, implemented and maintained over time.

134. In the absence of a uniform and strengthened enabling environment to protect the region's biodiversity from the possible risks associated with modern biotechnology, it is highly likely that illicit introduction and planting of GM-crops will continue and expand, thereby increasing the danger of dispersal of transgenes into wild and domestic plant varieties. This scenario will result in irreversible damage to biodiversity conservation efforts in the Caribbean region, with consequent loss to global environmental services and benefits and global biodiversity.

135. GEF support is urgently needed to enhance awareness among policy makers and the public as to the potential risks -and costs- to national sustainable development agendas presented by LMOs, so that political support to incorporate biosafety into national development plans can be realized. In this manner, the GEF contribution will support project activities that will influence and attempt to change human behavior that will result in benefit to global biodiversity.

136. Through the achievement of project outcomes and their catalytic impacts, GEF support will bring about the following changes in the enabling environment for the protection of biodiversity in the participating Caribbean countries:

- Developing and reforming biosafety policies and regulations and improving the biosafety governance regime thereby contributing to national sustainable development agendas and the protection of national and regional biodiversity;
- Addressing biosafety issues in the policies of other sectors that may affect biodiversity through the use of modern biotechnology;
- Achieving regional cooperation in protecting and managing the possible risks to key biodiversity resources that may be affected by modern biotechnology;
- Developing and implementing fiscal (and other) incentives to promote biosafety risk management in support of biodiversity conservation;
- Leveraging additional resources from national, regional and other international sources in support of the effective implementation of the Cartagena Protocol;
- Raising public awareness of the importance of biological diversity and its conservation and the potential risks associated with modern biotechnology, through education and dissemination in the media;
- Building individual, institutional, and systemic capacity to manage the possible risks of modern biotechnology for biodiversity and human health.

GEF support through this regional project will also have the following indirect impacts:

- *Political influence:* Contributing to an enhanced political profile for biosafety and the Cartagena Protocol, its links to trade and R&D, and the advantage of managing risks to biodiversity from modern biotechnology;
- *Higher profile* of biosafety concerns and risks to biodiversity and human health;
- *Enhancement of information and access to information:* Supporting biosafety regulatory regimes to facilitate broad public access to information on LMO risk assessments and through the establishment of clearing house mechanisms at the national and regional levels;
- *Replication*: Promoting the adoption of validated standards and protocols for biosafety risk assessment in other locations and for potential regional harmonization;
- *Synergy*: Fostering positive synergies between biosafety and the management of IAS and other living organisms subject to biosecurity measures as well as know-how gained by other biosafety projects for NBF implementation.

137. An incremental cost matrix is attached as *Appendix 3* of this document; this matrix estimates incremental costs as a function of progress expected from a baseline course of action, an alternative scenario linked to the current project's investments and outputs, and the incremental gains for the global environment. The consolidated Results Framework for the project (including relevant indicators, risks and assumptions), which describes both the GEF increment in achieving global environmental benefit and the underlying interventions related to the "business-as-usual" is attached as *Appendix 4.*

3.8 Sustainability

138. The sustainability of the proposed project is to be determined by *the extent to which benefits continue, within or outside the project domain, from a particular project or programme, after GEF assistance/external assistance has come to an end*[3]. The key indicators against which the sustainability of such benefits are to be measured are: (a) sustained improvements in the enabling environment to adequately protect national biodiversity and human health from the eventual risks posed by modern biotechnology in the participating Caribbean countries; and (b) sustained effective implementation of the Cartagena Protocol with concurrent reduced risks to global environmental services/benefits and global biodiversity.

139. Achieving (a) sustained improvements in the enabling environment to adequately protect national biodiversity and human health from the possible risks of modern biotechnology in the participating Caribbean countries - Among the range of factors which will contribute to and enhance sustainability, the key elements for this project will include the long-term strengthening of the biosafety legal and policy frameworks in participating Caribbean countries, strengthening biosafety risk assessment and management capacities and services at the national and regional level; improving coordination of biosafety risk management activities at the national and regional levels; and strengthening regional cooperation and access to information on biosafety. The key elements that will ensure the sustainability of these factors is the ability of the participating countries to retain the human resources that have been trained in biosafety management (i.e. reverse the "brain drain" that has caused the loss of talented individuals from the Caribbean region to more lucrative employment elsewhere), and the ability to sustainably finance the risk management measures required for effective

[3] *Guidelines for Implementing Agencies to conduct Terminal Evaluations (GEF, 2003)*

implementation of NBFs and the Cartagena Protocol. The first element is largely beyond the scope of this project to influence and is largely driven by global economic factors. In regards to the second element, the pressing financial situation facing participating Caribbean countries which has been created by the current global economic downturn has resulted in government financial allocations to biosafety activities being inadequate, thereby requiring an exploration of alternative financial mechanisms, including opportunities for developing financial sustainability through cost recovery mechanisms. The second element will be directly addressed through project support for the evaluation of possible self-financing mechanisms to sustain national and regional biosafety management and the implementation of viable self-financing measures to ensure the continued effective implementation of the Cartagena Protocol after project completion.

