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December 16, 2009

Dear Council Member,

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

This project aims to make the National Biosafety Framework fully operational for the benefit of the people and environment of Bhutan, and consistent with the provisions of the Cartagena Protocol and the Constitution of the Kingdom.

The project proposal is being posted for your review. We would welcome any comments you may wish to provide by January 05, 2010, in accordance with the new procedures approved by the Council. You may send your comments to gcoordination@TheGEF.org.

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

Sincerely,





REQUEST FOR CEO ENDORSEMENT/APPROVAL
PROJECT TYPE: Medium-sized Project
THE GEF TRUST FUND

Submission Date: 25 November 2009

PART I: PROJECT INFORMATION

GEFSEC PROJECT ID: 3850

GEF AGENCY PROJECT ID:

COUNTRY(IES): : Royal Kingdom of Bhutan

PROJECT TITLE: Implementation of the National Biosafety Framework of Bhutan

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

OTHER EXECUTING PARTNER(S): Bhutan Agriculture and Food Regulatory Authority (BAFRA), Ministry of Agriculture

GEF FOCAL AREA(S): Biodiversity

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

Name of parent program/umbrella project: biosafety

Expected Calendar (mm/dd/yy)	
Milestones	Dates
Work Program (for FSPs only)	
Agency Approval date	01/01/2010
Implementation Start	05/01/2010
Mid-term Evaluation (if planned)	05/01/2012
Project Closing Date	05/01/2014

A. PROJECT FRAMEWORK (Expand table as necessary)

Project Objective: To make the National Biosafety Framework fully operational for the benefit of the people and environment of Bhutan consistent with the provisions of the Cartagena Protocol and the Constitution of the Kingdom.

Project Components	Indicate whether Investment, TA, or STA ²	Expected Outcomes	Expected Outputs	GEF Financing ¹		Co-Financing ¹		Total (\$) c=a+ b
				(\$ a)	%	(\$ b)	%	
1. Stocktaking Analysis	STA	Baseline established for information on the safe use of biotechnology in Bhutan through a stocktaking analysis	1.1 Inventory of current national human, technical and institutional capacities to implement a comprehensive biosafety management system 1.2 Accurate information on how Biosafety can be harmonized with National Laws, policies and plans, and built into existing Monitoring and Enforcement systems. 1.3 Biosafety systems are consistent with national priorities on gender mainstreaming, and human rights, including participation by	29,500	45	36,000	55	65,500

			all sectors in decision-making.					
2. Integration of Biosafety into Bhutan's Tenth Plan, particularly the National Priorities on Poverty Reduction and Environment.	TA	Biosafety integrated & incorporated into National Priorities on poverty reduction & environment, as well as sectoral action plans & strategies, in conformity with Bhutan's Tenth Plan.	2.1 Biosafety policy approved & implemented by Government. 2.2 Biosafety policy integrated into the Tenth Plan and reflected in the National Priorities, and sectoral action plans.	30,500	43	40,000	57	70,500
3. Regulatory Regime for Biosafety in place in Bhutan for control of introduction of LMOs into the environment.	TA	A legal and regulatory framework on biosafety in place that is consistent with the CPB, and is workable and responsive to national needs and the National Priorities of the Tenth Plan	3.1 Biosafety regulation promulgated by the Minister of Agriculture under the Food Act of Bhutan, 2005 to replace the existing Moratorium on import of LMOs. 3.2 Relevant biosafety rules and guidelines prepared and promulgated by relevant Government agencies. 3.3 Existing laws and legislations revised to ensure consistency with biosafety regulation and CBP.	102,000	53	90,000	47	192,000
4. Systems for handling requests for LMOs	STA	A workable system for handling requests, carrying out risk assessment, & decision making for LMOs in place that reflects the priorities of the Tenth National	4.1 A fully functional administrative system for handling requests for LMOs 4.2 A fully functional system for risk assessment and decision-making. 4.3 An efficient system for handling,	125,000	41	180,000	59	305,000

		Plan.	storing and exchanging information on biosafety in place under the nBCH as established under the BCH project. (also see Output 6.1)					
5. Systems for Monitoring & flow-up consistent with national priorities on environment & disaster management	STA	A workable and effective national system for monitoring, inspections & enforcement in place, including monitoring of socio-economic impacts, that is consistent with National Priority on environment and disaster management.	5.1 Fully functional and effective inspection, monitoring and enforcement system in place in BAFRA*. 5.2 Strengthened BAFRA laboratories able to detect LMOs. 5.3 Emergency response procedures (ERP) established & made operational by BAFRA, the NEC* and relevant Govt agencies.	333,000	57	248,000	43	581,000
6. Systems for public awareness & participation	TA	A workable and effective national system for public awareness, education & participation in decision making for LMOs in place, in support of the National Priority on good governance	6.1 Fully functional system for access to, and sharing of information in place in Bhutan, inter alia through the nBCH (see Output 4.3). 6.2 Strengthened system for public awareness on the safe use of LMOs in place. 6.3 Strengthened system for public participation in decision-making on LMOs in place.	97,000	46	112,000	54	209,000
7. regional cooperation in SAARC on Biosafety	STA	Enhanced regional cooperation on biosafety in SAARC*, as	7.1 Technical expertise, decision-making tools, training activities and	62,000	62	38,000	38	100,000

		well as sharing of experiences with other NBF Implementation projects globally.	materials for training and outreach developed and shared with other countries in SAARC. 7.2 Alignment of biosafety policies, regional mechanisms and common formats for sharing of information amongst SAARC countries on biosafety. 7.3 Establish networks established with other Implementation project teams for sharing experiences, lessons & best practices.					
8. Project MTE, terminal evaluation, monitoring & auditing		Accountability & Learning	8.1 Mid-term review. 8.2 End-of-project evaluation. 8.3 End-of-project audit. 8.4 Periodic project monitoring Reports	10,000	25	30,000	75	40,000
9. Project management				80,000	50	80,000	50	160000
Total Project Costs				A869,000		B854,000		1,723,000

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

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

*Abbreviations; BAFRA – Bhutan Agriculture and Food Regulatory Authority; SAARC – South Asia Association for Regional Cooperation; NEC – National Environment Commission.

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

<i>Name of Co-financier (source)</i>	<i>Classification</i>	<i>Type</i>	<i>Project</i>	<i>%*</i>
Government project contribution	Nat'l Gov't	In-kind	854,000	100
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
	(select)	(select)		
Total Co-financing			B854,000	100%

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

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

	<i>Project Preparation a</i>	<i>Project b</i>	<i>Total c = a + b</i>	<i>Agency Fee</i>	<i>For comparison: GEF and Co- financing at PIF</i>
GEF financing	0	A869,000	869,000	86,900	955,900
Co-financing	0	B854,000	854,000		854,000
Total	0	1,723,000	1,723,000	86,900	1,809,900

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

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

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

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

E. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:

<i>Component</i>	<i>Estimated person weeks</i>	<i>GEF amount(\$)</i>	<i>Co-financing (\$)</i>	<i>Project total (\$)</i>
Local consultants*	46	31,000		31,000
International consultants*	42	126,000		126,000
Total	88	157,000		157,000

* Details to be provided in Annex C.

F. PROJECT MANAGEMENT BUDGET/COST

<i>Cost Items</i>	<i>Total Estimated person weeks/months</i>	<i>GEF amount (\$)</i>	<i>Co-financing (\$)</i>	<i>Project total (\$)</i>
Local consultants*		0	0	0
International consultants*		0	0	0
Office facilities, equipment, vehicles and communications*		0	56,000	56,000
Travel*		9,200	4,000	13,200
Others**		70,800	20,000	90,800
Total		80,000	80,000	160,000

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

Note: The “others” category for project management includes:

(1) Employment of project staff - NPC, Project Assistant and administrative staff. This includes a GEF contribution of \$70,800 plus a Government contribution of \$20,000 - see Appendix 1 and 2 of UNEP prodoc.

(2) Travel is primarily for Project Steering Committee meetings. Other non-project management related travel for specific project components are listed under each of the components in Appendix 1 and 2 of UNEP prodoc.

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

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

H. DESCRIBE THE BUDGETED M & E PLAN: Monitoring will be conducted at two levels: at the national level by the Project Steering Committee (PSC) and at the international level by the Implementing Agency (UNEP). At the national level, the PSC, which will have representation from all stakeholders, including the Gross National Happiness Commission (GNHC), will have the primary responsibility for monitoring both the implementation of project activities, and progress towards the achievement of project outputs. The PSC will be accountable to the Government through the GNHC, which oversees the implementation of all activities in Bhutan in support of the Tenth Plan. As BAFRA has included implementation of the NBF in the Ministry of Agriculture's (MOA) Renewable Natural Resource (RNR) Sector of the Tenth Plan, and mentioned these biosafety targets specifically in programmes MOA 28 on Biosecurity systems and 29 on Biodiversity Conservation, it will be reporting against these targets, through the MOA, to the GNHC on an annual basis. The PSC and BAFRA will therefore receive periodic reports on progress from the project team and, in addition to its progress reports to the GNH Commission, will make recommendations to UNEP concerning the need to revise any aspects of the Results Framework or the M&E plan.

Monitoring of the progress of project activities and financial expenditure which reflect and support project activities will be undertaken in accordance with UNEP's internal guidelines for project supervision, monitoring and evaluation. Project oversight to ensure that the project meets UNEP and GEF policies and procedures is the responsibility of the Task Manager in UNEP-GEF. The Task Manager will receive reports and recommendations from the PSC and 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.

A mid-term management review or evaluation will take place in April 2012 as indicated in the project milestones. The review will include all parameters recommended by the GEF Evaluation Office for terminal evaluations and will verify information gathered through the GEF tracking tools, as relevant. 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.

The cost of monitoring the project at the national and international levels, as well as the costs of the mid-term and terminal evaluation are built into the project cost and the IA fees respectively. The costed M&E plan is attached. (Appendix 7 of UNEP Project Doc.)

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

A. STATE THE ISSUE, HOW THE PROJECT SEEKS TO ADDRESS IT, AND THE EXPECTED GLOBAL ENVIRONMENTAL BENEFITS TO BE DELIVERED: Bhutan has a rich and varied biological diversity of regional and global importance that can be matched by very few countries in the world, both in terms of species biodiversity, which includes a large percentage of endemics, and ecosystems diversity, which is still largely intact. Natural forests cover over 64% percent of the country and are protected through a comprehensive Protected Area System; land utilized for agriculture consists largely of traditional, highly integrated farming systems.

Prior to the formulation of its National Biosafety Framework (NBF), Bhutan did not have a biosafety policy as such although a ministerial decree issued by the Ministry of Agriculture in 2000 banned all imports of LMOs into the country. This decree was an attempt to ensure that Bhutan was free of LMOs since the domestic biotechnology sector was non-existent at that time, and the only source of LMOs was from food imports. However, this moratorium has proved inadequate in meeting the country's food security needs as Bhutan imports more than 35% of its food from neighbouring countries, which have active biotechnology industries and use LMOs in the production and processing of FFPs. Also, national priorities on poverty reduction mean that

there is a necessity to increase food production through the safe application of biotechnology in order to increase yields so as to ensure food security. Therefore, the Government of Bhutan intends to lift the existing moratorium and to replace it with adequate biosafety systems that will help minimise any risks to the environment and human health from imports that may contain LMOs, as well as enabling the country to import LMOs for crop and livestock breeding programmes in order to increase yields.

In line with its National Priorities set out in the Tenth Plan (2008-2012), Bhutan is seeking to provide viable alternatives to the high level of food imports and the Government is promoting food security through investment in R&D to meet the needs of small farmers in all regions of the country. The mandate of the Research Centres of the Ministry of Agriculture is to improve agriculture production, and raise the per capita income of the rural population through technologies and information that will help to maintain and improve existing genetic and biophysical resources of the country. Therefore it is very likely that these research centres will, in future, be the main entry points for LMO crops, seeds, and livestock; they would also be responsible for carrying out extensive field trials of new crops, seeds and livestock imported from outside prior to release to farmers. Bhutan therefore needs to have in place adequate biosafety systems to enable the country to benefit from the safe application of modern biotechnology. The project will enable Bhutan to: (i) Monitor imports of foods and seeds to control any illegal transboundary movement of LMOs; (ii) monitor illegal planting of LMOs from seeds smuggled across its borders from neighbouring countries; (iii) evaluate dossiers for applications to import LMOs; and (iv) carry out risk assessments and monitor field trials for LMOs introduced by CGIAR centres in conjunction with the research Centres of the Ministry of Agriculture. Further assistance for the implementation of the NBF for Bhutan is therefore timely and would address its concerns as a landlocked country with an open and porous border. Bhutan's major concern is the safety of its citizens and its almost pristine environment; but at the same time, increasing food security and food self-sufficiency are critical objectives. The use of biotechnology to achieve these objectives is a likely course of action for the country. Therefore the NBF takes a balanced approach to safeguard Bhutan while meeting important food security objectives.

