

# **United Nations Environment Programme**

# Terminal Evaluation of the Project "Implementation of the National Biosafety Framework of Bhutan"

Camillo Risoli

**Evaluation Office** 

February 2015

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### **Identification Table**

	2050		CEL (2220 271 C 4522
GEF project ID:	3850	IMIS number:	GFL/2328-2716-4B22
Focal Area(s):	BD3 – SP6 (Biosafety)	GEF OP #:	
GEF Strategic	Environmental	CEE annual data:	08/01/2010
Priority/Objective:	governance	GEF approval date:	
UNEP approval date:	19/03/2010	First Disbursement:	22/03/2010
Actual start date:	01/07/2010	Planned duration:	48 months
Intended completion date:	18/03/2014	Actual or Expected completion date:	18/10/2014 (7 m. ext.)
Project Type:	MSP	GEF Allocation:	\$869,000
PDF GEF cost:	\$869,000	PDF co-financing*:	\$854,000
Expected MSP/FSP Co-financing:	\$854,000	Total Cost:	\$1,723,000
Mid-term review/eval. (planned date):	30/06/2012	Terminal Evaluation (actual date):	29/10 to 03/11 2014
Mid-term review/eval. (actual date):	23/08/2012	No. of revisions:	5
Date of last Steering Committee meeting:	24/09/2014	Date of last Revision:	25/04/2014
Disbursement as:	854,500.00 (04/08/2014)	Date of financial closure:	na
Date of Completion:	18/10/2014 (technically extended to 30/11/2014)	Actual expenditures reported as of:	823,376.33 (30/09/2014)
Total co-financing realized	\$655,573.83 (30/09/2014)	Actual expenditures entered in IMIS as 30 June 2014	
Leveraged	\$ 106.500 (from		
financing:	various sponsors)		

## Project "Implementation of the National Biosafety Framework of Bhutan"

### List of Acronyms and Abbreviations

ANUBIS	UNEP Biosafety Information System
BAFRA	Bhutan Agriculture and Food Regulatory Authority
ВСН	Biosafety Clearing House
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
EA	Expected Accomplishments (of UNEP)
EO	Evaluation Office (of UNEP)
GEB	Global Environmental Benefit
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
GNHC	Gross National Happiness Commission
ICGEB	International Centre for Genetic Engineering and Biotechnology
LMO	Living Modified Organism
NBC	National Biosafety Commission
NBF	National Biosafety Framework
NCA	National Competent Authority
NEA	National Executing Agency
NPC	National Project Coordinator
MEA	Multilateral Environmental Agreement
MoAF	Ministry of Agriculture and Forests
MTS	Medium Term Strategies (of UNEP)
PIR	Project Implementation Review
PoW	Programme of Work (of UNEP)
ProDoc	Project Document
PSC	Project Steering Committee
RA	Risk Assessment
RM	Risk Management
SAARC	South Asian Association for Regional Cooperation
TOC	Theory Of Change
TOR	Terms Of Reference
TWG	Technical Working Groups
UNDP	United Nations Development Program
UNEP	United Nations Environmental Programme

#### **Executive Summary**

1 This is the final report of the Terminal Evaluation of the Project "Implementation of the National Biosafety Framework of Bhutan" (GFL/2328-2716-4B22). The Project was approved on 03/2010 for a duration of 4 years (2010-14) and a total budget of USD 1.723.000, the 50,5% of which represents the GEF allocation (USD 869.000), while the remaining 49,5% (USD 854.000) is provided by the Government of Bhutan. The Project has been extended for 7 months until 18/10/2014, and further technically extended until 30/11/2014, in order to follow the process of adoption of the National Biosafety Act, finally approved by the Upper House of the Parliament on 24/11/2014. The Evaluation took place in the period between September and November 2014 and included a mission to Bhutan from 29/10/2014 to 03/11/2014.

2 The Project, conceived to make operational the National Biosafety Framework (NBF) prepared in 2006, is essentially an Institution & Capacity Building Project aiming at strengthening national capacities for setting up of the policy, legislative, administrative, monitoring and enforcement systems foreseen in the NBF. The Bhutan Agriculture and Food Regulatory Authority (BAFRA), National Competent Authority (NCA) for the application of the CPB, has also been the National Executing Agency (NEA) of the Project.

3 BAFRA is a solid and dynamic institution playing a strategic role at national level, being responsible for the application of relevant national policies and legal instruments such as the Plant Quarantine Act, Seed Act, Pesticide Act, Livestock Act, Food Act, Forest and Nature Conservation Act, Biodiversity Act and, eventually, the Biosafety Act. It functions as the National Food Quality and Safety Control agency and is the National Competent Authority not only for the CPB, but also the IPPC (International Plant Protection Convention), CAC (Codex Alimentarius Commission), the WTO-SPS Agreement (World Trade Organization-Sanitary and Phytosanitary Agreement). Biosafety can therefore take profit from a robust and polyvalent institutional anchorage, which offers large guarantees of institutional and socio-political sustainability.

4 The Project has been highly instrumental in supporting the country in the implementation of the National Biosafety Framework (NBF). Biosafety is now regulated by a National Law approved in November 2014 and the Secondary Law (Rule and Regulations) are ready for approval, too. The integration of Biosafety, Biosecurity, Food Safety and Quality Assurance under a single, coordinated Programme of the 11th Plan of the Ministry of Agriculture and Forests provides strength and sustainability to the Biosafety agenda in the country, as well as enabling its inclusion in the National Budget, hence contributing to financial sustainability.