140. Achieving (b) sustained effective implementation of the Cartagena Protocol with concurrent reduced risks to global environmental services/benefits and global biodiversity - A key factor that will contribute to achieving sustained effective implementation of the Cartagena Protocol will be the ability of the project to deliver NBF implementation plans tailored to the capacity and resource limitations of the countries concerned, and to capitalize on the best practices and biosafety know-how of those countries with greater advances in biotechnology applications for the benefit of those making slower progress. Another key factor will be the exploration and, if agreed, development of a harmonized biosafety risk management framework that can be universally implemented by participating Caribbean countries within limited available resources (human, technical, financial). Collaboration made possible through the pooling of risk assessment and management resources and laboratories that will be fostered and supported under the project could provide participating Caribbean countries with a mechanism to sustain and boost their risk management frameworks. Moreover, if the adoption and coordinated implementation of common biosafety management standards, protocols and identification norms significantly reduces the burden of effort on individual countries and helps to spread recurrent costs, this approach would be conducive to greater NBF sustainability. An additional factor that will contribute to achieving sustained effective implementation of the Cartagena Protocol is the level of political influence that will be generated. Increased levels of public engagement and concern with the potential risks associated with modern biotechnology will contribute to sustainability, both by improving the general public's ability to identify and report risks associated with LMOs (and particularly new organisms), and by generating political will to give biosafety issues higher priority on the national agenda.

141. *Institutional sustainability* will be ensured through the strengthening of the NBF for each participating country which includes legally constituted and functional cross-sectoral technical and coordinating committees to coordinate biosafety risk assessment and management at the national level. The project will strengthen institutional aspects on biosafety, including building capacity for the NCA and the national authorities for biosafety management, and developing a workable system for risk assessment, handling requests, taking decisions, and follow-up. Through the capacity-building activities, the project will also aim to strengthen cooperation and coordination between different government agencies, as well as promoting public awareness, information dissemination and participation in decision-making on LMOs. At the regional level, a regional node will be established to facilitate a sustained flow of information of biosafety, and public access to risk management activities. The sustainability of the project will be measured at project end by the biosafety policy and regulatory instruments enacted, the level of

public awareness of and engagement in biosafety, and the risk management measures implemented. Sustainability will be enhanced through the capacity built and the awareness-raising achieved at national and regional levels. The use of national experts in carrying out project activities in cooperation with regional and international experts will help to strengthen and sustain national and regional capacity for biosafety. Sustainability of national efforts at capacity building for biosafety will be enhanced through sharing of expertise, networking and sharing of laboratory and other technical resources. By building a critical core of national and regional experts, it is anticipated that the sustained effective implementation of NBFs and the Cartagena Protocol can be assured.

142. *Social sustainability* will be achieved at national level through a multi-sectoral consultative process, with participation of policy makers, private sector and government institutions critical to enact and implement the necessary biosafety policy and regulatory instruments. Cross-sectoral coordination will be fostered in implementing biosafety risk management measures across key sectors including agriculture, animal and human health, fisheries, food safety, resource management, transportation and trade. National level consultations will support the development and implementation of biosafety standards, protocols and labeling, and will be a key element of national and eventually regional biosafety risk assessment processes. The effective establishment of biosafety clearing house mechanisms at the national and regional level will ensure improved public access to information and greater participation in biosafety risk decision-making. The Caribbean region possesses in-house biosafety expertise which will be made more broadly available by updating the roster of biosafety experts and in particular by taking advantage of qualified resources persons in training activities (e.g. the Regional BCH Advisors trained through the global BCH (UNEP-GEF) Project). The expanded use of in-house expertise should also increase the social sustainability of the biosafety system.

143. *Financial sustainability* is a critical factor. Sustainability will be promoted by demonstrating the value of biosafety risk management in the context of trade liberalization under the CSME and in the achievement of national sustainable development agendas, thereby encouraging participating governments to allocate scarce financial resources to effective NBF implementation. Government commitment to the Cartagena Protocol and the effective implementation of their NBF has been demonstrated through a direct match in co-financing with governmental resources. Limited and constrained government financial resources will be best utilized through the coordinated use of a range of government agencies in the implementation of biosafety, who are also linked to biosecurity/IAS risk management, which is a key operational approach that will be fostered throughout the project. The ongoing policy dialogue on biosafety and biotechnology at CARICOM level and the adoption of these issues at the program level within CARICOM may serve to ensure the continued provision of financial resources to sustain biosafety measures within the region. However, as highlighted earlier, a critical factor supporting financial sustainability is the implementation of viable self-financing measures to ensure the continued effective implementation of the Cartagena Protocol after project completion.