The Global Environmental Benefits (GEB) from implementation of this project include the conservation and sustainable use of Bhutan's rich biodiversity by minimizing any risks to economically important plants and animals as well as their wild relatives, from the application of biotechnology in the country, or from the importation of LMOs in food or feed products.

Bhutan's wealth of agrobiodiversity includes a number of economically significant plants and animals; for instance, many of Bhutan's crop varieties represent adaptations to some of the most extreme altitudinal agricultural lands in the world, with cultivation in the alpine agro-ecological zone extending up to 4600m. While wheat is not an indigenous crop, varieties grown around Laya are adapted to higher elevations and more extreme conditions than wheat varieties in any other part of the world. Maize is another example of a crop that was originally exotic, but which has undergone a process of breeding and selection to create unique high-elevation varieties.

Other crop plants have also been domesticated *in situ*. For example, buckwheat is an indigenous crop, and at least one putative wild relative, *Fagopyrum debotrys*, is found in natural ecosystems in Bhutan. Foxtail millet is another indigenous crop, with a wild relative, *Setaria viridis*. Two wild relatives of oats, *Avena fatua* and *A. sativa* are found in Bhutan. There are also numerous wild relatives of horticultural crops like apple, pear and citrus in the temperate and sub-tropical forest zones of Bhutan. These wild relatives of crop and horticultural plants in Bhutan provide a potential genetic resource that could prove beneficial for international breeding programmes for increasingly important crops such as buckwheat (e.g. for production of gluten-free flour), oats and millet.

Bhutanese rice is unique in that it represents an intermediate type between the two major groups of *Oryza sativa*, "indica" and "japonica" ("javanica" is a less significant third group). There are an estimated 250-300 varieties of rice in Bhutan, many adapted to very localized conditions, and thus representing a unique genetic resource. Some of these traditional varieties are very close to wild relatives; for example, Bhutan is also home to at least two wild relatives of rice, *O. minuta* and *O. rufipogon*.

Among the livestock genetic resources, siri is a *Bos indicus* breed of cattle, believed to have originated in

Sombe geog, in Haa dzongkhag. It is characterized by disease resistance, strength and high butterfat content of its milk. Mithun is a descendent of gaur, and probably originated in India, Burma and/or Bangladesh, but has been bred in Bhutan since at least the 17th century. Mithun are often crossbred with siri. Yak is a *Bos gruniens* bovine species, used throughout the Himalayas and on the Tibetan plateau. There appear to be distinct genetic differences between yaks in eastern and western Bhutan, with higher levels of genetic diversity in the east. Goleng is a *Bos taurus* cattle, probably originating in Tibet, and sometimes used for cross-breeding with yak. Other significant animal breeds include the Nublang (a local native cattle breed), blue sheep, Takin (*Budorcas taxicolor*), and at least four unique breeds of horse known as *Bayta*, *Yuta*, *Mera-Saktenpata*, and *Jata*. There are also breeds of sheep, pigs, and poultry that are unique to Bhutan.

These traditional plant varieties and animal breeds are the genetic foundation for future breeding programmes and R&D efforts to meet national food security priorities and to address global challenges such as innovative, adaptive agriculture to mitigate climate change. However, as local traditional farming practices often result in close cohabitation of domesticated and wild species, the risks of gene transfer from field release of genetically modified species to traditional or wild varieties and breeds are significant. The biosafety systems that will be put in place through the implementation of this project will therefore ensure that any field releases of transgenic plants or animals will undergo thorough scientific risk assessment, and the imposition of stringent safeguards to prevent any risks to the country's rich agrobiodiversity.

Although the GEB that will accrue from the protection of Bhutan's flora and fauna are highly significant, most of these potential benefits are intangible and will be apparent only in the long term, particularly as this Biosafety project will contribute to several cross-cutting areas, such as environment, agriculture, health and good governance. As stated in its Policy statement 1, GEF support is intended to "improve the global environment or advance the prospect of reducing risks to it". In the absence of quality baseline data for biodiversity and the rate of change in biodiversity arising from other causes, it is very difficult, if not impossible, to provide measurable indicators of the impact of biosafety on biodiversity – these would arise only as a "decline-avoided" by the rejection of an unsafe application of biotechnology. An adequate biosafety regulatory system thus fits well with "advancing the prospect of reducing risks to the global environment".

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

Bhutan's priority is to safeguard the biodiversity of the country and the health of its citizens from the potential adverse effects of modern biotechnology and, at the same time, to be able to benefit from the safe and proven benefits of this technology. Currently, the Royal Government of Bhutan has in place several pieces of legislation on environment, agriculture, food, health, and trade policy to protect the country's rich biological diversity and the well-being of the people whilst promoting sustainable development. These policies have a direct or indirect impact on biotechnology and biosafety issues, and regulation of LMOs. For example, the foreword of the Biodiversity Action Plan for Bhutan 2002 clearly articulates the desire to pursue the use of LMOs to increase agricultural productivity: "For our country, biotechnology holds bright prospect, and we must move that direction as quickly as possible. The golden bridge linking development and conservation is biotechnology".

The current project proposal will help Bhutan to strengthen its capacity for the implementation of the NBF in the context of both the Cartagena Protocol, and national development priorities. This is crucial for the success and sustainability of the NBF. A key issue is the strengthening and development of human resources for biosafety, and the strengthening of appropriate facilities involving the transfer of know-how. The stocktaking exercise, which will be undertaken at the inception of the project, will help to ensure that the project will build on the existing human and institutional resources in the country, and that the biosafety laws and regulations will be harmonised with existing laws and policies so as to promote and support the country's national development priorities.

Specifically, these project outputs will contribute to the following National Priorities in the Tenth Plan (2008-2012), and the outcomes for the UNDAF for the period 2008-2012:

a. The strengthening of biosafety systems by the project will enable Bhutan to harness biotechnology in order to improve agricultural production particularly for subsistence crops, thus enhancing sustainable livelihoods for the rural poor. This will contribute to income generation in rural areas, thus helping to reduce poverty; this is one of the key National Priorities under the Tenth Plan, and more specifically reflected in the 10th Five Year Plan of BAFRA under Program 3- Plant and Livestock Quarantine, and the first planned outcome of the UNDAF.

- b. The strong emphasis on promoting public participation in decision-making on LMOs through awareness and education as well as strengthening institutional systems to enable effective participation will enhance good governance; this is also a National Priority under the Tenth Plan and the fourth planned outcome of the UNDAF.
- c. By putting in place functional systems for biosafety, including ERP, the project will help to safeguard the biodiversity of the country, and so will contribute to the National Priority of the Tenth Plan and the fifth planned outcome of the UNDAF on environmental sustainability and disaster management.

The project will also contribute Government's plans for gender mainstreaming through: (i) the stocktaking exercise which will help ensure that project activities are consistent with all national priorities, including gender mainstreaming; (ii) establishing monitoring systems that take into account socio-economic impacts on all sectors of society, including both men and women; (iii) Ensuring participation by all stakeholders, both men and women, in decision-making on LMOs. The project will also contribute to Government's priorities on human rights by promoting good governance through the participation of all stakeholders in decision-making on LMOs, and the strengthening of institutions that will promote effective participation by all stakeholders. This will include participation by stakeholders in the development of the project design and in the stocktaking exercises.

The NBF project will also contribute to a GEF Funded project on "Integrated Livestock and Crop Conservation" that is currently being implemented by the National Biodiversity Centre, Ministry of Agriculture. This 5 year project aims to mainstream agrobiodiversity conservation into livestock and crop development policy and practice in Bhutan; this project also supports Government's priorities on the conservation and sustainable utilisation of the plant and animal genetic resources in Bhutan.

The project will also support Government's objectives on promoting regional cooperation with SAARC countries in a number of areas including biotechnology and environment. By helping to include biosafety into the agendas of the SAARC Working Groups on Biotechnology and on the Environment, the project will help initiate discussion and cooperation on biosafety within SAARC. Bhutan is well placed to do this as it currently chairs the Environment Working Group for SAARC. The project will also strive to ensure that Biosafety is included in the planned SAARC activities in Biotechnology such as the "Plan of Action for Cooperation in Biotechnology" and the "Institutional Framework for biotechnological Cooperation".

C. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH [GEF STRATEGIES](#) AND STRATEGIC PROGRAMS: The project belongs to the Biodiversity Focal Area and falls within the strategic programme 6 on "Building capacity for the Implementation of the Cartagena Protocol on biosafety". Successful implementation of the project would help to ensure that Bhutan, as a Party to the Protocol, is able to build its national capacity so that its decision-making processes on LMOs are consistent with the CPB. The project will also help to promote regional cooperation on biosafety with other countries in the SAARC sub-region thus helping to ensure that common approaches for risk assessment and management are developed across the sub-region, and that the monitoring of LMOs is carried out on a region-wide basis. Regional cooperation is particularly important as Bhutan shares its rich biodiversity with other countries in the sub-region and most of its trade in agricultural products is with countries in SAARC.

D. JUSTIFY THE TYPE OF FINANCING SUPPORT PROVIDED WITH THE GEF RESOURCES. The financial support from GEF resources is important for Bhutan because, as a Lower Middle Income Country (LMC) with a per capita Gross National Income (GNI) of \$1,770 based on 2007 figures (World Development Report, 2009), the Government needs external support in order to be able to protect its rich biodiversity heritage of global importance and to meet its obligations as a Party to the CPB.

The need to have adequate Biosafety systems in place to protect the country's biodiversity stems from the risks of transboundary movement of LMOs from two sources: the first is from trade and the second is from introduction of transgenic plants and animals for increasing agricultural production. Trade is a particularly important issue for Bhutan as the country imports some 35% of its food requirements. Moreover, Bhutan faces extra challenges as a landlocked country with a relatively open border, surrounded to the north and south by China and India respectively, both of which have active biotechnology sectors. Thus there is an urgent need to ensure that transboundary movement of LMOs via imports of food is properly regulated. The second potentially important source derives from the fact that the Government is striving to promote food security by increasing food production, especially for staple crops such as rice. In order to be able to benefit from the fruits of biotechnology and protect its rich biodiversity, the country must have in place systems for scientific risk assessment, decision-making and risk

management, as well as for monitoring any field releases of LMOs.

However, without GEF financial support, Bhutan would not have sufficient national resources to be able to have adequate Biosafety systems in place so as to regulate transboundary movement of LMOs. As a result, without support from GEF, Bhutan would not be in a position to implement the Cartagena Protocol on Biosafety and would thus be unable to comply with its international obligations as a Party, especially with respect to cross-border movement of LMOs. This would adversely impact the overarching GEF goal of assisting CPB Parties to implement the CPB and Bhutan's capability to protect her biodiversity, thus contributing to global environmental good. These statements are supported by the incremental cost analysis, (Appendix 3 of UNEP prodoc), Bhutan has relatively low baselines for most of the key outcomes. It can be safely assumed that, without GEF intervention, Bhutan will not be able to build the necessary human and institutional capacity in its national institutions for the safe application of biotechnology. Therefore the most important project intervention is capacity building in scientific, technical and administrative areas of biosafety. When sufficient national capacity has been built, it will be possible to put in place all the necessary outcomes for the safe use of biotechnology. Although a small number of individuals received some training in biosafety under the previous UNEP/GEF project on NBF Development, further training on more specific areas like risk assessment, biosafety administration, monitoring and legal drafting are required. Without this key intervention on scientific and technical training, this critical group of national "experts" will move away, and the results of the previous project, which provide building blocks for this project, will be lost. Also, without the vital interventions on administrative training and coordination, effective implementation of biosafety systems will not be possible. Applications for LMOs will not be processed within time frames stipulated by the CPB, and decision-making will be delayed owing to inadequate technical capacity. International trade on LMOs could therefore be disrupted, and imports of food and feed could be adversely affected. In addition, the country will not be able to make use of transgenic breeding materials for improving agricultural production for plants and animals.

- E. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES:** The NBF implementation project has been developed by BAFRA in close cooperation with the National Environment Commission (NEC), and will be implemented by BAFRA, an agency of the Ministry of Agriculture. A project steering committee with representatives of all relevant Government agencies, including the NEC, will help ensure coordination with Government priorities and with other externally funded development projects. This will include projects such as the "Integrated Livestock and Crop Conservation" and the national capacity self-assessment programmes, and projects such as the gender-mainstreaming project.