5 The two main bodies established by the new Biosafety Law (the National Biosafety Commission with responsibility for strategic guidance and coordination, and the Technical Working Groups with advisory function) are the natural evolution of implementing mechanisms set by the Project and have already given evidence of meaningful participation and of strategic and technical capacities. The wider membership of the NBC, by incorporating more representatives from the Civil Society and Private Sectors, remains an open question.

6 Biosafety has already been inserted in the plan of work of BAFRA's Inspectors and Officers, through staff capacity building, laboratory upgrading, LMOs specific guidelines, laboratory protocols and technical manuals. Key human resources have been exposed to a variety of training activities in the country, conducted by international consultants in the framework of the Project, as well as abroad, through tailored training in the Netherlands (financed by the Netherlands Fellowship Programme), study tours in Thailand, India, Australia, Malaysia and Italy, regional conferences and workshops in the SAARC region. Actually, the country, which has a very young and limited academic system, has to be proactive in finding external sources and resources for knowledge and training.

7 Bhutan is investing in regional cooperation, not only for the Biosafety sector, in order to minimise the shortcomings of its condition of small and landlocked country. It is a dynamic actor in creating Biosafety partnerships within the SAARC umbrella, which seems to be leading to interesting opportunities that have to be fostered and followed up, also with the support of UNEP.

8 The Evaluation has therefore concluded that relevant factors exist for believing that the National Biosafety Framework in place can move forward and consolidate in Bhutan. However, the systems for handling and managing LMOs have to prove efficient and effective to the test of daily reality and it must not be omitted that Biosafety is still a very young subject in Bhutan. Existing material, financial and human resources are not only to be maintained at a suitable level, but also upgraded and improved. Key human resources at central level, as well as the inspectors at the border points, need to consolidate their "know how" on Biosafety, through specific, tailored trainings enabling them to continuously update and improve their capability of inspection, detection, risk assessment and risk monitoring.

9 As requested by the TOR, twenty-two different evaluation criteria have been rated<sup>1</sup>, as shown in the Table of Chapter 5.1 of the Report (Conclusions). As a whole, <u>the Project can be rated as Satisfactory (S)</u>. The summary assessment and the rating of some of the main evaluation criteria are synthetized here below:

Criterion	Summary Assessment	Rating
A. Strategic relevance	The Project confirms all its relevance in addressing challenging and crucial issues and needs in the area of biodiversity's sustainable use, in achieving internationally agreed environmental objectives and goals and in contributing to fulfil UNEP's mandate and policy, as well as GEF priorities and strategies.(see 4.1)	S
B. Achievement of outputs	The Project has very satisfactorily delivered the expected outputs.(see 4.2 and Table 1)	ня
C. Effectiveness: Attainment of project objectives and results	Virtually all the direct Outcomes have been achieved, as well as the main Project Outcome (A National Biosafety Framework fully operational), though not yet consolidated due to the lack of concrete opportunities of application. (see 4.3.2)	S
D. Sustainability and replication	The Five-year Plan of the MoAF integrates Biosafety with Biosecurity, Food Safety and Quality Assurance under the same Programme hence enabling synergies, cooperation and socio- political sustainability. The NCA (BAFRA) is a solid and dynamic institution playing a strategic role at national level, as well as National Focal Point for several international agreements. Financial sustainability rises some concerns, though the inclusion of Biosafety in the national Plans and Budget gives elements of optimism. Regional cooperation (SAARC) can strengthen institutional and financial sustainability.	L
E. Efficiency	Project quite cost-effective in its execution, thanks to its institutional integration within the BAFRA and the MoAF. Cost-effectiveness also enhanced through a successful strategy of fund-raising.	S

<sup>1. &</sup>lt;sup>1</sup> Using a six-point scale as follows: Highly Satisfactory (HS); Satisfactory (S); Moderately Satisfactory (MS); Moderately Unsatisfactory (MU); Unsatisfactory (U); Highly Unsatisfactory (HU). Sustainability is rated from Highly Likely (HL) down to Highly Unlikely (HU).

10 The Project has allowed to learn how relevant is the institutional setting for Biosafety agenda. The institutional anchorage within the BAFRA is conducive to a tight linkage between Biosafety, Food Safety and Quality Control, increasing cost effectiveness of detection, inspection and monitoring activities, good coordination and a stronger institutional presence in socio-political arena. Thanks to the small dimension and dynamism of the country, some interesting lessons can also be drawn regarding the need of a stronger regional cooperation and a more effective collaboration within UN Agencies (see chapter 5.2).

11 The Evaluation has presented two main Recommendations:

Recommendation 1: to UNEP, NCA (BAFRA), NBC

#### **Recommendation 1:**

In order to consolidate the positive achievements obtained so far and considering the challenges of the implementation of the National Biosafety Programme, it is recommended to give continuity to GEF/UNEP assistance through a follow-up phase or project focused on:

a) Training needs assessment and targeted, intensive training to key human resources responsible for and/or directly involved in LMOs Inspection, Detection, Risk Assessment and Monitoring.

#### Recommendation 2: to UNEP, NCA (BAFRA), NBC

#### **Recommendation 2:**

It is recommended that Bhutan keeps on playing a dynamic role in enhancing SAARC cooperation in order to improve areas of particular relevance for the country, possibly through a sub-regional project aiming at implementing:

a) shared services in the area of LMOs detection (e.g. regional reference laboratory), harmonized labelling, border inspections (e.g. Green Customs initiative), aggregate purchasing of laboratory material;

b) regional capacity building programme, particularly in the area of Risk Assessment and Risk Monitoring.

c) additional Biosafety and Food Safety capacity building through bilateral or multilateral cooperative agreements with key trading partners in the region (e.g. Japan, India, Netherlands, EU).