3.9 Replication

135. Mechanisms to facilitate regional cooperation within the CARICOM sub-region on biosafety and the safe use of biotechnology will be disseminated through sharing of experiences on implementing the project through regional meetings and support for the

regional BCH node that will facilitate the sharing of information on biosafety. Should the project pioneer a model for regional harmonization on biosafety risk management standards, protocols and identification, and the pooling of laboratories services and capacities, this approach will be disseminated through UNEP for possible replication in other regions interested in harmonizing LMO management. Lessons learned and best practices gathered from project implementation will be shared with other countries through regional meetings, exchanges of personnel and networking between those involved in biotechnology and biosafety. These lessons can be used for better project design and best practices can be replicated in other similar capacity-building projects.

3.10 Public awareness, communications and mainstreaming strategy

136. A key element of the project's public awareness, communications and mainstreaming strategy is the development and operation of biosafety clearing house mechanisms at the regional and national level. In keeping with requirements of the Cartagena Protocol, such clearing houses will be established in order to:
    (i) facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
    (ii) assist participating Caribbean countries to implement the Cartagena Protocol, taking into account their special and individual needs.

137. The project clearing houses will comprise a Regional Node with linkages to a distributed network of national, regional and international nodes/databases, and will be compatible with the Cartagena Protocol's BCH Central Portal. The Regional Node will be hosted and maintained by a regional entity (to be established under the project as an output from the capacity needs assessment to be undertaken as an early regional component activity) and will provide the gateway to all sections of national clearinghouses (nBCH), including the search pages, the Management Centre where information is entered or updated, links to other websites, discussion forums where clearinghouse users can talk to each other about issues of common interest, and a toolkit that is designed to help users understand how to use the clearinghouse.

138. The regional and national clearing houses will function like a central biosafety information marketplace for the Caribbean, where the providers and users of biosafety information in the Caribbean interact and exchange that information in a transparent manner. The regional node will systematically collate existing biosafety information (inventories, databases, etc) relevant to the Caribbean region and will link to global initiatives such as the BCH established under the Cartagena Protocol (Central Portal), as well as regional initiatives, particularly IABIN-I3N. The regional node will be a key forum for regional mainstreaming of the CARICOM Biotechnology and Biosafety Policy. It is envisaged that by the end of the project, all participating countries will have a functional nBCH linked to the regional node.

139. Importantly, the regional clearing house has the potential to become the "gatekeeper" of regional biosafety applications, electronically tracking applications and permits granted, ensuring adequate public access to information on the processing of such applications, and even facilitating public input into the risk assessment process. In the first instance, the regional node will contain the database of LMOs that have been approved for use in the Caribbean, and will seek linkages to IABIN and other databases on IAS. It will also contain risk assessment tools that have been developed under the project, including

standards, protocols and labels, and training manuals that will be made freely accessible to the public.

140. The project will support the development of a public education and outreach (PEO) strategy which will guide the development and sharing of public awareness material regarding biotechnology and access to information on the biosafety risk assessment process. Countries will undertake awareness raising activities at the national level covering biosafety, biotechnology, bio-security and invasive species, and will directly benefit from implementation of the regional strategy that will provide a common webpage, brochures, monthly e-newsletter, posters, periodic project country exchanges, a public information educational/informational pack (comprising an environmental education series), public service announcements, regional article blasts, and videos for public education. The project will also support stakeholder consultations to enact biosafety policy and regulations, the convening of workshops, and targeted outreach for stakeholders.

141. All project partners will be regularly apprised of progress via reports and/or meetings.

3.11 Environmental and social safeguards

142. The project is considered to have positive environmental and social impacts due to improving biosafety management and enhancing regional collaboration in the insular Caribbean to reduce the potential risk posed by modern biotechnology to biodiversity of global significance. The ability to undertake biosafety risk assessments, risk management and risk communication will be a significant contribution to environmental safeguards in the region. This will be achieved through project investment in national capacity building, in national and regional infrastructure, in knowledge generation and dissemination and public awareness-raising. Social and environmental safeguards have been integral to the project during its design and development phases and will be also be adhered to during its implementation. Both the NEAs and the Lead Executing Agency will uphold environmental considerations in all project interventions.