Oversight of all projects and programmes in Bhutan is the responsibility of the Gross National Happiness (GNH) Commission; this project has been developed by BAFRA in consultation with the GNH Commission, which will continue to provide policy direction and ensure that project implementation is consistent with national priorities. Sub-regional cooperation within SAARC on biosafety and the safe use of biotechnology will be enhanced through sharing of experiences on implementing the NBF with other countries also implementing their NBF, such as India, Pakistan, Sri Lanka and Bangladesh, through regional meetings and support for the sub-regional mechanisms for sharing information developed through the SAARC networks on environment and biotechnology. The sharing of information on LMOs with other members of SAARC will eventually promote regional harmonization of standards and regulations on LMO management. The sharing of technical facilities and expertise between members of SAARC will also help promote sub-regional and South-South cooperation.

- F. DISCUSS THE VALUE-ADDED OF GEF INVOLVEMENT IN THE PROJECT DEMONSTRATED THROUGH INCREMENTAL REASONING :** Prior to the formulation of its NBF, Bhutan did not have any biosafety systems in place except for a ministerial decree issued by the Ministry of Agriculture in 2000 that banned all imports of LMOs into the country. This attempted to ensure that Bhutan would be free of LMOs since the domestic biotechnology sector was non-existent at that time and the only source of LMOs was from imports. However, this decree was never put into practice as the country does not have the institutional, legislative or human capacity to be able to monitor imports. This gap needs to be urgently addressed as Bhutan imports its food needs from Asian countries which have active biotechnology industries and use LMOs in the production of FFPs. Moreover, a ban on importation is not consistent with Bhutan's obligations as a Party to the Cartagena Protocol.

The ban on LMOs and their products, if it were to be enforced, would cause severe problems with food security in the country as more than a third of its food is imported. In the long term, the ban on LMOs also means that the

national agricultural research institutes in the country are unable to have access to new cultivars developed through gene technology. In particular, transgenic cultivars developed by CGIAR institutes in Asia are not accessible to the country since both IRRI and ICRISAT will only introduce genetically-modified cultivars of crops in countries that have working biosafety regulations. Although transgenic subsistence crops have the potential to improve agricultural production by small farmers in Bhutan and promote food security, the NARIs are currently unable to bring in these GM cultivars and test them in Bhutan. Allowing this to be done on a case-by-case basis would therefore improve both food security and the livelihoods of small farmers in Bhutan. Moreover, regulated importation of GM food and feed products would also be facilitated by effective application of the new regulations. Therefore it is crucial that the regulatory, administrative, monitoring and public participation systems contained in the NBF are operationalised as soon as possible so that the country is able to manage importation of LMOs and their products in line with its obligations under the Cartagena Protocol and in support of national development plans.

The draft NBF helps to set up the systems necessary for the safe transfer, handling and use of LMOs resulting from modern biotechnology, including a regulatory instrument under the Food Act 2005 that will replace the previous ban with a system based on the Cartagena Protocol which will consider all imports of LMOs and their products on a case-by-case basis. Implementation of the NBF will also help to bring into force the new Biosafety Rules and Regulations, and to put in place systems for handling of applications, risk assessment, decision-making, monitoring, enforcement, and public participation in decision-making.

The proposed NCA has been assigned the task of carrying out the administrative tasks for the NBF as well as the monitoring and inspection of LMO releases. Although it has facilities for monitoring food and seed quality for conventional crops, it lacks both the laboratory facilities and human resources to be able to carry out its assigned functions for the regulation of LMOs and their products. Therefore, unless adequate support is provided to the country for the implementation of its NBF, it is likely to become a document that sits on the shelf rather than forming the basis of a functioning system to meet the country's environmental and development needs and priorities.

Bhutan has a rich and varied biological diversity that has regional and global importance, and very few countries in the world of a comparable size can match its biological diversity; Bhutan ranks in the top ten percent of countries with the highest species density (species richness per unit area) in the world. Therefore, unless the NBF is made operational in an effective and efficient manner, there is a potential threat to this rich biodiversity, both to native ecosystems and species and to plants and animals of agricultural importance. There is an urgent need to protect this rich biodiversity by building human capacity, strengthening institutional facilities (including laboratories) and implementing regulatory instruments for the safe and sound management of LMOs.

GEF involvement would lead to the successful implementation of the NBF and enable Bhutan to fulfill its obligations as a Party to the Cartagena Protocol, and to meet its national needs and priorities for sustainable development. The involvement of GEF would also help to act as a catalyst to enlist financial and political support from the Government, thus promoting sustainability of the outcomes of the project. Further details are provided in Appendix 3 of the UNEP prodoc, which discusses the incremental cost analysis of domestic and global benefits from implementing the project.

- G. INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS, THAT MIGHT PREVENT THE PROJECT OBJECTIVE(S) FROM BEING ACHIEVED AND OUTLINE RISK MANAGEMENT MEASURES:** A major risk to the achievement of the project's objectives is that biosafety capacity in Bhutan is relatively underdeveloped. As food security is a major development priority for Bhutan, there is increasing pressure both for the importation of LMOs in food and food products into the country, as well as for the application of biotechnology in order to increase agricultural production and promote food security. The project will help the country to build up its biosafety capacity in order to:
- (i) Ensure that adequate safeguards are in place (i.e. systems for handling applications and monitoring mechanisms)) for regulating imports of LMOs so that Bhutan is able to promote trade in agricultural products with its neighbours in SAARC.
 - (ii) Put into place systems (i.e. monitoring mechanisms, emergency responses, enforcement) in case releases of LMOs in neighbouring countries result in accidental or illegal transboundary movement into Bhutan. Strengthened biosafety systems in Bhutan, as well as the fostering of regional cooperation within SAARC, will help promote

sharing of information between countries to prevent such occurrences, and to build up mechanisms for working cooperatively on responses to any emergencies concerning LMOs.

(iii) Put in place systems for managing the safe application of biotechnology in the country so that Bhutan is able to harness the potential benefits of biotechnology for improving food security through more effective utilisation of the country's genetic biodiversity whilst ensuring that systems are in place for protecting biodiversity and human health. Moreover, it will be possible for the biotechnology sector to assist farming systems to adapt to changes in ecosystems caused by climate change.

Functional biosafety systems will also help to ensure that adequate risk assessment, post release monitoring strategies, technical capabilities and information are available at the national and regional level to minimize any potential loss of genetic resources and biodiversity due to the transboundary movement of LMOs as well as through the impacts of climate change.

Another potential risk to the successful implementation of the project is the split between environment and agricultural development priorities as biosafety is often seen as a constraint to the application of biotechnology to help improve food security. However, in Bhutan, the implementation of the NBF will be under the Ministry of Agriculture, which will work with the NEC to ensure that the biosafety systems are fully integrated into biodiversity and agricultural priorities in the country. The stocktaking at the inception of the project will be a crucial step in this integration of the work of the project into national priorities, plans and policies in biotechnology, agricultural development and environmental conservation.

Another potential risk is the lack of political support from Government with respect to the implementation of the Biosafety Rules and Regulation in Bhutan. Successful implementation of the project will not only demonstrate international commitment to the implementation of the CPB through the financial involvement of GEF, but will also require the Government to demonstrate its commitment by allocating financial, human and institutional resources to the project. The process of integration of biosafety into national plans has already begun with the inclusion of the implementation of the NBF in the Tenth Plan under biosecurity priorities in the Renewable Natural Resources Sector. Further efforts to implement the Biosafety Policy and to integrate it into sectoral policies in line with the Tenth Plan will help promote political support for biosafety by demonstrating how adequate biosafety systems would enhance the safe application of biotechnology in order to deal with challenges of food security and climate change. It will also establish the importance of biosafety within the SAARC sub-region by promoting regional cooperation on biosafety and the safe use of biotechnology.

Another major challenge is the need to ensure sustainability of the project outcomes once the project activities have completed. The project strategy is to build capacity within the country on implementing the biosafety policy, strengthening the regulatory regime and systems for handling request for permits, as well as follow-up and public participation. The project activities will therefore focus on ensuring the sustainability and viability of the project impacts in the following areas:

(i) **Institutional and operational terms:** the project will strengthen institutional aspects on biosafety, including building capacity for the national competent authority, i.e. BAFRA in biosafety management, and developing a workable system for follow-up, risk assessment and handling requests. 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 and participation in decision-making on GMOs. When BAFRA as the NCA has been strengthened, and biosafety has been fully integrated into BAFRA's biosecurity systems, they themselves can manage and deal with biosafety issues as part of the national biosecurity system after the end of the project. Furthermore, the project will help to develop a legal framework, which clearly defines functions and responsibilities of relevant institutions/ministries on biosafety, and makes provision for LMO management and for commercializing LMOs and their products. The legal framework will facilitate Bhutan's ability to fulfill its obligations to the Cartagena Protocol.

Sub-regional cooperation with South Asian countries on biosafety and the safe use of biotechnology will be promoted by working with SAARC and sharing of training activities with other countries also implementing their NBF. This will help to make best use of existing scientific expertise and institutional resources within the SAARC sub-region; the sharing of training costs will enable the projects to call in more resource people for the training activities. 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.

(ii) **Financial and political terms:** the most significant activity that the project will carry out will be to help Government recognize the importance of biosafety for sustainable development by approving the National Policy on Biosafety. The project will also help to integrate biosafety into relevant national sectoral plans and strategies so as to demonstrate the importance of biosafety for a wide range of sectors such as agriculture, livestock, forestry, health, trade, etc. The project also aims to enhance the awareness of Government, organizations and individuals about biosafety and will help these players to recognize the importance of biosafety for national development, thus encouraging investment in biosafety and the safe use of biotechnology.

The project activities are designed to promote financial sustainability of the systems for handling LMO applications by exploring and putting in place “fees-based” or “user-pays” financial mechanisms for funding most of the costs of running these systems after the completion of the project. These fees for handling LMO applications will complement both investments by government in technical facilities, as well as future ongoing budgetary allocations for recurrent costs of implementing the NBF. The monitoring systems to be put in place as part of the implementation of the NBF will include systems for inspections and enforcement (see Component 5 of project).

(iii) **Environment terms:** The effectiveness with which the Cartagena Protocol is implemented will help avoid any adverse impacts on Bhutan’s rich biodiversity as well as on human health. Thus the global contribution of Bhutan’s rich heritage of species and ecosystems diversity will be conserved and will help promote the sustainable management of these resources in order to provide both national and global benefits.

H. EXPLAIN HOW COST-EFFECTIVENESS IS REFLECTED IN THE PROJECT DESIGN: This project will take a cost effective approach by promoting cooperation at the national level in Bhutan between agencies whose mandates impact on biosafety and the safe application of biotechnology. As many of the activities in this project are directly or indirectly linked to the regulatory, research and extension services of the Ministry of Agriculture, the project will aim to enhance cooperation between different departments of the Ministry, i.e. agriculture, forestry, livestock, agricultural research, planning, and BAFRA in order to ensure that Government resources are harnessed effectively to further the objectives of this project. This will require strengthened cooperation between the departments and BAFRA at the national level, as well as between the field staff of the agencies at the district and regional levels so as to promote communication and to ensure that monitoring activities are carried out effectively. BAFRA, in implementing the project will also work closely with other Government agencies such as the National Environment Commission, Trade and Industry, Customs and Excise, and Health in order to promote the mainstreaming of biosafety into their activities; this will help to ensure a cost-effective approach to project implementation as well as promoting sustainability of project outcomes.

Similarly, sub-regional cooperation will help ensure that biotechnology and biosafety technical and human resources within SAARC are harnessed to both help with capacity building activities, such as training and study tours, as well as access to technical facilities such as laboratories and equipment for LMO detection. The project activities are designed to promote sharing of information on biotechnology and biosafety within SAARC, working through existing regional structures such as the Working Group on Environment (chaired by Bhutan) and that on Biotechnology. These negotiations will help to develop mechanisms for information sharing within SAARC on biosafety and will enhance a cost-effective approach to setting up regional systems for monitoring and surveillance on LMOs.

PART III: INSTITUTIONAL COORDINATION AND SUPPORT

A. INSTITUTIONAL ARRANGEMENT: The project will be implemented by UNEP and managed at the country level by BAFRA as the National Executing Agency (NEA). The project team responsible for implementing the project will operate under the supervision and guidance from the Project Steering Committee (PSC), which will include representatives from the GNH Commission, and various line Ministries and Agencies, as well as representatives from UNEP, the private sector and civil society. The project team will consist of a full-time National Project Coordinator and 1 administrative-cum-financial assistant; the Executive Director of BAFRA, as the Project Director, will provide overall advice and direction. The PSC will be assisted by Scientific and Technical Advisory Committees, either on a fixed term or an ad hoc basis as necessary. The project team will report to the PSC on implementation of project activities and on progress towards

achievement of project outputs as set out in the M&E plan (Appendix 7 of the UNEP Project Document). The PSC will report to the GNH Commission on progress as set out in Appendix 10.