#### 1 Introduction

- 1. In its capacity as an Implementing Agency of the Global Environmental Facility (GEF), UNEP has been providing administrative and technical assistance to parties to the Cartagena Protocol on Biosafety (CPB) for the development and implementation of National Biosafety Frameworks (NBF). The frameworks are a combination of policy, legal, administrative and technical instruments enabling the countries to manage the safe transfer, handling and use of living modified organisms (LMOs) from modern biotechnology<sup>2</sup>.
- 2. This is the final report of the Terminal Evaluation of the Project "Implementation of the National Biosafety Framework of Bhutan" (GFL/2328-2716-4B22). The Project was approved on 03/2010 for a duration of 4 years (2010-14) and a total budget of USD 1.723.000, the 50,5% of which represents the GEF allocation (USD 869.000), while the remaining 49,5% (USD 854.000) is provided by the Government of Bhutan. The Project has been extended for 7 months until 18/10/2014, and further technically extended until 30/11/2014.
- 3. The Evaluation took place in the period between September and November 2014 and included a mission to Bhutan from 29/10/2014 to 03/11/2014. The Evaluation Team consisted of one consultant specialist of projects evaluation in the environmental sector (See Annex 6), working under the methodological guidance of the Evaluation Office (EO) of UNEP.

#### 2 The Evaluation

- 4. In line with the UNEP Evaluation Policy and Evaluation Manual and following the Guidelines for GEF Agencies on Conducting Terminal Evaluations, the Terminal Evaluation has been undertaken immediately before the completion of the Project to assess project performance (in terms of relevance, effectiveness and efficiency), and determine outcomes and impacts (actual and potential) stemming from the project, including their sustainability. The evaluation had two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP, the GEF and their executing partners the National Executing Agency (BAFRA, Bhutan Agriculture and Food Regulatory Authority) and the national partners.
- 5. According to the UNEP evaluation methodology, most criteria have been rated on a six-point scale as follows: Highly Satisfactory (HS); Satisfactory (S); Moderately Satisfactory (MS); Moderately Unsatisfactory (MU); Unsatisfactory (U); Highly Unsatisfactory (HU). Sustainability is rated from Highly Likely (HL) down to Highly Unlikely (HU).
- 6. As requested by the UNEP's methodology for Terminal Evaluations, an Inception Report was produced at the beginning of the mission, containing a review of the project context, of project design quality, a draft reconstructed Theory of Change of the project, the evaluation framework and a tentative evaluation schedule.
- 7. According to the TOR received, a participatory approach has been used since the preparation of the field mission, through a preliminary exchange of evaluation tools with the National Project Coordinator and the joint preparation of the agenda for the country visit. Once fielded, the mission provided the opportunity to meet with relevant stakeholders and to collect and discuss first-hand information, opinions and suggestions or recommendations.
- 8. Quantitative and qualitative methods and indicators have been used, taking into account that the Project was expected to mostly deliver institutional and capacity building outputs and outcomes. Being so,

 $<sup>^2</sup>$  In this Report, the terms LMO (Living Modified Organism) and GMO (Genetically Modified Organism) are considered synonymous and indifferently used.

quantitative outputs were also assessed against their quality and effectiveness, particularly their capacity to drive and sustain changes at higher level of objectives.

- 9. As far as possible, the information received has been triangulated among the stakeholders and with the existing written reports available in the ANUBIS platform. Triangulation, especially interviews with project managers, partner institutions, trainers and trainees, has been particularly useful in assessing training effectiveness. A joint meeting involving different stakeholders was also held, trying to capture the highest number possible of opinions and concerns during the limited timeframe of the country-visit.
- 10. The main methods and tools used in the Evaluation have been:

• The Desk Review of all project documents and tools the consultant has access to (see Annex 4), including the Anubis platform.

• Exchanges with the Project Management Team at UNEP, namely the Task Manager and the Fund Management Officers.

• The Country Visit. The interviews during the country visit included the National Project Coordinator, Director and Officials of the National Executing Agency, also NCA (the Bhutan Agriculture and Food Regulatory Authority, BAFRA, of the Min. of Agriculture and Forests) and of other Divisions of the Ministry, members of the Technical Working Group, the UNDP Portfolio Manager<sup>3</sup>.

11. The succession, back to back, of three different terminal evaluations of analogous projects in three countries (Mongolia, Lao PDR, Bhutan) has permitted some interesting comparison and was obviously more resource efficient (time and travel costs).<sup>4</sup>

#### 3 The Project

#### 3.1 Context

- 12. 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 and ecosystems diversity, ranking in the top ten percent of countries with the highest species density in the world. Bhutan's wealth of agro-biodiversity includes a number of economically significant plants and animals, such as 250 to 300 traditional rice varieties, 50 of maize, 24 of wheat, and 30 of barley, as well as local animal breeds that could be put at risk by the indiscriminate release of LMOs.
- 13. 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. However, that moratorium has proved difficult to be enforced and inadequate in meeting the country's food security needs, as Bhutan imports more than 35% of its food from neighboring countries (e.g. India and Thailand), which have active biotechnology industries and use LMOs in the production and processing of Food and Feed Products.
- 14. After adhering to the Cartagena Protocol on Biosafety (CPB) in 2002<sup>5</sup>, Bhutan has identified and prepared in 2006 the National Biosafety Framework (NBF), as the crucial instrument to address all challenges outlined above. Aiming at making the NBF operational through the setting up of the policy,