143. Social safeguards are incorporated into the project through empowering public access to information on biosafety risk assessments, and facilitating public input into the risk assessment process. Public awareness campaigns addressing the risks and benefits presented by modern biotechnology and the role of biosafety management aim to engage local communities with the project. This will provide buy-in from the general public, raise the sensitivity and understanding of biosafety issues and their impact on biodiversity and livelihoods, and ensure continued support for biosafety systems beyond the duration of the project. Considerations of gender balance will be integrated into the project’s service procurement and public participation processes.

SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS

144. The UNEP as the ***GEF Implementing Agency*** for this project, is responsible for overall project oversight and performance appraisal vis-à-vis the GEF. The UNEP's Division of GEF Coordination (DGEF) will support project partner to ensure that the project meets its stated objectives, operates according to the required UNEP/GEF standards and that its outcomes are aligned with global biosafety policy, in particular with the CPB. Project execution structures and their roles and responsibilities are detailed in *Appendix 11* (Terms of Reference) and summarized below, while the project's organogram is shown in *Appendix 10*.

145. How the project will be executed and how an eventual regional biosafety system may operate may seem like different issues, but in this case, both speak of biosafety management needs and are inter-related. Hence the choice of Lead Executing Agency purposefully coupled these issues by considering properties that were relevant to both functions: biosafety management and project management. At the request of participating countries, and by means of a prolonged consultation exercise, it was determined that the project should be executed by an institution that:
    i) Is preferably be a "creature of CARICOM" or has close affiliations to CARICOM, and is a Caribbean institution (ie. of the region and based in the region) with strong links to CARICOM Member States.
    ii) Has operational structures already in place to promptly upstart the project.
    iii) Has prior experience with large multi-national and donor-funded projects, preferably with GEF projects in the region.
    iv) Has a mandate that is applicable /relevant to biosafety
    v) Could potentially become a biosafety service provider, and -should the decision arise- could eventually be designated "Regional Biosafety Authority" or act as a regional hub or coordinating entity for biosafety
    vi) Has the capacity to mobilize or provide co-financing towards the project, and eventually towards the functioning of NBFs to ensure their sustainability over time.

146. As a result, the conglomerate of the University of the West Indies – UWI (including its UWI-Consulting branch) was selected amongst several institutions to act as the project's ***Lead Executing Agency (LEA).*** UWI has a history of managing a diverse range of externally-funded projects with regional impact and will draw upon its own capacity and expertise and its established links with regional institutions international partners and networks of professionals to bring the project to fruition. In addition to a consulting branch, the UWI comprises four campuses, the first at Mona, Jamaica, the second at St. Augustine, Trinidad and the third at Cave Hill, Barbados; the fourth is an Open Campus established in 2008 that provides services throughout a network of forty centers in all contributing countries.

147. As LEA, UWI will manage all project operations and administration, including financial book-keeping, contracting, procurements, organization of events, reporting to UNEP, etc. The LEA will be legally responsible for delivering project results, facilitating regional collaboration for the project, hosting the ***Project Management Unit (PMU)***, monitoring project progress and performance, and ensuring periodic reports, reviews and audits take place as required by GEF and UNEP. The LEA will provide all the support services and strategic orientation that the PMU may need to effectively run project operations as a delegated responsibility.

148. Project activities will be managed and coordinated by a ***Regional Project Manager (RPM)***, to be hired by the LEA as the head of the PMU. The PM will be responsible for the timely and targeted implementation of all aspects of the project. The PM will respond to the LEA and the Project Steering Committee as the senior body with the responsibility for project oversight. The PM will liaise closely with NBF Coordinators, who will be responsible for all activities within their respective countries. The LEA, including support services, and the PM together comprise the core management team of the project. They will meet at least every three months, and hold teleconferences at least once a month. Progress in implementation will be monitored against the work plan (*Appendix 5*), the half yearly project progress reports and expenditure reports.

149. The LEA will work closely with the designated ***National Executing Agencies (NEAs)*** in each project country, as listed below. The NEAs will be responsible for implementing the project's national-level work programmes; they will provide feedback on project progress at the national-level, including obstacles faced, and will participate in the Regional Steering Committee. Each will designate a ***National Project Focal Point (NPFP)***, conform a National Steering Committee and hire a NBF Coordinator to work closely with the Focal Point. The role of the NEA will include managing project funds at the national level and procuring project staff, equipment and services. Liaisons with the PMU will take place through the National Focal Point and/or the NBF Coordinator, as determined by each NEA. The designated NEAs are as follows:
    - Antigua and Barbuda - The Environment Division currently within the Ministry of Agriculture;
    - The Bahamas - The Bahamas Environment, Science and Technology (BEST), Ministry of Environment;
    - Barbados - The Ministry of Environment, Water Resources, and Drainage in collaboration with the Ministry of Agriculture;
    - Belize - Belize Agriculture and Health Authority, Ministry of Agriculture;
    - Dominica - The Environmental Coordinating Unit within the Ministry of Health and Environment;
    - Grenada - The Ministry of Agriculture, Lands, Forestry and Fisheries;
    - Guyana - The Environmental Protection Agency;
    - St. Kitts and Nevis - The Ministry of Sustainable Development;
    - Saint Lucia - The Ministry of Agriculture, Lands, Fisheries and Forestry;
    - St. Vincent and the Grenadines - The Ministry of Health and the Environment;
    - Suriname - The Ministry of Labour, Technological Development and Environment;
    - Trinidad and Tobago - The Environment Management Authority (EMA).