B. PROJECT IMPLEMENTATION ARRANGEMENT:

National Executing Agency: The Bhutan Agriculture and Food Regulation Authority (BAFRA), which has been designated as the National Competent Authority by the Government of Bhutan under the NBF, will be the National Executing Agency for this project. In implementing the project, BAFRA will work closely with the National Environment Commission (NEC), which is the focal point for Bhutan to the Cartagena Protocol on Biosafety. BAFRA will work on behalf of the Government of Bhutan to manage the project, ensuring that its objectives are met by the end of the project. BAFRA will also provide the necessary scientific, technical, financial and administrative support to the project, working in close co-operation with the NEC and relevant government agencies, the scientific community and the public and private sectors.

The Project Steering Committee (PSC): will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will have representation from the Gross National Happiness (GNH) Commission and government agencies with mandates relevant to the Cartagena Protocol on Biosafety. These will comprise the Ministries of Agriculture, Trade and Industry, Health, Finance, Home and Cultural Affairs, Office of Legal Affairs, and the National Environment Commission. The PSC will also include representation from UNEP, the private sector and civil society. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The PSC will be chaired by the National Project Director; the representative from the GNH Commission will serve as the co-chair. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the PSC are in Appendix 11 of the UNEP prodoc.

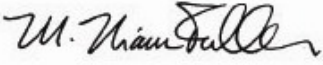
National Project Director: The National Project Director, as head of BAFRA, the National Executing Agency, will provide policy advice and overall direction to the project, as well as coordinating project activities with the NEC and relevant government agencies. He will work on a 25% basis for the project. He will supervise the National Project Coordinator.

National Project Coordinator: The National Project Coordinator will be appointed by the NEA after consultation with UNEP, for the duration of the National Project on a full-time basis. The National Project Coordinator, with assistance from a full-time project administrative/financial assistant, shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the Project Steering Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project, including the preparation of the annual Project Implementation Review (PIR), and participate in the mid-term review and terminal evaluation. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Appendix 11 of the UNEP prodoc.

PART IV: EXPLAIN THE ALIGNMENT OF PROJECT DESIGN WITH THE ORIGINAL PIF: This project design is very closely aligned with the original PIF, which had been revised to incorporate review comments from the GEF Secretariat (Annex B). However, there are two minor changes from the PIF that was approved. The first is that one activity, i.e. a survey of public attitudes about biosafety, which was originally part of Component 2 on Policy, has been shifted to Component 1 on stocktaking as it belongs better there. The costs of this survey and accompanying activities have been also shifted from Component 2 to Component 1. The second difference is that for Component 7 on Regional cooperation, the 8 outputs originally listed in the PIF, which were more activities, have been rephrased and consolidated into 3 more specific outputs; this has not necessitated any change in the budget for this component.

PART V: AGENCY(IES) CERTIFICATION

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

Agency Coordinator, Agency name	Signature	Date (Month, day, year)	Project Contact Person	Telephone	Email Address
<i>Dr. Maryam Niamir-Fuller, Director, UNEP Division. of GEF Coordination, PO Box 30552 Nairobi, Kenya</i>		November 25, 2009	<i>Alex Owusu- Biney, Task Manager, UNEP-GEF</i>	+254-(20)- 762-4066	alex.owusu- biney@unep.org

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

This annex is not applicable as the project was prepared without assistance from a PPG grant from GEF. The project design, utilizing a logical framework analysis, was prepared at the end of the NBF Development in 2006 in consultation with relevant stakeholders through two participatory workshops. The PIF was then prepared by BAFTA and after approval by the GEF CEO, the UNEP project document and the prodoc for GEF CEO endorsement were prepared and discussed with stakeholders at a consultative workshop before finalization. After approval of the PIF by the GEF CEO, the project design was finalized by BAFRA and endorsed at a stakeholder meeting chaired by the Secretary of the Ministry of Agriculture, Mr Sherub Gyaltshen, and opened by the Minister of Agriculture, Dr Pema Gyamtshi.

- A. EXPLAIN IF THE PPG OBJECTIVE HAS BEEN ACHIEVED THROUGH THE PPG ACTIVITIES UNDERTAKEN.**
N/A
- B. DESCRIBE FINDINGS THAT MIGHT AFFECT THE PROJECT DESIGN OR ANY CONCERNS ON PROJECT IMPLEMENTATION, IF ANY: NONE**
- C. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES AND THEIR IMPLEMENTATION STATUS IN THE TABLE BELOW: N/A**

<i>Project Preparation Activities Approved</i>	<i>Implementation Status</i>	<i>GEF Amount (\$)</i>				<i>Co-financing (\$)</i>
		<i>Amount Approved</i>	<i>Amount Spent To date</i>	<i>Amount Committed</i>	<i>Uncommitted Amount*</i>	
N/A	(Select)	N/A	N/A	N/A	N/A	N/A
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
	(Select)					
Total						

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

ANNEX E: CALENDAR OF EXPECTED REFLOWS

NOT APPLICABLE TO THIS PROJECT

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



UNITED NATIONS ENVIRONMENT PROGRAMME

Programme des Nations Unies pour l'environnement Programa de las Naciones Unidas para el Medio Ambiente
 Программа Организации Объединенных Наций по окружающей среде برنامج الأمم المتحدة للبيئة
 联合国环境规划署



PROJECT DOCUMENT

SECTION 1: PROJECT IDENTIFICATION

1.1	Project title:	Implementation of the National Biosafety Framework of Bhutan	
1.2	Project number:	GFL/3850	
		PMS:	
1.3	Project type:	MSP	
1.4	Trust Fund:	GEF	
1.5	Strategic objectives:		
	GEF strategic long-term objective:	BD3 –SP6 (Biosafety)	
	-		
1.6	UNEP priority:	Environmental Governance	
1.7	Geographical scope:	National	Royal Kingdom of Bhutan
1.8	Mode of execution:	External	
1.9	Project executing organization:	Bhutan Agriculture and Food Regulatory Authority, Ministry of Agriculture	
1.10	Duration of project:	48 months	
		Commencing: May 2010	
		Completion: May 2014	
1.11	Cost of project	US\$	%
	Cost to the GEF Trust Fund	869,000	50.4
	Co-financing		
	Cash		
	None		
	<i>Sub-total</i>		
	In-kind		
	Government in-kind contribution	854,000	49.6
	<i>Sub-total</i>	854,000	49.6
	Total	1,723,000	100

Project summary

Bhutan ratified the Convention on Biological Diversity on 25th August 1995 and the Cartagena Protocol on 26th August 2002 and completed its National Biodiversity Strategy and Action Plan in 2002; the BSAP recognized the potential contribution of modern biotechnology to development and conservation of biodiversity.

Bhutan started its project on the development of National Biosafety Framework in May 2004. The final draft of the NBF was completed in June 2006; this draft includes a draft biosafety policy, a draft regulatory framework, a system for handling request to be in conformity with the provisions of the Cartagena Protocol, a system for monitoring and enforcement, and a system for public awareness, education and participation in decision-making on LMOs. The draft NBF was approved by the Royal Government of Bhutan on 2 August 2006.

This project would help Bhutan to strengthen its existing institutional and technical structures and systems needed to meet the obligations of the Protocol and have the National Biosafety Framework fully operational. This project will contribute to:

- The implementation of the Bhutan's legislative framework on the safe use of biotechnology through regulations, orders, guidelines and procedures;
- The preparation of specific technical guidelines, forms and manuals;
- The strengthening of appropriate institutional structures for risk assessment and decision making;
- The development and implementation of policies for biotechnology and biosafety;
- The training of decision makers, scientists, and administrative and technical staff on legal and technical matters;
- The reinforcement of the existing infrastructures (laboratories) to strengthen monitoring
- The setting up of a mechanism for monitoring and enforcement
- The strengthening of communication and information exchange relating to biosafety both at the national level as well as through the BCH
- Systems for strengthening public awareness, education and participation in decision making on LMOs.
- Enhanced regional cooperation on biosafety and biotechnology in the SAARC subregion that will promote: sharing of technical resources and expertise; networking and sharing of information as well lessons and best practices; and alignment of biosafety policies amongst member countries.

Project Objective

To make the National Biosafety Framework fully operational for the benefit of the people and environment of Bhutan consistent with the provisions of the Cartagena Protocol and the Constitution of the Kingdom.

Expected Outcomes

1. Baseline established for information on the safe use of biotechnology in Bhutan through a stocktaking analysis.
2. Biosafety integrated and incorporated into National Priorities on poverty reduction and environment, as well as sectoral action plans and strategies, in conformity with Bhutan's Tenth Plan.
3. A legal and regulatory framework on biosafety in place that is consistent with the CPB, and is workable and responsive to national needs and the National Priorities of the Tenth Plan.
4. A workable system for handling requests, carrying out risk assessment, and decision making for LMOs in place that reflects the priorities of the Tenth National Plan.
5. A workable and effective national system for monitoring, inspections & enforcement in place, including monitoring of socio-economic impacts, that is consistent with National Priority on environment and disaster management.
6. A workable and effective national system for public awareness, education and participation in decision making for LMOs in place, in support of the National Priority on good governance.
7. Enhanced regional cooperation on biosafety in SAARC, as well as sharing of experiences with other NBF Implementation projects globally.

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ACRONYMS AND ABBREVIATIONS

AIA	Advanced Informed Agreement
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
COP/MOP	Conference of the Parties of the Meeting of the Parties
CPB	Cartagena Protocol on Biosafety
EOU	Evaluation and Oversight Unit
ERP	Emergency Response Procedures
FFP	Food, Feed and Processing
GEB	Global Environmental Benefits
GEF	Global Environmental Facility
GNHC	Gross National Happiness Commission
LMO	Living Modified Organism
M&E	Monitoring and Evaluation
MOA	Ministry of Agriculture
NARI	National Agricultural Research Institute
nBCH	National Biosafety Clearing House
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plan
NCA	National Competent Authority
NCB	National Committee on Biosafety
NEA	National Executing Agency
NEC	National Environment Commission
NGO	Non-governmental Organization
NPC	National Project Coordinator
NPD	National Project Director
PIR	Project Implementation Review
PSC	Project Steering Committee
R&D	Research and Development
RNR	Renewable Natural Resources
SAARC	South Asian Association for Regional Cooperation
TOR	Terms of Reference
UNDAF	United Nations Development Assistance Framework
UNEP	United Nations Environment Programme

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

2.1. Background and context

1. Bhutan has a rich and varied biological diversity of regional and global importance that can be matched by very few countries in the world, both in terms of species biodiversity, which includes a large percentage of endemics, and ecosystems diversity, which is still largely intact. The natural forests cover over 64% percent of the country, and Bhutan has a comprehensive Protected Area System, whilst agriculture consists largely of traditional, highly integrated farming systems.
2. Prior to the formulation of its National Biosafety Framework (NBF), Bhutan did not have a biosafety policy per se, but a ministerial decree issued by the Ministry of Agriculture in 2000 banned all imports of LMOs into the country. This was an attempt to ensure that Bhutan was free of LMOs since the domestic biotechnology sector was non-existent, and the only source of LMOs was from imports. However, this moratorium has proved inadequate in meeting the country's food security needs as Bhutan imports more than 35% of its food from neighbouring countries, which have active biotechnology industries and use LMOs in the production and processing of FFPs. Also, national priorities on poverty reduction mean that there is a necessity to increase food production through the safe application of biotechnology in order to increase yields so as to ensure food security. Therefore, the Government of Bhutan intends to lift the existing moratorium and to replace it with adequate biosafety systems that will help minimise any risks to the environment and human health from imports that may contain LMOs, as well as enabling the country to import LMOs for crop and livestock breeding programmes in order to increase yields.
3. In line with its National Priorities set out in the Tenth Plan (2008-2013), Bhutan is seeking to provide viable alternatives to the high level of food imports and the Government is promoting food security through investment in R&D to meet the needs of small farmers in all regions of the country. The mandate of the Research Centres of the Ministry of Agriculture is to improve agriculture production, and raise the per capita income of the rural population through technologies and information that will help to maintain and improve existing genetic and biophysical resources of the country. Therefore it is very likely that these research centres will, in future, be the main entry points for LMO crops, seeds, and livestock; they would also be responsible for carrying out extensive field trails of new crops, seeds and livestock imported from outside prior to release to farmers. Bhutan therefore needs to have in place adequate biosafety systems to enable the country to benefit from the safe application of modern biotechnology. In order to do this, Bhutan has developed a NBF with assistance from UNEP-GEF, and is seeking further assistance in order to implement this NBF.
4. The implementation of the NBF for Bhutan is therefore timely and would address its concerns as a landlocked country with an open and porous border. Bhutan's major concern is the safety of its citizens and its almost pristine environment; but at the same time, increasing food security and food self-sufficiency are critical objectives. The use of biotechnology to achieve these objectives is a likely course of action for the country. Therefore the NBF takes a balanced approach to safeguard Bhutan while meeting important food security objectives.
5. The project will enable Bhutan to: (i) Monitor imports of foods and seeds to control any illegal transboundary movement of LMOs; (ii) monitor illegal planting of LMOs from seeds smuggled across its borders from neighbouring countries; (iii) evaluate dossiers for applications to import LMOs; and (iv) carry out and monitor field trials for LMOs introduced by CGIAR centres in conjunction with the research Centres of the Ministry of Agriculture.