<sup>&</sup>lt;sup>3</sup> See list of people met in Annex 3

<sup>&</sup>lt;sup>4</sup> Annex 7 presents some elements for a comparative analysis of the three Projects

<sup>&</sup>lt;sup>5</sup> Bhutan was one of the first countries to adhere to the Protocol (August 2002), hence permitting the entry into force of the Protocol in September 2003 (<u>https://bch.cbd.int/protocol/parties</u>)

legislative, administrative, monitoring and enforcement systems foreseen in it, the country requested the support of UNEP-GEF, which was provided with the current project.

#### **3.2** Objectives and components

- 15. The Project Objective defined in the ProDoc is "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". The Project has been designed with seven (7) components, each of them with a specific Outcome to achieve. They are:
  - 1. Establishment of baseline information on the safe use of biotechnology in Bhutan;
  - 2. Integration of Biosafety into National Priorities, in conformity with Bhutan's Tenth Plan;
  - 3. Legal and regulatory framework on biosafety;
  - 4. System for handling requests, carrying out risk assessment and decision making on LMOs;
  - 5. System for monitoring, inspections & enforcement;
  - 6. System for public awareness, education and participation in decision making for LMOs;
  - 7. Enhanced regional cooperation on biosafety in SAARC.

#### **3.3** Target areas/groups

16. The Project is essentially an Institution & Capacity Building Project aiming at strengthening national capacities to fulfil the national and international obligations of the Cartagena Protocol on Biosafety (CPB), mainly through the setting and consolidation of the National Biosafety Framework (NBF). Main target groups are the national institutions involved in the implementation of the NBF, particularly the National Competent Authority (NCA), BAFRA, and its main partners: Governmental institutions (both from the Ministry of Agriculture and from other line-Ministries), as well as other institutions from the Scientific and Academic community, from Civil Society and private sector.

#### 3.4 Milestones/key dates in project design and implementation

17. The Project has been approved by GEF on the 08/01/2010 and by UNEP on the 19/03/2010, for a duration of 48 months (4 years). The first disbursement occurred on the 22/03/2010. The first Project Steering Committee took place in October 2010. A mid-term review of the Project was carried out in August 2012. Due to some delays in the start of the operations, a delay note was addressed by the Government to UNEP and eventually an extension of seven (7) months was agreed upon in 2013, shifting the end date of the Project to 18/10/2014. Additionally, a technical extension has been granted for the closure of the activities, until November 2014.

#### **3.5** Implementation arrangements

- 18. The Bhutan Agriculture and Food Regulatory Authority (BAFRA), which is the NCA for the application of the CPB, was also designated as the National Executing Agency (NEA) of the Project. A Project Steering Committee (PSC) was established by the NEA to advise and guide the implementation of the National Biosafety Framework. The PSC included representation from the Gross National Happiness Commission (GNHC) and other government agencies with mandates relevant to the Cartagena Protocol on Biosafety, such as 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, which is also the Focal Point for CBD, CPB and the BCH.
- 19. The National Project Director is the head of BAFRA and provides policy advice and overall direction to the project, including the supervision of the National Project Coordinator (NPC), who is recruited by the Project for all its duration, on a full-time basis. The NPC, with assistance from a full-time project administrative/financial assistant, is responsible for the overall co-ordination, management and supervision of all aspects of the National Project, according to TOR agreed upon BAFRA and UNEP.

#### 3.6 Project financing

20. The Project had an estimated cost of USD 1.723.000, the 50,5% of which was represented by the GEF allocation (USD 869.000), while the remaining 49,5% (USD 854.000) represented the Government of Bhutan's in-kind contribution.

#### 3.7 Project partners

21. The Bhutan Agriculture and Food Regulatory Authority (BAFRA), NEA of the Project, is an agency of the Ministry of Agriculture and Forests (MoAF) with a large mandate to promote the quality of goods and products related to the MoAF and its clients, and to implement legislation such as the Food Act, Seeds Act, the Plant Quarantine Act and the Livestock Act. Main partners of BAFRA are other Divisions and Departments within the MoAF, but also the National Environment Commission, the Ministry of Health, the Ministry of Trade, Department of Revenue and Customs, the Royal Society for the Protection of Nature, the Bhutan Trust Fund for Environment Conservation.

#### **3.8** Changes in design during implementation

22. The Project design did not suffer any major change during the implementation. Five (5) Budget Revisions have been progressively adopted so far, without substantive changes in the project design, activities and results. The Project has benefited from a no-cost extension of seven (7) months (until 18/10/2014) and a technical extension until November 2014, in order to follow the process of adoption of the National Biosafety Act, finally approved by the Upper House of the Parliament on 24/11/2014.