150. At the country level, project activities will be managed by a ***NBF Coordinator*** who will be based in each of the participating countries, preferably within the NEA, and who will function as an extension of the PMU. These Coordinators will maintain a close working relationship with the PM but will report to the NEA. Draft Terms of Reference are provided in *Appendix 11*.

151. In addition, a ***National Steering Committee (NSC)*** will be established in each project country (with preference as a re-constitution of the National Coordinating Committees established under the UNEP global project on "Development of National Biosafety Frameworks" and/or the Task Group involved in the BCH projects) and will meet every

3-6 months. This NSC will comprise the NBF Coordinator, representatives of partner organizations, and technical experts, as well as NEA staff. By explicit request from the GEF Council, the Ministries of Environment and Agriculture (or their equivalents) must be represented on the NSC, given the biosafety competencies and responsibilities that each harbors as key stakeholders in NBF implementation. The NSC will, whenever possible, be housed in the NEA or the agency leading the country's biosafety program. The NSC will have overall responsibility for oversight and direction of in-country project activities, including the review and approval of annual detailed work plans and financial plans, as well as review of the deliverables and outputs of in-country project components including reports. The NSC will foster inter-institutional coordination at the national level, and also review and advise the Project Steering Committee on the scope and effectiveness of regional coordination activities. The NSCs may be assisted by scientific and technical advisors, or advisory committees, either on a fixed term or an *ad hoc* basis.

152. A ***Regional Steering Committee (RSC)*** will be established to provide the overall policy direction to project implementation. It will comprise of the National Project Focal Points of all the participating countries (and/or the NBF Coordinators) and representatives of the main project organizations involved in technical and administrative delivery of the project as well as regional government bodies: UWI, CARICOM Secretariat, CARDI, CAHFSA, and UNEP (DGEF). The Committee is to be chaired by a national representative on a rotational basis, subject to endorsement by all RSC members. PMU staff will provide secretariat services. The RSC will oversee progress in project execution, provide strategic and policy guidance, exchange experiences and best practices for optimizing the region's approach to biosafety management, and review and approve project work plans and budgets, as needed. The RSC will endorse all reports the PMU presents to UNEP, and will ensure that project monitoring and evaluation, and adaptive management, serve to maintain the project on target with respect to its outputs. Importantly, it will advise the LEA on biosafety issues, especially in relation to the regional and international arena (including the CPB).

153. For delivery of results under the project's technical components, UWI will work in partnership with other regional organizations with recognized technical capacity and know-how in biosafety. Although these collaborations are neither exclusive nor definitive, below is the expected partnership scheme based on the nature and scope of each project component. At inception, the viability and pertinence of these proposed partnerships will be reviewed and either confirmed or revised.

Component 1: with NEAs principally
Component 2: with IICA principally, with involvement from CROQS and CAHFSA
Component 3: with other Universities -including UG- and teaching centres.
Component 4: with CARICOM Secretariat and CAHSFA

SECTION 5: STAKEHOLDER PARTICIPATION

154. The main project stakeholders include Government Ministries and agencies, Universities throughout the region, the business community involved in trade, as well as NGOs. Furthermore, a range of regional and international agencies are involved in specific aspects of the project, particularly in the biosafety risk management process.

155. Stakeholder groups in each of the participating countries contributed actively to the project design during the PIF phase. The main objective of the PIF was to confirm which countries would be involved in the project and revisit the 'baseline situation' in order to refine the objectives of the project and define specific project activities, logframes and budgets. In each country, national consultations were coordinated by one or more lead agencies, using existing structures to involve relevant stakeholders in the process. Key stakeholders attended a Regional Consultative Meeting on the Implementation of National Biosafety Frameworks held jointly by UNEP, CARICOM and IICA in Barbados between 22 and 24 July 2009. The objective of the Regional Consultative Meeting was to obtain stakeholder input into the elaboration of the Regional Biosafety Project and the Regional Biotechnology Policy and Strategy. More specifically, stakeholders attending the regional consultation:

    i. Reviewed the science underpinning issues and national/regional capacity issues relating to biosafety, bio-security and biotechnology;
    ii. Examined the implications of biosafety/biotechnology/bio-security for trade and the preservation of the environment, including the socio-cultural environment;
    iii. Reviewed the *CARICOM Biotechnology Policy and Strategy*;
    iv. Reviewed and adopted the broad parameters of the Regional GEF project on the Implementation of the National Biosafety Frameworks.