6. Bhutan successfully completed the preparation of its draft NBF in 2006 and developed draft Biosafety Rules and Regulation under the Food Act of Bhutan, 2005. The National Environment Commission (NEC) adopted the NBF, including the draft regulation in August 2006. This regulation will become law once it is promulgated by the Minister of Agriculture under the Food Act. The project for the implementation of Bhutan's NBF will help to operationalise the policy, legislative, administrative, monitoring and enforcement systems set up in the draft NBF, and help to ensure that these are fully integrated into the country's development plans and decision-making processes; this will help to promote sustainability of the outcomes.

2.2. Global significance

7. Bhutan ranks in the top ten percent of countries with the highest species density (species richness per unit area) in the world. Bhutan's richness in biological diversity is due to its location at the juncture of the Palearctic realm of the temperate Eurasia and the Indo-Malayan realm of the Indian sub-continent, and also due to the country's geological relief and climatic heterogeneity. The **Global Environmental Benefits (GEB)** from implementation of this project include the conservation and sustainable use of Bhutan's rich biodiversity by minimizing any risks to economically important plants and animals as well as their wild relatives, from the application of biotechnology in the country, or from the importation of LMOs in food or feed products. Bhutan's wealth of agrobiodiversity includes a number of economically significant plants and animals; for instance, many of Bhutan's crop varieties represent adaptations to some of the most extreme altitudinal agricultural lands in the world, with cultivation in the alpine agro-ecological zone extending up to 4600m. While wheat is not an indigenous crop, varieties grown around Laya are adapted to higher elevations and more extreme conditions than wheat varieties in any other part of the world. Maize is another example of a crop that was originally exotic, but which has undergone a process of breeding and selection to create unique high-elevation varieties.
8. Other crop plants have also been domesticated *in situ*. For example, buckwheat is an indigenous crop, and at least one putative wild relative, *Fagopyrum debotrys*, is found in natural ecosystems in Bhutan. Foxtail millet is another indigenous crop, with a wild relative, *Setaria viridis*. Two wild relatives of oats, *Avena fatua* and *A. sativa* are found in Bhutan. There are also numerous wild relatives of horticultural crops like apple, pear and citrus in the temperate and sub-tropical forest zones of Bhutan. These wild relatives of crop and horticultural plants in Bhutan provide a potential genetic resource that could prove beneficial for international breeding programmes for increasingly important crops such as buckwheat (e.g. for production of gluten-free flour), oats and millet. Bhutanese rice is unique in that it represents an intermediate type between the two major groups of *Oryza sativa*, "indica" and "japonica" ("javanica" is a less significant third group). There are estimated 250-300 varieties of rice in Bhutan, many adapted to much localized conditions, and thus representing a unique genetic resource. Some of these traditional varieties are very close to wild relatives; for example, Bhutan is also home to at least two wild relatives of rice, *O. minuta* and *O. rufipogon*.
9. Among the livestock genetic resources, siri is a *Bos indicus* breed of cattle, believed to have originated in Sombe geog, in Haa dzongkhag. It is characterized by disease resistance, strength and high butterfat content of its milk. Mithun is a descendent of gaur, and probably originated in India, Burma and/or Bangladesh, but has been bred in Bhutan since at least the 17th century. Mithun are often crossbred with siri. Yak is a *Bos gruniens* bovine species, used throughout the Himalayas and on the Tibetan plateau. There appear to be distinct genetic differences between yaks in eastern and western Bhutan, with higher levels of genetic diversity in the east. Goleng is a *Bos taurus* cattle, probably originating in Tibet, and

sometimes used for cross-breeding with yak. Other significant animal breeds include the Nublang (a local native cattle breed), blue sheep, Takin (*Budorcas taxicolor*), and at least four unique breeds of horse known as *Bayta*, *Yuta*, *Mera-Saktenpata*, and *Jata*. There are also breeds of sheep, pigs, and poultry that are unique to Bhutan.

10. These traditional plant varieties and animal breeds are the genetic foundation for future breeding programmes and R&D efforts to meet national food security priorities and to address global challenges such as innovative, adaptive agriculture to mitigate climate change. However, as local traditional farming practices often result in close cohabitation of domesticated and wild species, the risks of gene transfer from field release of genetically modified species to traditional or wild varieties and breeds are significant. The biosafety systems that will be put in place through the implementation of this project will therefore ensure that any field releases of transgenic plants or animals will undergo thorough scientific risk assessment, and the imposition of stringent safeguards to prevent any risks to the country's rich agrobiodiversity.
11. The global benefits from the project include the conservation and sustainable use of Bhutan's rich biodiversity by minimizing any risks to economically important plants and animals as well as their wild relatives, from the application of biotechnology in the country, or from the importation of LMOs. As stated in its Policy statement 1, GEF support is intended to "improve the global environment or advance the prospect of reducing risks to it". In the absence of quality baseline data for biodiversity and the rate of change in biodiversity arising from other causes, it is very difficult, if not impossible, to provide measurable indicators of the impact of biosafety on biodiversity – these would arise only as a "decline-avoided" by the rejection of an unsafe application of biotechnology. An adequate biosafety regulatory system thus fits well with "advancing the prospect of reducing risks to the global environment".

2.3. Threats, root causes and barrier analysis

12. In Bhutan, there is a low awareness of both the potential costs and benefits of biotechnology and the need for the introduction of biosafety systems as these are relatively new concepts to the country. This lack of awareness could hamper the successful implementation of the project; hence capacity building activities, particularly in terms of awareness raising for both decision-makers and the public, are key project components.
13. In addition to the lack of awareness, Biosafety capacity in Bhutan is relatively underdeveloped whilst there is increasing pressure both for the importation of LMOs into the country and for application of biotechnology in order to increase agricultural production and promote food security. Therefore the primary focus of this project is on capacity building, institutional strengthening and the introduction of systems for risk assessment and management, as well as monitoring and surveillance in order to ensure the safe and sound application of biotechnology.
14. Another threat that could impact on the successful implementation of this project results from a lack of coordination both within and between Government institutions in some areas. For example, whilst monitoring and surveillance systems for animal health function well in the country, those for plant health suffer from poor coordination both between different agencies at the local level and between different levels from local to district to national. The project aims to identify these constraints and to utilize the lessons and best practices from animal health surveillance systems to ensure sound coordination of biosafety monitoring and surveillance activities.
15. Another potential threat is the liberalization of border and trade controls as a result of regionalization and the introduction of free trade agreements with neighbouring countries such

as India that could result in lax controls on the transboundary movement of LMOs and their products. Therefore, the emphasis on regional cooperation in the project, which includes the alignment of policies and procedures as well as mechanisms for information sharing on biosafety, will help to ensure that these initiatives contain biosafety safeguards that meet Bhutan's requirements under its NBF.

2.4. Institutional, sectoral and policy context

16. The NEC as the CBD and CPB Focal Point coordinated the formulation of the NBF for Bhutan. One of the key recommendations of the NBF, which was accepted by the Government, was that the Bhutan Agriculture and Food Regulatory Authority (BAFRA) be designated as the National Competent Authority (NCA) as required by the CPB. BAFRA is an agency of the Ministry of Agriculture (MOA) and has experience implementing legislation such as the Food Act, Seeds Act, the Plant Quarantine Act, and the Livestock Act, all of which impact on biosafety. Although BAFRA lacks autonomous decision-making power since it is under the MoA, it has several advantages such as experience with biosafety related legislation, human resources that can be further developed to meet specific biosafety needs, and infrastructure such as laboratories that can be upgraded for biosafety purposes. BAFRA's chief mandate is to promote the quality of goods and products related to the MoA and its clients, and coordinate and liaise with other agencies concerned with the quality of local and imported products. With its crosscutting mandates, BAFRA therefore is an ideal choice to serve as a key regulatory and monitoring agency with regards to import of LMOs for food, feed and processing (FFP), whilst the NEC would continue to function as the National Focal Point under the CPB.
17. A number of other Government agencies are also likely to be involved in the implementation of the NBF project. These include the NEC, departments and agencies of the Ministry of Agriculture, i.e. Forestry, Agriculture, Livestock, Council of RNR Research of Bhutan, and National Biodiversity Centre, the Ministry of Health, Ministry of Trade, Department of Revenue and Customs, and the Ministry of Home and Cultural Affairs.
18. The overall policy context for biosafety is provided by the Constitution of Bhutan, which was adopted in 2008, provides the overall guiding principles for the National Biosafety Policy; Article 5, Section 1 of the constitution states that: *“Every Bhutanese is a trustee of the Kingdom's natural resources and environment for the benefit of the present and future generations and it is the fundamental duty of every citizen to contribute to the protection of the natural environment, conservation of the rich biodiversity and prevention of all forms of ecological degradation including noise, visual, and physical pollution through the adoption of environment friendly practices and ethos.”*
19. Currently, the Royal Government of Bhutan has in place several pieces of legislation on environment, agriculture, food, health, and trade policy to protect the country's rich biological diversity and the well being of the people, which have an indirect impact on biosafety and regulation of LMOs. These are listed in the country's NBF.

2.5. Stakeholder mapping and analysis

20. Biosafety is a cross-cutting issue, which relates to several sectors, including environment, agriculture, rural development, health, science and technology, industry, trade, etc as well as community-based organizations, consumer association. NGOs and the private sector. These stakeholders were identified during the NBF development project and have been increasingly involved both in the development of the NBF and the preparation of this proposal. The main stakeholders involved in designing this project include Government agencies such as the Ministries of Agriculture, Trade and Industry, Health, Finance; Department of Tourism;

National Environment Commission; private sector representatives; NGOs including women's groups and environmental organizations. These stakeholders were involved through meetings to discuss the different components of the project, as well as by giving comments on drafts of the proposal. Once the project is approved, the different stakeholders will be involved in carrying out project activities, including researching, taking part in workshops, seminars and others.

21. This project will also promote public participation in decision making on LMOs by ensuring that mechanisms for public involvement in biosafety management are developed as part of component 6 on public awareness and participation. However, at present general public awareness, education, and participation for biosafety-related issues is in its infancy; the project will need to follow the examples of other sectors such as health and diseases awareness, agricultural extension, and so on, in order to raise awareness of the general public on biosafety.
22. For example, the Information and Communication Bureau, Ministry of Health, the leading institution in health education and communication, aims to achieve a significant reduction in morbidity and mortality through changing health behaviour. This is done by developing and implementing communication initiatives such as newspaper advertisements, TV commercials, and door to door campaigning.
23. Another example is the Information and Communication Services of the Ministry of Agriculture, which consists of four functional sections: Publications, Audio/Video, Information Technology and One Stop Information Shop. Its mandate is to design, develop, and produce information and communication materials in support of the Renewable Natural Resource (RNR) programs, serve as the portal of RNR information and activities and promote RNR programs and activities. BAFRA would be able to utilize its services for publicity campaigns on biosafety.

2.6. Baseline analysis and gaps

24. Prior to the formulation of its NBF, Bhutan did not have any biosafety systems in place except for a ministerial decree that banned all imports of LMOs into the country (see section 2.1 above). However, this decree was never put into practice, as the country does not have the institutional, legislative or human capacity to be able to monitor imports. This gap needs to be urgently addressed both in terms of regulating imports of food and food products and for promoting food security through increased agricultural production. Moreover, a ban on importation is not consistent with Bhutan's obligations as a Party to the Cartagena Protocol.
25. The draft NBF helps to set up the systems necessary for the safe transfer, handling and use of LMOs resulting from modern biotechnology, including a regulatory instrument which was approved by the Government in June 2006 but has yet to be promulgated. However, the existing systems for implementing the regulations, including handling applications, risk assessment, decision-making, monitoring, enforcement, and public participation in decision-making do not have the institutional and human resources capacity to be able to operationalize the NBF in order to enable Bhutan to fulfil its obligations as a Party to the Cartagena Protocol and to meet its national needs and priorities for sustainable development.
26. BAFRA, as the NCA, has been assigned the task of carrying out the administrative tasks for the NBF as well as the monitoring and inspection of LMO releases. Although it has facilities for monitoring food and seed quality for conventional crops, it lacks both the laboratory facilities and human resources to be able to carry out its assigned functions for the regulation of LMOs and their products. Therefore, unless adequate support is provided to the country for the implementation of its NBF, it is likely to become a document that sits on the shelf rather

than a workable system able to meet the country's environmental and development needs and priorities.