#### **3.9** Reconstructed Theory of Change of the project

- 23. In the Inception Report of the mission<sup>6</sup>, the consultant presented a reconstructed Theory Of Change (TOC) of the Project, based on the project design, other UNEP-GEF Biosafety Unit documents and the comments received from UNEP Evaluation Office. As a result, the mapping of the possible pathway of change from the projects Outputs<sup>7</sup> to the expected Outcomes<sup>8</sup>, up to the intended Impact, was produced. The reconstructed ToC has been a valuable instrument of analysis all along the evaluation exercise and its design has been tested by the consultant during the evaluation. It has particularly contributed to assess the effectiveness and the sustainability of the project's results, as well as the likelihood to achieve the intended impact, as discussed in Section 4 (Evaluation findings) of this report.
- 24. As mentioned above (see 3.2), the project's objective is "to make the National Biosafety Framework (NBF) 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". Therefore, "A fully operational NBF" is the main Project Outcome to be achieved.
- 25. The National Biosafety Framework (NBF) is a comprehensive institutional instrument that guides the country towards the achievement of the objective of the Cartagena Protocol on Biosafety (CPB), as stated in the art. 1 of the Protocol<sup>9</sup>, and eventually towards the Global Environmental Benefit (GEB)

<sup>&</sup>lt;sup>6</sup> Inception Report of the Terminal Evaluation of the Project "Implementation of the National Biosafety Framework of Bhutan". C. Risoli, September 2014

<sup>&</sup>lt;sup>7</sup> Outputs : the goods and services that the project must deliver in order to achieve the project outcomes ("the ROtI Handbook", GEF, 2009)

<sup>&</sup>lt;sup>8</sup> Outcomes: the short to medium term behavioural or systemic effects that the project makes a contribution towards, and that are designed to help achieve the project's impacts ("the ROtI Handbook", GEF, 2009)

<sup>&</sup>lt;sup>9</sup> Art. 1 of CPB: "Adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".

representing the Intended Project Impact: the "Enhanced conservation and sustainable use of biological diversity in Bhutan".

- 26. The exercise of reconstruction of the Theory Of Change has permitted to visualize and organise the Results Framework of the Project around seven (7) clusters of Outputs, seven (7) Direct Outcomes and one main Project Outcome. Chapter 4.3.2 and Diagram 1 describe and illustrate the causal logic of the Project from Outputs to Outcomes.
- 27. The TOC also depicts the pathway from Outcomes to Impact and any intermediate change required between them, called intermediate states. It permits to appreciate to what extent the project has to date contributed, and is likely in the future to further contribute, to changes in stakeholders behavior as a result of the project's direct outcomes, and the likelihood of those changes in turn leading to environmental benefits (impact). The pathway is described and discussed in chapter 4.3.3 and Diagram 2. The TOC further defines the external factors that influence change along the pathways, called drivers (when the project has a certain level of control) or assumptions (when the project has no control).

#### 4 Evaluation Findings

#### 4.1 Strategic relevance

#### 4.1.1 <u>Sub-regional environmental issues and needs</u>

- 28. Concerns are growing about food and livelihood security throughout Asia, currently home to nearly 60% of the world's population. After a spectacular rise during 1970s and 1980s, the region has experienced a slow down or even stagnation in food production during recent years. Several countries are increasingly resorting to imports either because domestic production is too low or because there are growing demands for food and feed grain. Actually, it is predicted that countries in Asia will account for half of the increase in global demand for the cereals by the year 2020. As a matter of fact, Bhutan imports almost 50% of its main staple (rice)<sup>10</sup>, and more than 35% of its food from neighboring countries (e.g. India and Thailand), which have active biotechnology industries and use LMOs in the production and processing of Food and Feed Products.
- 29. The Royal Government of Bhutan, based on the Precautionary Principle, has put in place several legislations on environment, agriculture, food, health and trade policy to protect the country's rich biological diversity and the well-being of the people. While a ministerial decree issued by the Ministry of Agriculture in 2000 banned all imports of GMOs into the country, it has been widely acknowledged the need for a more comprehensive biosafety policy and a legal system for regulating the safe transfer, handling and use of GMOs, as well as for building technical capacity and required infrastructure to implement a national policy on Biosafety. The Project has been conceived and implemented to fill in the major gaps on this regard and, in retrospect, its strategic relevance for the country has been largely confirmed, as discussed in this report, particularly in Chapter 4.3.

#### 4.1.2 UNEP mandate and policies

30. UNEP has a rich history of assisting governments in advancing national and regional implementation of environmental objectives, enhancing global and regional environmental cooperation, as well as developing and applying national and international environmental law. Biosafety has become an increasingly relevant sector of UNEP intervention since the first group of Pilot Biosafety Enabling Projects started in 1997 in 18 countries. From 2000 onward, UNEP has supported around 140 countries to develop and implement their National Biosafety Framework (NBF) and/or to participate and benefit from the Biosafety Clearing House (BCH). The current Project under evaluation is part of this large

<sup>&</sup>lt;sup>10</sup> "Towards Food Security: Challenges and Strategies for Bhutan", MoAF, 2012

UNEP's effort to support CPB signatory countries in implementing sound NBFs, hence fulfilling the Protocol's national and international obligations.