    Structures to guide the in-country activities under the project were also discussed. During the meeting, the participants exchanged information, refined objectives and outcomes of the FSP and drew up tentative co-finance plans taking into consideration GEF's new Resource Allocation Framework IV (RAF IV). They also deliberated on coordination mechanisms for the project.

155. A follow-up biosafety/biotechnology consultative meeting and workshop was held in St Vincent & the Grenadines from 28 to 29 September 2009 to provide biosafety laboratory leaders with an opportunity to network and discover possible cross-country synergies in support of biosafety and biotechnology in the region. The meeting also provided the opportunity for Caribbean decision-makers to develop a better understand the science behind modern technology and its implications for food production, food safety and the environment; enhance knowledge of the current technology trends in biosafety and biotechnology, both locally and globally as well as biotechnology products from which Caribbean producers and consumers benefit and how to communicate this information to the public and a clearer understanding of their international trade obligations under various international agreements and fora. An outline of the project was presented and reviewed during the consultative meeting, which was co-sponsored by IICA in collaboration with CARICOM and UNEP.

156. During 2010, UNEP/ROLAC and UWI /UWI-Consulting led the final stages of project preparation which included national processes for baselining and needs analyses, an ample regional consultation workshop held in Barbados in July, and elaboration of the project proposal draft. All countries and key stakeholders actively participated in

providing inputs to the formulation of the project, including proposed organizational structures for project execution, the project's regional component, co-finance requirements, and consideration of regional factors that could influence project progress. The project preparation phase culminated in a regional workshop held with Caribbean GEF Operational Focal Points and national biosafety representatives in Barbados in June 2010, where final agreements were reached with regards to national expectations, co-financing targets, the scope of the project's regional component, and project execution arrangements.

SECTION 6: MONITORING AND EVALUATION PLAN

157. 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.

158. The project M&E plan is consistent with the GEF Monitoring and Evaluation policy. The Consolidated Project Results Framework presented in *Appendix 4* includes indicators for each expected outcome, while mid-term and end-of-project targets are set out in *Appendix 7*. These indicators along with the key regional and national 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*. Other M&E related costs are also presented in the costed M&E Plan and are fully integrated in the overall project budget.

159. 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 Regional Project Manager (RPM) 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.

160. The Regional Steering Committee will receive periodic progress reports 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 of the Task Manager in UNEP. 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.

161. At the time of project approval approximately 75 percent of baseline data is available. Baseline data gaps will be addressed during the first year of project implementation. The main aspects for which additional information are needed are: (a) the in-house capacities and equipment available within the regional laboratories that have a LMO detection capacity; (b) an assessment of the viability and resource implications of deploying regional mechanisms for specific aspects of biosafety management, in particular harmonized standards and approval processes; (c) the volume and nature of regional trade involving products and produce derived from modern biotechnology; and (d) the types of organisms from modern biotechnology that may pose risks to biodiversity and human health in the Caribbean and the likely pathways by which such organisms will be introduced.

162. Project supervision will take an adaptive management approach. The UNEP 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 Regional 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.

163. A mid-term management review or evaluation will take place 24 months after project commencement as indicated in the project milestones. The mid-term review (MTR) will be carried out by a panel of 1-3 experts, selected by the Evaluation and Oversight Unit (EOU) of UNEP, and paid from the relevant project budget for M&E. This MTR will comprise a desk review of the project and *may* also include country visits to selected project partners. These expert(s) will review all parameters recommended by the GEF Evaluation Office 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 section 2.5. of the project document). The Regional Steering Committee, together with selected National Steering Committees, will participate in the mid-term review. With the assistance of the UNEP Task Manager, the Regional Steering Committee will develop a management response to the evaluation recommendations along with an implementation plan; the UNEP Task Manager will be responsible for monitoring whether the agreed recommendations are being implemented.

164. 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.

165. The GEF tracking tools for participating countries 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. Importantly, the project design has included feedback loops that will allow verification of outcomes and targets, at project mid-term and end-of term. A key element will be the application of mock cases for LMO decision-making (trial runs) which will double as a training tool from which all project countries will have a chance to learn and gain practical experience, and as an evaluation method and a means of verification that will attest to the project's desired impacts. The use of survey questions will also provide feedback from trainees and project beneficiaries, and will allow expected results to be verified in a measurable fashion. These M&E instruments are further explained in the project M&E plan (*Appendix 7*) and as part of the activities workplan (*Appendix 5*).