27. At the same time, the unique and globally significant biological diversity in the country needs to be protected from the inadvertent impacts of biotechnology. Therefore, unless the NBF is made operational in an effective and efficient manner, there is a potential threat to this rich biodiversity, both to native ecosystems and species and to plants and animals of agricultural importance. There is an urgent need to protect this rich biodiversity by building human capacity, strengthening institutional facilities (including laboratories) and implementing regulatory instruments for the safe and sound management of LMOs.

2.7. Linkages with other GEF and non-GEF interventions

28. The NBF implementation project has been developed by the BAFRA in close cooperation with the National Environment Commission (NEC), and will be implemented by BAFRA, an agency of the Ministry of Agriculture. A project steering committee with representatives of all relevant Government agencies, including the NEC, will help ensure coordination with Government priorities and with other externally funded development projects. This will include projects such as the "Integrated Livestock and Crop Conservation" and the national capacity self-assessment programmes, and projects such as the gender-mainstreaming project.
29. Oversight of all projects and programmes in Bhutan is the responsibility of the Gross National Happiness (GNH) Commission; this project has been developed by BAFRA in consultation with the GNH Commission, which will continue to provide policy direction and ensure that project implementation is consistent with national priorities.
30. Sub-regional cooperation within SAARC on biosafety and the safe use of biotechnology will be enhanced through sharing of experiences on implementing the NBF with other countries also implementing their NBF, such as India, Pakistan, Sri Lanka and Bangladesh, through regional meetings and support for the sub-regional mechanisms for sharing information developed through the SAARC networks on environment and biotechnology. The sharing of information on LMOs with other members of SAARC will eventually promote regional harmonization of standards and regulations on LMO management. The sharing of technical facilities and expertise between members of SAARC will also help promote sub-regional and South-South cooperation.

SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)

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

31. The implementation of the NBF for Bhutan is timely and addresses the concerns of Bhutan as a landlocked country with an open and porous border. Bhutan's major concern is the safety of its citizens and its almost pristine environment. Yet at the same time increasing food security and food self-sufficiency are critical objectives pursued by Bhutan as a sovereign kingdom. The use of biotechnology to achieve these objectives cannot be denied. Therefore the NBF is a balanced approach to safeguard Bhutan while meeting important food security objectives.
32. This project proposal was prepared by BAFRA as the national competent authority under the NBF as approved by government. The project was designed using the information collected during the stocktaking exercise carried out for the development of the NBF, and in consultation with stakeholders through a workshop to help identify the components and structure of the project logframe.
33. This project is designed to implement the national Biosafety Policy of Bhutan, which is framed within the overall context of Bhutan's unique development philosophy of increasing Gross National Happiness. The Government shall safeguard the health of the citizens of Bhutan and protect the biodiversity and the natural environment of Bhutan from the adverse impacts of modern biotechnology. At the same time Bhutan should benefit from the safe use of modern biotechnology and the Government shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve food security, improve health services, and promote industrial development. The guiding principles for the biosafety policy are based on national and international law.
34. The Global Environmental Benefits (GEB) that would be derived from the implementation of this project, which would build a workable and robust management system of biosafety, is the avoidance of harm to some 250 to 300 traditional rice varieties, some of which are very close to wild relatives in Bhutan. In addition to rice, Bhutan also has vast biodiversity in other food crops (legumes, millet, buck-wheat, etc.) and local animal breeds that could be put at risk by the indiscriminate release of LMOs. These traditional varieties are the genetic foundation for future breeding programmes and R&D efforts to meet national priorities, for example food security, and to address the global challenges such as innovative, adaptive agriculture to mitigate climate change. Although the GEB that will accrue from the protection of Bhutan's flora and fauna are highly significant, most of these potential benefits are intangible and will be apparent only in the long term, particularly as this Biosafety project will contribute to several cross-cutting areas, such as environment, agriculture, health and good governance.

3.2. Project goal and objective

35. To make the National Biosafety Framework fully operational for the benefit of the people and environment of Bhutan consistent with the provisions of the Cartagena Protocol and the Constitution of the Kingdom.

3.3. Project components and expected results

36. The project components and expected results are as follows:

Project Component	Expected Results
1. Baseline established for information on the safe use of biotechnology in Bhutan through a stocktaking analysis.	1.1 Inventory of current national human, technical and institutional capacities to implement a comprehensive biosafety management system. 1.2 Accurate information on how Biosafety can be harmonized with National Laws, policies and plans, and built into existing Monitoring and Enforcement systems. 1.3 Biosafety systems are consistent with national priorities on gender mainstreaming, and human rights, including participation by all sectors in decision-making.
2. Biosafety integrated and incorporated into National Priorities on poverty reduction and environment, as well as sectoral action plans and strategies, in conformity with Bhutan's Tenth Plan.	2.1 Biosafety policy approved & implemented by Government by end of 2010. 2.2 Biosafety policy integrated into the Tenth Plan and reflected in the National Priorities, and sectoral action plans by end-2011.
3. A legal and regulatory framework on biosafety in place that is consistent with the CPB, and is workable and responsive to national needs and the National Priorities of the Tenth Plan.	3.1 Biosafety Rules and Regulation promulgated by the Minister of Agriculture under the Food Act of Bhutan, 2005 to replace the existing Moratorium on import of LMOs. 3.2 Relevant biosafety procedures, protocols and guidelines prepared and promulgated by relevant Government agencies. 3.3 Existing laws and legislations revised to ensure consistency with biosafety regulation and CBP by end of 2012.
4. A workable system for handling requests, carrying out risk assessment, and decision making for LMOs in place that reflects the priorities of the Tenth National Plan.	4.1 A fully functional administrative system for handling requests for LMOs. 4.2 A fully functional system for risk assessment and decision-making. 4.3 An efficient system for handling, storing and exchanging information on biosafety in place under the nBCH.
5. A workable and effective national system for monitoring, inspections & enforcement in place, including monitoring of socio-economic impacts, that is consistent with National Priority on environment and disaster management.	5.1 Fully functional and effective inspection, monitoring and enforcement system in place in BAFRA. 5.2 Strengthened BAFRA laboratories able to detect LMOs. 5.3 Emergency response procedures (ERP) established & made operational by BAFRA, the NEC and relevant Govt agencies.
6. A workable and effective national system for public awareness, education and participation in decision making for LMOs in place, in support of the National Priority on good governance:	6.1 Fully functional system for access to, and sharing of information in place in Bhutan by end of 2011, inter alia through the establishment of a national BCH under the BCH project. 6.2 Strengthened system for public awareness on the safe use of LMOs in place. 6.3 Strengthened system for public participation in decision-making on LMOs in place.

<p>7. Enhanced regional cooperation on biosafety in SAARC, as well as sharing of experiences with other NBF Implementation projects globally:</p>	<p>7.1 Technical expertise, decision-making tools, training activities and materials for training and outreach with other countries in SAARC.</p> <p>7.2 Alignment of biosafety policies, regional mechanisms and common formats for sharing of information amongst SAARC countries on biosafety.</p> <p>7.3 Establish networks established with other Implementation project teams for sharing experiences, lessons & best practices.</p>
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3.4. Intervention logic and key assumptions

37. The main objective of this project is to assist Bhutan to have a workable and transparent NBF by May 2014 so as to contribute to the fulfilment of the Tenth Plan whilst ensuring that consistency with the provisions of the Constitution of the Kingdom and to fulfil its obligations as a Party to the CPB. As shown by the incremental cost analysis, (Appendix 3), Bhutan has relatively low baselines for most of the key outcomes. It can be safely assumed that, without GEF intervention, Bhutan will not be able to build the necessary human and institutional capacity in its national institutions for the safe application of biotechnology. Therefore the most important project intervention is capacity building in scientific, technical and administrative areas of biosafety. When sufficient national capacity has been built, it will be possible to put in place all the necessary outcomes for the safe use of biotechnology. Although a small number of individuals received some training in biosafety under the previous UNEP/GEF project on NBF Development, further training on more specific areas like risk assessment, biosafety administration, monitoring and legal drafting are required. Without this key intervention on scientific and technical training, this critical group of national "experts" will move away, and the results of the previous project which provide building blocks for this project, will be lost. Another assumption is that without the vital interventions on administrative training and coordination, effective implementation of biosafety systems will not be possible. Applications for LMOs will not be processed within time frames stipulated by the CPB, and decision making will be delayed owing to inadequate technical capacity. International trade on LMOs could therefore be disrupted, and imports of food and feed could be adversely affected. In addition, the country will not be able to make use of transgenic breeding materials for improving agricultural production for plants and animals.

3.5. Risk analysis and risk management measures

38. The following table summarizes the “Risks” and “Mitigation Measures”; these are elaborated on further in the subsequent paragraph, 39 to 43. Presently, there are no reported climate change risks associated with the release of LMOs.

Major Risks	Mitigation Measures
Biosafety capacity in Bhutan is relatively underdeveloped whilst there is increasing pressure both for the importation of LMOs into the country and for application of biotechnology in order to increase agricultural production and promote food security.	<p>The project will:</p> <ol style="list-style-type: none"> 1. Help put in place systems for handling LMO applications, including risk assessment; 2. Put in place systems for monitoring and enforcement for all LMO application; 3. Put in place systems for monitoring and emergency responses in case of illegal or accidental transboundary movement of LMOs from neighbouring countries; 4. Build national capacity for the safe use of biotechnology; 5. Promote regional cooperation on biosafety within SAARC for information sharing on intentional or accidental LMO releases as well as coordination of emergency responses.
Biosafety is often seen as a constraint to the application of biotechnology to help improve food security.	<ol style="list-style-type: none"> 1. Implementation of the NBF will be under the Ministry of Agriculture, which will work with the NEC to ensure that biosafety systems are fully integrated into biodiversity and agricultural priorities in the country. 2. Project activities will also focus on raising awareness amongst decision-makers about the synergies between biosafety and application of biotechnology for food security.
Possible lack of political support from Government with respect to the implementation of the Biosafety Regulations in Bhutan.	<ol style="list-style-type: none"> 1. International commitment demonstrated through GEF funding also requires an equal financial contribution from Government. 2. Integration of biosafety into national plans and policies will help promote political support for biosafety by demonstrating how adequate biosafety systems would enhance the safe application of biotechnology in order to deal with challenges of food security and climate change 3. Bhutan’s role as a leader in environmental issues within SAARC will also help to establish the importance of regional cooperation on biosafety and the safe use of biotechnology.

39. As highlighted in the table above, major risk to the achievement of the project's objectives is that biosafety capacity in Bhutan is relatively underdeveloped. As food security is a major development priority for Bhutan, there is increasing pressure both for the importation of LMOs into the country, as well as for the application of biotechnology in order to increase agricultural production and promote food security. The project will help the country to build up its biosafety capacity in order to:

- (i) Ensure that adequate safeguards are in place (i.e. systems for handling applications and monitoring mechanisms)) for regulating imports of LMOs so that Bhutan is able to promote trade in agricultural products with its neighbours in SAARC.
- (ii) Put into place systems (i.e. monitoring mechanisms, emergency responses, enforcement) in case releases of LMOs in neighbouring countries result in accidental or illegal transboundary movement into Bhutan. Strengthened biosafety systems in Bhutan, as well as the fostering of regional cooperation within SAARC, will help promote sharing of information between countries to prevent such occurrences, and to build up mechanisms for working cooperatively on responses to any emergencies concerning LMOs.
- (iii) Put in place systems for managing the safe application of biotechnology in the country so that Bhutan is able to harness the potential benefits of biotechnology for improving food security through more effective utilisation of the country's genetic biodiversity whilst ensuring that systems are in place for protecting biodiversity and human health. Moreover, it will be possible for the biotechnology sector to assist farming systems to adapt to changes in ecosystems caused by climate change.
40. Functional biosafety systems will also help to ensure that adequate risk assessment, post release monitoring strategies, technical capabilities and information are available at the national and regional level to minimize any potential loss of genetic resources and biodiversity due to the transboundary movement of LMOS as well as through the impacts of climate change.
41. Another potential risk to the successful implementation of the project is the split between environment and agricultural development priorities as biosafety is often seen as a constraint to the application of biotechnology to help improve food security. However, in Bhutan, the implementation of the NBF will be under the Ministry of Agriculture, which will work with the NEC to ensure that the biosafety systems are fully integrated into biodiversity and agricultural priorities in the country. The stocktaking at the inception of the project will be a crucial step in this integration of the work of the project into national priorities, plans and policies in biotechnology, agricultural development and environmental conservation.
42. Another potential risk is the lack of political support from Government with respect to the implementation of the Biosafety Regulation in Bhutan. Successful implementation of the project will not only demonstrate international commitment to the implementation of the CPB through the financial involvement of GEF, but will also require the Government to demonstrate its commitment by allocating financial, human and institutional resources to the project. The integration of biosafety into national plans and policies will help promote political support for biosafety by demonstrating how adequate biosafety systems would enhance the safe application of biotechnology in order to deal with challenges of food security and climate change. It will also establish the importance of biosafety within the SAARC sub-region by promoting regional cooperation on biosafety and the safe use of biotechnology.
43. The project activities are designed to promote financial sustainability of the systems for handling LMO applications by exploring and putting in place "fees-based" or "user-pays" financial mechanisms for funding most of the costs of running these systems after the completion of the project. These fees for handling LMO applications will complement both investments by government in technical facilities, as well as future ongoing budgetary allocations for recurrent costs of implementing the NBF. The monitoring systems to be put in place as part of the implementation of the NBF will include systems for inspections and enforcement (see Component 5 of project).