- 31. At the time of Project design, Biosafety was one of the main areas where UNEP was playing its strategic role of Implementing Agency of the Global Environmental Facility (GEF). However, biosafety was not formally and explicitly recognized as thematic priority in any of UNEP's instruments of strategic planning that were, in those years, also in a phase of progressive restructuring. On this regard, it has to be observed that Biosafety, as such, is not mentioned in any of UNEP's Expected Accomplishments (EA) of its more recent Medium Term Strategies (MTS). It only comes to appear in the biennial PoW for 2012–2013 as one of the five potential areas mentioned in one of the Outputs of the Sub-Programme Environmental Governance.
- 32. All the same, the relevance of Biosafety can be reconstructed through its evident insertion in some EAs of two strategic cross-cutting areas of UNEP's intervention: Ecosystem Management and Environmental Governance, as widely discussed in Chapter 4.7 (Complementarity). Moreover, the Project is absolutely instrumental to the achievement of the five strategic objectives of the Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020: 1. Facilitating the establishment and further development of effective biosafety systems for the implementation of the Protocol; 2. Capacity-building; 3. Compliance and review; 4. Information sharing; 5. Outreach and cooperation.
- 33. The Project presents a regional dimension, as clearly expressed by one of its expected outcomes. Therefore, it makes part of UNEP's regional and sub-regional support for the coordination of regional strategies on Access and Benefit Sharing (ABS), National Reporting, and Liability & Redress, hence contributing to the reform of the International Environmental Governance addressing the complex and fractured system of MEAs, including the biodiversity-related MEAs.

#### 4.1.3 GEF Biodiversity focal area, strategic priorities and operational programme(s)

- 34. As the financial mechanism of the Convention on Biological Diversity (CBD), the Global Environment Facility (GEF) is also called upon under the Biosafety Protocol to serve as its financial mechanism. At its meeting in November 2000, the GEF adopted the "Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety", the main objectives of which are: to assist countries in the establishment of national biosafety frameworks; to promote information sharing and collaboration (in particular at the regional and sub-regional level); and, to promote collaboration with other organisations to assist in capacity building for the Protocol.
- 35. The Strategy for Financing Biosafety was approved by the GEF Council on an interim basis in December 2006 and became part of the GEF Focal Area Strategies and Strategic Programming for GEF-4 approved by the GEF Council in June 2007. Under GEF-5, the strategy for the Biodiversity Focal Area contemplates as its Objective 3: "Build Capacity for the Implementation of the Cartagena Protocol on Biosafety (CPB)". To achieve this Objective, a comprehensive Projects Support structure has been established, including three types of Projects: Single-country project, Regional or sub-regional projects, Thematic projects.
- 36. The Project under current evaluation is therefore strategically relevant to GEF priorities. According to data displayed in GEF web site, the Biodiversity portfolio (including Biosafety) represented in 2013 almost 40% of the GEF Portfolio in the country. The allocation of GEF 6 was under discussion in Bhutan during the country visit.

#### 4.1.4 Overall Strategic Relevance

37. As discussed above, the Project, in retrospect, confirms all its relevance in addressing challenging and crucial issues and needs in the area of biodiversity's sustainable use in the country and the region, in achieving internationally agreed environmental objectives and goals, and in contributing to fulfil

UNEP's mandate and policy, as well as GEF priorities and strategies. As a whole, the strategic Relevance of the Project is rated as <u>S (Satisfactory)</u>.

#### 4.2 Achievement of outputs

- 38. The Evaluation has assessed the delivery of Project Outputs against the planned Outputs of the Results Framework (App. 4 of the ProDoc), in close collaboration with the National Project Coordinator. The revision of the outputs produced (e.g. trainings report, training material, awareness material, etc.), their good level of systematisation and filing (also in ANUBIS), as well as the interviews with different stakeholders have permitted to confirm the quality of the outputs and the participatory process of their production.
- 39. Table 1, produced by the National Project Coordinator<sup>11</sup>, discussed and revised during the country visit, synthetises the main findings on Outputs delivery, under each of the expected Outcomes presented in the Results Framework. As clearly shown by the Table, the Project has very satisfactorily contributed to the delivery of virtually all expected outputs, among which we can underline: the National Biosafety Law (endorsed by the National Assembly in November 2014), Rules and Regulations, Guidelines and Manuals, a wide and diversified programme of Human Resources capacity building, the implementation of a GMO laboratory and Bhutan's active role at sub-regional level (SAARC, South Asian Association for Regional Cooperation) on Biosafety policy and strategies.
- 40. It is widely recognized that the main drivers have been the high dedication of the project team, the strong institutional support of the NCA (BAFRA) and the personal commitment of BAFRA officers and members of the Technical Working Group on Biosafety, foreseen by the Law "to advise on technical and scientific issues related to genetically modified organisms". All these drivers have, in sum, created a favourable environment for the setting and implementation of the Biosafety Agenda in the country. Overall, Outputs Achievement is considered <u>Highly Satisfactory (HS)</u>.

<sup>&</sup>lt;sup>11</sup> Based on a format that the Consultant had shared with the team of the Project before the country visit

Expected Outputs <sup>12</sup>	Indicators <sup>13</sup>	Outputs delivered by the Project (October 2014)	Evidence	Comments
Expected Outputs <sup>12</sup> Outcome 1:Baseline established forinformation on the safe use ofbiotechnology in Bhutanthrough a stocktaking analysis.1.1 Inventory of currentnational human, technical andinstitutional capacities toimplement a comprehensivebiosafety management system.1.2 Accurate information onhow Biosafety can be	Indicators <sup>13</sup> <ul> <li>Indicators<sup>13</sup></li> <li>Stocktaking of national biosafety and biotechnology capacity completed ;</li> <li>Assessment report submitted to Government for approval.</li> <li>Review report completed ;</li> <li>Assessment report includes a</li> </ul>	<ul> <li>Inventory of national human, technical and institutional capacities to implement a comprehensive biosafety management system</li> <li>Findings<sub>1</sub> survey and recommendations of the</li> </ul>	Evidence	Comments This activity has been very useful for the preparation of the Biosafety Act
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.	<ul> <li>review of all relevant legislation with respect to biosafety and biotechnology;</li> <li>Assessment report prepared</li> <li>Assessment report on biosafety includes analysis of:</li> <li>Gender impacts;</li> <li>traditional knowledge;</li> <li>traditional farmers' rights;</li> <li>with respect to application of biotechnology;</li> <li>Assessment report includes analysis of existing mechanisms for public participation.</li> </ul>	<ul> <li>assessment submitted to the Ministry of Agriculture on December 2010.</li> <li>Harmonization of the National Biosafety Framework of Bhutan with existing Laws and Policies (e.g. Food Act)</li> </ul>		