SECTION 7: PROJECT FINANCING AND BUDGET

7.1. Overall project budget

166. The overall project budget is **US$ 12,870,075** comprising **US$ 5,972,493** from the GEF and **US$ 6,897,582** in co-financing. The latter consists in **US$ 3,697,582** from participating Caribbean countries and **US$ 3,200,000** as co-financing being provided or leveraged by regional partners, namely CARICOM (in cash and in kind), IICA, UWI and UG. Co-financing commitment letters are shown in *Appendix 12* for confirmed co-financing pledges, while additional unconfirmed but potential co-financing sources are cited below. Opportunities to leverage contributions from these additional co-funding sources will be sought during project execution. The project budget is presented in detail in *Appendix 1* (budget requested from GEF Trust Fund, according to UNEP format) and *Appendix 2* (co-financing).

167. GEF funds for activities in Jamaica are contingent on Jamaica's formal ratification of the Cartagena Protocol; funding will hence derive from an add-on Medium-Size Project to be presented under GEF-V and implemented alongside this project.

168. The project comprises 5 components, of which one relates exclusively to regional-level responsibilities, including project management commitments and project M&E. The GEF funding for the regional project management (Comp 5.2) has been capped below 10% of the full GEF budget. The funding distribution amongst project components is as follows:

	CO-FINANCE	GEF FUNDS
	US$	US$
Comp 1	1,739,590	1,788,300
Comp 2	2,667,013	1,464,800
Comp 3	958,206	1,178,800
Comp 4	666,109	535,800
Comp 5		
5.1 Regional biosafety support mechanisms	288,250	94,816
5.2 Regional Project management	410,500	582,403
5.3 Regional Project M&E	167,914	327,574
TOTALS	**6,897,582**	**5,972,493**

7.2. Project co-financing

169. The co-finance committed for the project sums **US$ 6,897,582** in both in-kind and cash contributions, and includes two elements: commitments from national partners, and commitments from regional partners which are not country-specific. In general, the latter type of co-finance provides more general support, including complementary activities which will add value to the project outputs. For project countries, indicative co-finance contributions were calculated based on the proportion of GEF-4 funding put forward by each country.

170. **Confirmed co-finance:** As shown in the co-finance commitment letters (*Appendix 12*), pledges have been received from the following partners:

a. UWI and the University of Guyana will provide **US$1,000,000** in counterpart funding (largely in-kind in the form of academic staff time, technical support, laboratory space, use of equipment, animals for testing, greenhouse, personnel, student housing) to support participating countries in the areas previously cited (see section 2.5).

b. Project countries: Confirmed co-finance contributions have come from all 12 national Governments, summing **US$ 3,697,582** principally as in-kind support to project implementation, biosafety coordination and technical inputs. The breakdown per country is provided below:

		"Cash"	**"In-kind"**		USD Total
1	Antigua & Barbuda	104,000	269,500	✓✓✓	373,500
2	Grenada	6,000	316,400	✓✓	322,400
3	Barbados	7,000	383,235	✓✓	390,235
4	St Lucia	2,560	289,640	✓✓	292,200
5	St Vincent & Grenadines	0	254,086	✓	254,086
6	St Kitts & Nevis	0	254,086	✓	254,086
7	Trinidad & Tobago	0	333,055	✓	333,055
8	Suriname	324,660	0	✓	324,660
9	Guyana	0	324,700	✓	324,700
10	Belize	0	250,000	✓	250,000
11	Dominica	0	254,000	✓	254,000
12	Bahamas	0	324,660	✓	324,660
	TOTALS	444,220	3,253,362		**3,697,582**

✓ Minimum amount expected / requested.
✓✓ Above minimum amount expected / requested.
✓✓✓ Significantly above minimum amount expected / requested

c. The Caribbean Community Secretariat through its Resources Mobilization Unit has identified a number of donor sources through which it can mobilize co-financing for the project, and in this regard has committed a minimum sum of **US$ 2,000,000**. Most of these funds will come from bilateral donor programmes and technical support programmes targeted regionally or thematically. It may also include in kind support from the Secretariat itself.