3.6. Consistency with national priorities or plans

44. Bhutan's priority is to safeguard the biodiversity of the country and the health of its citizens from the potential adverse effects of modern biotechnology and, at the same time, to be able to benefit from the safe and proven benefits of this technology. Currently, the Royal Government of Bhutan has in place several pieces of legislation on environment, agriculture, food, health, and trade policy to protect the country's rich biological diversity and the well-being of the people whilst promoting sustainable development. These policies have a direct or indirect impact on biotechnology and biosafety issues, and regulation of LMOs. For example, the foreword of the Biodiversity Action Plan for Bhutan 2002 clearly articulates the desire to pursue the use of LMOs to increase agricultural productivity: "For our country, biotechnology holds bright prospect, and we must move that direction as quickly as possible. The golden bridge linking development and conservation is biotechnology".
45. The current project proposal will help Bhutan to strengthen its capacity for the implementation of the NBF in the context of both the Cartagena Protocol, and national development priorities. This is crucial for the success and sustainability of the NBF. A key issue is the strengthening and development of human resources for biosafety, and the strengthening of appropriate facilities involving the transfer of know-how. The stocktaking exercise, which will be undertaken at the inception of the project, will help to ensure that the project will build on the existing human and institutional resources in the country, and that the biosafety laws and regulations will be harmonised with existing laws and policies so as to promote and support the country's national development priorities.
46. Specifically, these project outputs will contribute to the following National Priorities in the Tenth Plan (2008-2013), and the outcomes for the UNDAF for the period 2008-2013:
 - a. The strengthening of biosafety systems by the project will enable Bhutan to harness biotechnology in order to improve agricultural production particularly for subsistence crops, thus enhancing sustainable livelihoods for the rural poor. This will contribute to income generation in rural areas, thus helping to reduce poverty; this is one of the key National Priorities under the Tenth Plan, and more specifically reflected in the 10th Five Year Plan of BAFRA under program 28 – Biosecurity and Quality Assurance Program, and the first planned outcome of the UNDAF.

The strong emphasis on promoting public participation in decision-making on LMOs through awareness and education as well as strengthening institutional systems to enable effective participation will enhance good governance; this is also a National Priority under the Tenth Plan and the fourth planned outcome of the UNDAF.
 - b. By putting in place functional systems for biosafety, including ERP, the project will help to safeguard the biodiversity of the country, and so will contribute to the National Priority of the Tenth Plan and the fifth planned outcome of the UNDAF on environmental sustainability and disaster management.
47. The project will also contribute to gender mainstreaming through: (i) the stocktaking exercise which will help ensure that project activities are consistent with all national priorities, including gender mainstreaming; (ii) establishing monitoring systems that take into account socio-economic impacts on all sectors of society, including both men and women; (iii) Ensuring participation by all stakeholders, both men and women, in decision-making on LMOs.

48. The project will contribute to human rights by promoting good governance through the participation of all stakeholders in decision-making on LMOs, and the strengthening of institutions that will promote effective participation by all stakeholders. This will include participation by stakeholders in the development of the project design and in the stocktaking exercises.
49. The project will also support Government's objectives on promoting regional cooperation with SAARC countries in a number of areas including biotechnology and environment. By helping to include biosafety into the agendas of the SAARC Working Groups on Biotechnology and on the Environment, the project will help initiate discussion and cooperation on biosafety within SAARC. Bhutan is well placed to do this as it currently chairs the Environment Working Group for SAARC. The project will also strive to ensure that Biosafety is included in the planned SAARC activities in Biotechnology such as the "Plan of Action for Cooperation in Biotechnology" and the "Institutional Framework for biotechnological Cooperation".

3.7. Incremental cost reasoning

50. Prior to the formulation of its NBF, Bhutan did not have any biosafety systems in place except for a ministerial decree issued by the Ministry of Agriculture in 2000 that banned all imports of LMOs into the country. This attempted to ensure that Bhutan would be free of LMOs since the domestic biotechnology sector is non-existent and the only source is from imports. However, this decree was never put into practice as the country does not have the institutional, legislative or human capacity to be able to monitor imports. This gap needs to be urgently addressed as Bhutan imports more than 35% of its food needs from Asian countries which have active biotechnology industries and use LMOs in the production and processing of food and feed. Moreover, a ban on importation is not consistent with Bhutan's obligations as a Party to the Cartagena Protocol.
51. The draft NBF helps to set up the systems necessary for the safe transfer, handling and use of LMOs resulting from modern biotechnology, including a regulatory instrument under the Food Act 2005 that will replace the previous ban with a system based on the Cartagena Protocol which will consider all imports of LMOs and their products on a case-by-case basis. However, at present Bhutan lacks the institutional capacity and human resources to be able to operationalise its NBF. Moreover, the country needs to develop and strengthen its existing systems in order to effectively implement the new regulations; these systems include handling of applications, risk assessment, decision-making, monitoring, enforcement, and public participation in decision-making.
52. The ban on LMOs and their products, if it were to be enforced, would cause severe problems with food security in the country as some 35% of the food needs are imported. In the long term, the ban on LMOs also means that the national agricultural research institutes in the country are unable to have access to new cultivars developed through gene technology. In particular, genetically modified cultivars developed by CGIAR institutes in Asia are not accessible to the country since both IRRI and ICRISAT will only introduce genetically modified cultivars of crops in countries that have working biosafety regulations. Although genetically modified subsistence crops have the potential to improve agricultural production by small farmers in Bhutan and thus promote food security, the NARIs are currently unable to bring in these genetically modified cultivars and test them in Bhutan. Allowing this to be done on a case-by-case basis would therefore improve both food security and the livelihoods of small farmers in Bhutan. Moreover, regulated importation of genetically modified food and feed products would also be facilitated by effective application of the new regulations. Therefore it is crucial that the regulatory, administrative, monitoring and public participation systems contained in the NBF are operationalised as soon as possible so that the country is

able to manage importation of LMOs and their products in line with its obligations under the Cartagena Protocol and in support of national development plans.

53. The proposed NCA has been assigned the task of carrying out the administrative tasks for the NBF as well as the monitoring and inspection of LMO releases. Although it has facilities for monitoring food and seed quality for conventional crops, it lacks both the laboratory facilities and human resources to be able to carry out its assigned functions for the regulation of LMOs and their products. Therefore, unless adequate support is provided to the country for the implementation of its NBF, it is likely to become a document that sits on the shelf rather than forming the basis of a functioning system to meet the country's environmental and development needs and priorities.
54. Bhutan has a rich and varied biological diversity that has regional and global importance. Very few countries in the world match Bhutan's biological diversity. Bhutan ranks in the top ten percent of countries with the highest species density (species richness per unit area) in the world. Therefore, unless the NBF is made operational in an effective and efficient manner, there is a potential threat to this rich biodiversity, both to native ecosystems and species and to plants and animals of agricultural importance. There is an urgent need to protect this rich biodiversity by building human capacity, strengthening institutional facilities (including laboratories) and implementing regulatory instruments for the safe and sound management of LMOs.
55. GEF involvement would lead to the successful implementation of the NBF and enable Bhutan to fulfil its obligations as a Party to the Cartagena Protocol, and to meet its national needs and priorities for sustainable development. The involvement of GEF would also help to act as a catalyst to enlist financial and political support from the Government, thus promoting sustainability of the outcomes of the project.

3.8. Sustainability

56. Bhutan faces many challenges in fulfilling its obligations to the Cartagena Protocol because of a lack of institutional capacity, inadequate laboratory facilities, and inexperienced scientific staff. By assisting Bhutan to have a workable and transparent National Biosafety Framework in place by end of 2014, this project will not only enable Bhutan to meet its obligations under the Cartagena Protocol, but will also promote the sustainability of the systems established under the NBF.
57. To overcome the challenges faced by Bhutan, project activities will focus on building capacity within the country on developing and implementing policy, strengthening the regulatory regime, strengthening systems for handling request for permits, follow-up and public participation. All these activities will be carried out in order to make long-term impacts in the following areas:

Institutional and operational terms: the project will strengthen institutional aspects on biosafety, including building capacity for the national competent authority (NCA) in biosafety management, and developing a workable system for follow-up, risk assessment and handling requests. 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 and participation in decision-making on LMOs. When the NCA has been strengthened, they themselves can manage and deal with biosafety issues after the end of the project.

Furthermore, project will help to develop a legal framework, which clearly defines functions and responsibilities of relevant institutions/ministries on biosafety, provides provisions for

LMO management, commercialising LMOs and their products. The legal framework will facilitate Bhutan's ability to fulfil its obligations to the Cartagena Protocol.

Sub-regional cooperation with South Asian countries on biosafety and the safe use of biotechnology will be promoted by working with SAARC and sharing of training activities with other countries also implementing their NBF. This will help to make best use of existing scientific expertise and institutional resources within the SAARC sub-region; the sharing of training costs will enable the projects to call in more resource people for the training activities. 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.

Financial and political terms: the most significant activity that the project will carry out will be to help Government recognize the importance of biosafety for sustainable development by approving the National Policy on Biosafety. The project will also help to integrate biosafety into relevant national sectoral plans and strategies so as to demonstrate the importance of biosafety for a wide range of sectors such as agriculture, livestock, forestry, health, trade, etc. The project also aims to enhance the awareness of Government, organizations and individuals about biosafety and will help these players to recognize the importance of biosafety for national development, thus encouraging investment in biosafety and the safe use of biotechnology.

The project activities will also promote the financial sustainability of the systems for handling LMO applications by exploring and putting in place "fees-based" or "user-pays" financial mechanisms to complement investment by government and budgetary allocations for recurrent costs of implementing the NBF.

Environment terms: The effectiveness with which the Cartagena Protocol is implemented will help avoid any adverse impacts on Bhutan's rich biodiversity as well as on human health. Thus the protection of the global contribution of Bhutan's rich heritage of species and ecosystems diversity will be conserved and will help promote the sustainable management of these resources in order to provide both national and global benefits.

3.9. Replication

58. This project is a "national executed" project that promotes the role of the recipient country in developing and implementing project activities. Experiences gained from the project implementation, particularly in terms of project management, coordination of activities of different agencies, promoting public participation in developing policies and in decision making, and ensuring that scientific development goes hand-in-hand with efforts in raising public awareness and education, will benefit and inform the development of public policies and processes in other areas of government endeavours, including science and technology R&D.
59. The lessons and best practices gathered from project implementation will be shared with other countries in Asia through regional meetings, exchanges of personnel and networking between those involved in biotechnology and biosafety.
60. The experiences of the project will be disseminated by posting regular reports on the progress of the project on the website on biosafety (which was set up under the BCH project), and by ensuring that results of risk assessment decisions are also posted on the BCH. In addition, project staff will participate actively in regular meetings of personnel from NBF Implementation projects from Asia as well as from other regions.
61. Sub-regional cooperation within SAARC on biosafety and the safe use of biotechnology will be enhanced through sharing of experiences on implementing the NBF through regional meetings and support for the sub-regional mechanisms for sharing information developed

through the SAARC networks on environment and biotechnology. The sharing of information on LMOs with other members of SAARC will eventually promote regional harmonization of standards and regulations on LMO management thus facilitating trade in the subregion. The sharing of technical facilities and expertise between members of SAARC will also help promote sub-regional cooperation.