Table 1: Assessment of Outputs Delivery (based on App.4 / Results Framework) Project "Implementation of the National Biosafety Framework of Bhutan"

<sup>&</sup>lt;sup>12</sup> As stated in the Results Framework (App. 4) of the Project Document

<sup>&</sup>lt;sup>13</sup> As stated in the Results Framework (App. 4) of the Project Document

Outcome 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	<ul> <li>Biosafety policy formally promulgated by government</li> <li>Biosafety Policy distributed to the public and government agencies</li> </ul>	- Biosafety Law endorsed by the National Assembly during the 3 <sup>rd</sup> session of the second parliament. (November 2014)	http://www.kuenselonline.co m/assembly-sticks-with- status-quo/#.VA_3PsKSxe8 http://www.nationalcouncil.bt /wp- content/uploads/Tentative%2 0Agenda%20For%2014th%2 0Session.pdf	After the endorsement by the Ministry in 2012, the draft was presented to the Cabinet of the Government. In 2013 a change of the Government, delayed the process. The new Min. of Agr. approved the draft in October 2013, the new Cabinet approved in January 2014 and eventually the Lower House of the National Assembly endorsed the Law in June 2014. The law has been finally approved by the Upper House the 24/11/2014
2.2 Biosafety policy integrated into the Tenth Plan and reflected in the National Priorities, and sectoral action plans	<ul> <li>Biosafety policy supported by relevant government agencies by integration of biosafety in their sectoral development plans and strategies</li> <li>National and sectoral five year plans include biosafety.</li> <li>Public support for biosafety policy</li> </ul>	<ul> <li>Biosafety included as one of the major activity (with Outcomes and Indicators) under the Eleventh Five Year Plan of BAFRA and of the Ministry of Agriculture and Forests (July 2013 to June 2018);</li> </ul>	The 11 <sup>th</sup> Plan (Anubis and BAFRA website) Section of the 11 <sup>th</sup> Plan regarding Biosafety analysed during the mission	This is a crucial step, because, this way, Biosafety is contemplated in the National Plan to be financed by the Gross National Happiness Commission (GNHC) and will access funding

Outcome 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.				from Min of Finance.
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.	<ul> <li>Biosafety Rules and Regulation signed by Minister of Agriculture and published in official gazette.</li> <li>National Biosafety Committee established;</li> <li>Biosafety procedures, protocols and guidelines promulgated by Minister of Agriculture.</li> <li>Biosafety procedures, protocols and guidelines comply with CPB and ICCP checklist.</li> </ul>	<ul> <li>The final draft of "Rules and Regulations" is ready to be approved (waiting for the formal approval of the Law, November 2014).</li> <li>Chapter II of the Biosafety Bill establishes the National Biosafety Commission, its composition and mandate.</li> <li>Guidelines and protocols promulgated by BAFRA:</li> <li>Risk assessment of food and feed products derived from genetically modified plants (2014)</li> <li>GMO Detection Methods &amp; Protocols (2014)</li> </ul>	Draft of Rules and Regulations	<ul> <li>"Rules and Regulations" were prepared by a National Consultant.</li> <li>Their approval only depends on the Min. of Agr. and Forests.</li> <li>"Rules &amp; regulations" is a single document, then Technical Guidelines will deal with specific aspects</li> </ul>
3.2 Relevant biosafety procedures, protocols and guidelines prepared and promulgated by relevant Government agencies.	<ul> <li>Biosafety procedures, protocols and guidelines prepared by relevant agencies and published in Official gazette;</li> <li>Two training workshops carried out in drafting legal instruments for biosafety relevant agencies</li> <li>One training workshop on preparation of rules and guidelines.</li> </ul>	<ul> <li><u>Documents produced</u>:         <ul> <li>Report on process for developing guidelines and training manual for handling applications, inspection and monitoring of genetically modified organisms (2014);</li> <li><u>Guidelines produced</u>:                 <ul> <li>Guidelines for handling applications for activities involving genetically modified organisms (GMOs)/living modified organisms (LMOs) and products thereof (2014)</li> <li>Guidelines for inspection and monitoring of activities involving genetically modified organisms (LMOs) / living modified organisms (LMOs) / living modified organisms (LMOs) / living modified organisms (LMOs) (2014)</li></ul></li></ul></li></ul>	Author: Biotech Consortium India Ltd. (BCIL), in Anubis	Biotech Cons. is promoted by the Department of Biotechnology (DBT), Ministry of Science & Technology, India