171. The project will receive co-financing support from IICA as a key regional partner that has manifested its intention to provide technical assistance and participate as a project co-financier but has yet to present it institutional commitment letter. IICA intends to support the capacity/needs assessment for regional biosafety laboratories and the upgrading of biosafety equipment, skills and risk management tools, and the establishment of a select number of detection facilities to service the needs of nearby participating countries. IICA can also support the development and application of biosafety risk management standards and protocols (of either national or regional character), LMO identification, and the creation a single biosafety permitting process for the region, should the need arise. Through cooperative agreement with partners of excellence (Universities, NGOs, CARDI), the IICA will provide support for meetings and workshops and other capacity building activities that aim to strengthen technical capacity in the region. The estimated value of the support to be provided by IICA is **US$ 200,000**.

172. **Potential co-finance sources:** Additional but unconfirmed sources of co-financing from technical partners willing to support project activities have also been identified; the project will continue to leverage such resources and seek further collaborative project funding during implementation. These sources include:

a. FAO, - In addition to the Regional Technical Programme prepared by the Caribbean Community Secretariat on the behalf of the participating countries, it is anticipated that the participating Member States will allocate the sum of USD 50,000 form their National technical cooperation program in support of the project for the biennium 2010-2012. Should this materialize, this would signify US$650,000 in supplementary co-financing from combined national totals.

b. IABIN/USGS could provide in the order of US$150,000 (cash and in-kind) to support participating country access to regional IAS database, resources and risk management tools including the pathways analysis tool which can be adapted to address regional biosafety pathways. IABIN/USGS could also collaborate in the development of a common risk assessment framework and on training in risk assessment, if needed.

173. Importantly, fund raising efforts will continue after project approval, as the greater portion of co-financing will be in-kind, and the expectation is for greater cash support (approx. US$ 500,000) in order to focus on national capacity development. Donor funding that emphasizes policy, legislation and technical know-how in areas relevant to biotechnology, biosafety, environment and sustainable development will hence be sought out. The intention is to replenish national level allocations lost to the regional component of the project and reinforce activities to be conducted at country level. UWI will play a key role in this regard and will secure the service of an accomplished and experienced specialist for this task.

7.3. Project cost-effectiveness

174. Project cost-effectiveness will be achieved within the context of promoting resource (human, technical, financial) efficiencies in the implementation of effective biosafety risk management frameworks. At the national level, through the promotion of an integrated and coordinated inter-institutional approach to detection, inspection, risk assessment and information management, the project will strengthen the capacities of various line agencies to undertake biosafety functions. In this manner, capacities will be strengthened in agencies responsible for human and animal health, agriculture, fisheries, forestry, customs, ports, quarantine, food inspection, and environmental health. By drawing upon a pool of agencies to implement the NBF, governments will be best able to effectively implement the Cartagena Protocol within existing and already over-burdened government services without creating new and costly institutional structures. Likewise, the project's proposed activities and investments in the institutional and administrative mechanisms established for LMOs will also benefit those that deal with alien species, in particular regarding transboundary issues and assessment and management capacities, as often the institutions and channels that deal with LMOs and IAS are basically the same and their actions can be integrated under the concept "biological safety", so an investment in one should automatically benefit the other.

175. At the regional level, cost-effectiveness will be achieved through the rationalisation of biosafety services to attend to the risk management needs of the 12 participating countries. It is not likely that a biosafety risk management facility can be established in each participating country. Rather, existing biotechnology laboratories will be strengthened through the upgrading of equipment, skills and risk management tools, and a select number of LMO detection facilities will be established to service the needs of nearby participating countries.

176. The regional project also affords other opportunities for achieving cost-effectiveness through harmonisation and coordination in the development and implementation of biosafety risk management standards, protocols and LMO identification of LMO shipments, and possibly a single biosafety permitting process for the region. Such an approach would be justified if it avoids duplication of efforts and considerably reduces wasted costs compared to undertaking operations on a country-by-country basis. More importantly, it could also provide considerable cost savings for any applicant seeking to obtain approval for any LMO that is to be traded within the region. The project will therefore support the concerted analysis of these regional mechanisms, as cost-effectiveness had been stated as a condition for their adoption. The project will also undertake needs assessment and the development of a self-financing plan should the creation of a regional coordinating biosafety entity be determined to take on the maintenance of the regional biosafety clearing house node and act as the "gatekeeper" for LMO applications that are processed in the region.

177. Efficiencies in costs and the use of human resources will also be achieved through project support for joint training programs to upgrade risk management capacities at the regional and national levels.

178. In the final accounting, cost-effectiveness will be achieved through the establishment of effective biosafety systems that will prevent impacts to fragile biodiversity, thereby avoiding costly remediation or containment which, in many instances, will not adequately reverse any damage that may have been caused. Strengthening the enabling environment, through the introduction of national policies and laws, and concomitant

region-wide actions and biosafety capacity building at both the country and regional levels is by far the most effective utilization of limited technical resources and scarce GEF funding.