3.10. Public awareness, communications and mainstreaming strategy

62. The Constitution of Bhutan guarantees the right to information for all citizens. The public can be meaningfully engaged in the decision-making process regarding biosafety in Bhutan through awareness and participation. Therefore raising the awareness of the public in general in the field of biosafety, and establishing the national Biosafety Clearing House with all relevant biosafety information in Bhutan are two key objectives to ensure effective public involvement and participation. BAFRA and other agencies will develop and implement programs for public awareness, education and participation, including public access to information, concerning the safe transfer, handling and use of LMOs. These agencies will use the media to promote public awareness and education concerning the safe transfer, handling and use of LMOs. BAFRA should also submit to the Biosafety Clearing-House information regarding their capacity needs, gaps, programs and priorities with respect to public awareness, education and participation.
63. Increasing public participation in decision-making processes will be facilitated through public hearings on proposed releases of LMOs by applicants, and proposed imports of LMOs by import houses. The outcomes of these public consultations must be legally recognized and the formulation of the Rules and Regulations of the Food Act must give due consideration for this requirement. Definite standards and procedures for public consultation must be specified in the Rules and Regulations.
64. With regard to access to relevant information, applicants and importers will have to submit information in the local spoken language for the population through appropriate communication means such as the media and the nBCH. Information would also be sent in a timely manner by official correspondence and by mass media in Dzongkha (the national language), to those local governments, i.e. the Dzongkhags and Gewogs, where field tests or commercial release are planned. In addition, an information sharing mechanism will be set up among ministries and relevant stakeholders. All project information will be posted on the website on biosafety. The national coordinating committee, set up under the NBF development project, will meet at Quarterly intervals to discuss the progress of the project. All findings and information of project will be disseminated to the public at large.

3.11. Environmental and social safeguards

65. The Project Steering Committee (PSC) will include representation from the Gross National Happiness Commission as well as civil society in order to ensure that environmental and social issues are fully integrated into the implementation of the project in a manner consistent with the Constitution. In addition, BAFRA will work closely with both Government agencies such as the National Environment Commission and the Nature Conservation Division of MoA, and environment NGOs such as the Royal Society for the Protection of Nature, the Bhutan Trust Fund for Environment Conservation, and national women's organization in order to ensure that environmental safeguards are given full consideration in day-to-day implementation of the project activities. The monitoring functions of the PSC, carried out with the help of the indicators in the results framework, will help to ensure that the project stays on track.

SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS

66. **National Executing Agency:** The Bhutan Agriculture and Food Regulation Authority (BAFRA), which has been designated as the National Competent Authority by the Government of Bhutan under the NBF, will be the National Executing Agency for this project. In implementing the project, BAFRA will work closely with the National Environment Commission (NEC), which is the focal point for Bhutan to the Cartagena protocol on Biosafety. BAFRA will work on behalf of the Government of Bhutan to manage the project, ensuring that its objectives are met by the end of the project. BAFRA will also provide the necessary scientific, technical, financial and administrative support to the project, working in close co-operation with the NEC and relevant government agencies, the scientific community and the public and private sectors.
67. **Project Steering Committee:** The Project Steering Committee (PSC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will include representation from the Gross National Happiness (GNH) Commission and government agencies with mandates relevant to the Cartagena Protocol on Biosafety. These will include the Ministries of Agriculture (including the Nature Conservation Division), Trade and Industry, Health, Finance, Home and Cultural Affairs, Office of Legal Affairs, and the National Environment Commission. The PSC will also include a representation from UNEP, the private sector and civil society. Civil society representation will include representatives of environment NGOs and the national women's organization (see Table below in Section 5). This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The PSC will be chaired by the National Project Director; the representative from the GNH Commission will serve as the co-chair. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the PSC are in Annex 11.
68. **National Project Director:** The National Project Director, as head of BAFRA, the National Executing Agency, will provide policy advice and overall direction to the project, as well as coordinating project activities with the NEC and relevant government agencies. He will work on a 25% basis for the project. He will supervise the National Project Coordinator.
69. **National Project Coordinator:** The National Project Coordinator will be appointed by the NEA after consultation with UNEP, for the duration of the National Project on a full-time basis. The National Project Coordinator, with assistance from a full-time project administrative/financial assistant, shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the Project Steering Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project, including preparation of the annual Project Implementation Review (PIR), mid term review and terminal evaluation. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex 11.

SECTION 5: STAKEHOLDER PARTICIPATION

70. The main stakeholders involved in designing the project include Government agencies such as the Ministries of Agriculture, Trade and Industry, Health, Finance; Department of Tourism; National Environment Commission; private sector representatives; NGOs including women's groups and environmental organizations. These stakeholders were involved through meetings to discuss the different components of the project, as well as by giving comments on drafts of the proposal. After approval of the PIF by the GEF CEO, the project design was finalized by BAFRA and endorsed at a stakeholder meeting chaired by the Secretary of the Ministry of Agriculture and opened by the Minister of Agriculture.

Once the project is approved, the different stakeholders will be involved in carrying out project activities, including researching, taking part in workshops, seminars and others (see Table below). This project will also promote public participation in decision making on LMOs by ensuring that mechanisms for public involvement in biosafety management are developed as part of component 6.

Table: Major Stakeholders and their Participation

STAKEHOLDERS	Type of involvement
Parliamentarians, decision-makers	Representative of Office of Government will take part in National Coordinating Committee. Decision-makers will be invited to take part in workshops, seminars, meetings, etc and will receive awareness materials of the project.
Government Agencies Gross National Happiness Commission; Ministry of Agriculture – agriculture, research, planning, forestry, livestock, Nature Conservation Division, National Biodiversity Centre, BAFRA; Ministry of Trade and Industry; Ministry of Health; Office of Legal Affairs; Ministry of Finance; Ministry of Home and Cultural Affairs; National Environment Commission.	Ministries are involved in carrying out project activities. A project steering committee (PSC) set up consists of representatives from relevant ministries. This committee will coordinate and supervise implementation of project.
Scientific community (including academic institutions): College of Natural Resources, Royal University of Bhutan Ugyen Wangchuk Institute of Forestry and Environment Council of Renewable Natural Resources (RNR) Research of Bhutan	Providing service on formulation of the implementing regulations and rules, manuals and training guidelines.
Civil Society and private sector Royal Society for the Protection of Nature; Bhutan Trust Fund for Environment Conservation; National Women's Association of Bhutan Bhutan Chamber of Commerce & Industry; Bhutan Agro Industries Limited; Food Corporation of Bhutan; Druk Seed Corporation.	Will be involved in activities on awareness raising and capacity building.

SECTION 6: MONITORING AND EVALUATION PLAN

71. 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.
72. The project M&E plan (Appendix 15) is consistent with the GEF Monitoring and Evaluation policy. The Project Results Framework presented in Appendix 4 includes SMART indicators for each expected outcome as well as mid-term and end-of-project targets. These indicators along with the key deliverables and benchmarks included in Appendix 6 will be the main tools for assessing project implementation progress and whether project results are being achieved. The means of verification and the costs associated with obtaining the information to track the indicators are summarized in Appendix 7. Other M&E related costs are also presented in the Costed M&E Plan and are fully integrated in the overall project budget.
73. The M&E plan will be reviewed and revised as necessary during the project inception workshop to ensure project stakeholders understand their roles and responsibilities vis-à-vis project monitoring and evaluation. Indicators and their means of verification may also be fine-tuned at the inception workshop. Day-to-day project monitoring is the responsibility of the project management team but other project partners will have responsibilities to collect specific information to track the indicators. It is the responsibility of the Project Manager to inform UNEP of any delays or difficulties faced during implementation so that the appropriate support or corrective measures can be adopted in a timely fashion.
74. The Project Steering Committee, which will have representation from all stakeholders, including the Gross National Happiness Commission (GNHC), will have the primary responsibility for monitoring both the implementation of project activities, and progress towards the achievement of project outputs. The PSC will be accountable to the Government through the GNHC, which oversees the implementation of all activities in Bhutan in support of the Tenth Plan. As BAFRA has included implementation of the NBF in the Ministry of Agriculture's (MOA) Renewable Natural Resource (RNR) Sector of the Tenth Plan, and mentioned these biosafety targets specifically in programmes MOA 28 on Biosecurity systems and 29 on Biodiversity Conservation, it will be reporting against these targets, through the MOA, to the GNHC on an annual basis. The PSC and BAFRA will therefore receive periodic reports on progress from the project team and, in addition to its progress reports to the GNH Commission, will make recommendations to UNEP concerning the need to revise any aspects of the Results Framework or the M&E plan. Project oversight to ensure that the project meets UNEP and GEF policies and procedures is the responsibility to the Task Manager in UNEP-GEF. 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.
75. At the time of project approval about 35 percent of baseline data is available. Baseline data gaps will be addressed during the first year of project implementation. A plan for collecting the necessary baseline data is presented in Appendix 5. The main aspects for which additional information are needed include: an updating of information on human, technical and institutional capacities; harmonization with the new Constitution (which came into effect in 2008), as well as updating relationships with relevant national laws, policies and plans.
76. Project supervision will take an adaptive management approach. The Task Manager will develop a project supervision plan at the inception of the project which will be communicated to the project partners during the inception workshop. The emphasis of the Task Manager supervision will be on outcome monitoring but without neglecting project financial management and implementation monitoring. Progress vis-à-vis delivering the agreed project

global environmental benefits will be assessed with the Steering Committee at agreed intervals. Project risks and assumptions will be regularly monitored both by project partners and UNEP. Risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR. Key financial parameters will be monitored quarterly to ensure cost-effective use of financial resources.

77. A mid-term management review or evaluation will take place in mid- 2012 as indicated in the project milestones. The review will include all parameters recommended by the GEF Evaluation Office for terminal evaluations and will verify information gathered through the GEF tracking tools, as relevant. The review will be carried out using a participatory approach whereby parties that may benefit or be affected by the project will be consulted. Such parties were identified during the stakeholder analysis (see section 5 of the project document). The project Steering Committee will participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented.
78. 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.
79. The GEF tracking tools are attached in Appendix 16. These will be updated at mid-term and at the end of the project, and will be made available to the GEF Secretariat along with the project PIR report. As mentioned above the mid-term and terminal evaluation will verify the information of the tracking tool.

SECTION 7: PROJECT FINANCING AND BUDGET

7.1. Overall project budget

80. The overall project budget is US\$ 1,723,000 comprising US\$ 869,000 from GEF and US\$854,000 from co-financing from the Royal Government of Bhutan. The detailed budget according to the UNEP format and by activities is attached in Appendix 1. This detailed budget is summarized in the Table below.

Component	GEF Financing	Government contribution	Total
1. Stocktaking	29,500	36,000	55,500
2. Integration into National plans	30,500	40,000	80,500
3. Regulatory regime	102,000	90,000	192,000
4. Handling requests	125,000	180,000	305,000
5. Monitoring	333,000	248,000	581,000
6. Public participation	97,000	112,000	209,000
7. Regional cooperation	62,000	38,000	100,000
8. Project monitoring & evaluation	10,000	30,000	40,000
9. Project Management	80,000	80,000	160,000
Total	869,000	854,000	1,723,000

7.2. Project co-financing

81. The GEF contribution and Government co-financing are summarised in the table below:

	Project Preparation*	Project	Agency Fee	Total
GEF	0	869,000	86,900	955,900
Co-financing	0	854,000		854,000
Total	0	1,723,000	86,900	1,809,900

7.3. Project cost-effectiveness

82. This project will take a cost effective approach by promoting cooperation at the national level in Bhutan between agencies whose mandates impact on biosafety and the safe application of biotechnology. As many of the activities in this project are directly or indirectly linked to the regulatory, research and extension services of the Ministry of Agriculture, the project will aim to enhance cooperation between different departments of the Ministry, i.e. agriculture, forestry, livestock, agricultural research, planning, and BAFRA in order to ensure that Government resources are harnessed effectively to further the objectives of this project. This will require strengthened cooperation between the departments and BAFRA at the national level, as well as between the field staff of the agencies at the district and regional levels so as to promote communication and to ensure that monitoring activities are carried out effectively. BAFRA, in implementing the project will also work closely with other Government agencies such as the National Environment Commission, Trade and Industry, Customs and Excise, Health in order to promote the mainstreaming of biosafety into their activities; this will help to ensure a cost-effective approach to project implementation as well as promoting sustainability of project outcomes.

83. At the regional level, the project will take a cost-effective approach by promoting regional cooperation in the SAARC sub-region through:

- * sharing of training opportunities and programmes in risk assessment and management;
- * sharing of human and institutional resources between different agencies and institutions;
- * sharing of laboratory, contained use and field testing facilities between different institutions;
- * sharing of experiences; information sharing on biosafety and biotechnology, both within Bhutan and with other South Asian countries, including the setting up of a possible regional BCH.

APPENDICES

- Appendix 1: Budget by project components and UNEP budget lines**
- Appendix 2: Co-financing by source and UNEP budget lines**
- Appendix 3: Incremental cost analysis**
- Appendix 4: Results Framework**
- Appendix 5: Workplan and timetable**
- Appendix 6: Key deliverables and benchmarks**
- Appendix 7: Costed M&E plan**
- Appendix 8: Summary of reporting requirements and responsibilities**
- Appendix 9: Standard Terminal Evaluation TOR**
- Appendix 10: Decision-making flowchart and organizational chart**
- Appendix 11: Terms of Reference**
- Appendix 12: Co-financing commitment letters from project partners**
- Appendix 13: Endorsement letters of GEF National Focal Points**
- Appendix 14: Draft procurement plan**
- Appendix 15: Tracking Tools**