3.3 Existing laws and legislations revised to ensure consistency with biosafety regulation and CBP	<ul> <li>Amendments for biosafety to sectoral regulations drawn up by relevant agencies.</li> <li>Amendments to sectoral regulations approved by relevant Ministers</li> <li>Sectoral biosafety guidelines prepared by agencies</li> </ul>	Under discussion waiting for the enactment of the Biosafety Law		GMO Act mentions the Food Act of 2005
Outcome 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	<ul> <li>Guidelines, manuals and procedures for handling all aspects of requests for LMOs prepared and made available for applicants and public;</li> <li>Clear definition of Roles and Responsibilities for functions related to LMO applications</li> <li>Clear definition of Roles and Responsibilities for ERP, illegal movement accidental release.</li> </ul>	<ul> <li>See 3.2 for Guidelines, etc. (not yet available for applicants and public)</li> <li>Chapter II of the Biosafety Law clearly indicates the Administrative functions of the National Biosafety Commission and the National Competent Authority.</li> <li>Guidelines produced on handlings applications (see 3.2) define roles and responsibilities (yet not formally published, waiting for Regulations)</li> </ul>	<ul> <li>According to the Law::</li> <li>BAFRA is NCA, also Nat Focal Point for CPB,</li> <li>the National Biosafety Commission (NBC) "is the highest decision making body for issues related to biosafety"</li> <li>The Technical Working Groups "to advise on technical and scientific issues "</li> </ul>	
4.2 A fully functional system for risk assessment and decision-making	<ul> <li>Risk assessment criteria for LMOs in Bhutan prepared and made available to stakeholders;</li> <li>Risk assessment and decision- making guidelines prepared and made available to all</li> </ul>	<ul> <li>Guidelines produced by BAFRA for Risk Assessment for Food &amp; Feed from GMOs (see 3.2) define roles and responsibilities</li> <li>Members of Biosafety Technical Working group (specialists and technical officials from relevant stakeholders) have been trained in carrying-out</li> </ul>	Guidelines available in Anubis. <u>http://www.moaf.gov.bt/bafra</u> <u>-prepares-for-regulation-of-genetically-modified- organism/</u>	

	stakeholders; • National roster of risk	risk assessment and decision making for GMOs		
	<ul> <li>assessment experts prepared and made available to NCA;</li> <li>Numbers of risk assessments carried out by NCA according to international standards</li> </ul>	No risk assessments carried out so far		
4.3 An efficient system for handling, storing and exchanging information on biosafety in place under the nBCH	<ul> <li>Information needs for biosafety in Bhutan made available to all stakeholders ;</li> <li>Roles and responsibilities clearly defined for biosafety information;</li> <li>Guidelines on biosafety information management in place;</li> <li>Data bank for biosafety information system in place;</li> <li>Information on LMO application made available to all stakeholders</li> </ul>	<ul> <li>GMO data base incorporated into the official website of BAFRA.</li> <li>Manual for operating database developed in July 2011 and distributed to all the BAFRA Inspectors (almost 150 inspectors in the field)</li> </ul>	The Manual for operating database	<ul> <li>With no IT official at BAFRA office, the database is yet to be operated.</li> <li>nBCH is operated by a different institution (NEC) and as such, the nBCH is still not operated as required.</li> <li>The issue of focal point for operating the nBCH being discussed between NCA and the existing nBCH focal (NEC). The database should be harmonized and consolidated as one site in line with the country's BCH obligations</li> </ul>

Outcome 5:				
A workable and				
effective national				
55				
system for				
monitoring,				
inspections &				
enforcement in				
place, including				
monitoring of				
socio-economic				
impacts, that is				
<b>A</b> 1				
consistent with				
National Priority				
on environment				
and disaster				
management				
5.1 Fully	• Clear guidelines and procedures on M&E	- Three Guidelines developed (see Output 3.2) for	Guidelines and Protocols	By Biotech Consortium
functional and	published by government and made	Handling Applications, for Inspection &	produced (also in Anubis)	(India) and BAFRA
effective	available to stakeholders;	Monitoring, for Risk Assessment;		(
	· · · · · · · · · · · · · · · · · · ·			
inspection,	• Clearly defined roles and responsibilities for	- One Protocol for Laboratory (see 3.2)		
monitoring and	NCA and relevant government agencies for		http://www.moaf.gov.bt/trai	
enforcement	monitoring and enforcement;	- A training information manual for handling	ning-workshop-on-	
system in place in		applications and inspections.	inspection-monitoring-and-	By Biotech Consortium
	creatly defined tores and tesponstonnes for	applications and inspections.		
BAFRA.	NCA for enforcement of decisions on LMO		handling-applications-of-	(2014)
	applications;		genetically-modified-	
	• % of staff in NCA completing legal training;		organisms/	
			<u>g</u>	
	• %of staff in NCA completing training in			
	identifying potential illegal imports of	<ul> <li><u>100% of BAFRA officials trained on</u>:</li> </ul>		There are three kinds of
	LMOs;			Inspectors in BAFRA:
	,	- GMO inspection, monitoring and handling		Plants (50), Animals
	• % of LMO releases that comply with	applications	2 weeks training / 45	(52), Food (28), in all the
	conditions of decisions	applications	e	
			participants	20 Districts (13 border
		- Annual Refresher Course		points).
			3 days (150 part., all	
			national inspectors also from	
		- GMO Detection	the field)	Internat. Consultants
				(Austria); hands-on
				(

	<ul> <li>At BAFRA Laboratory (2 weeks, 13 participants)</li> <li>In Netherlands. 2013 (2 weeks, 11 part.)</li> </ul>	training Neth. Fellowship Programme (tailored course)
<ul> <li>Risk assessment for members of the Technical Working Groups and other officials</li> <li>BCH training</li> <li>Training on GMO risk assessment and traceability in Europe (June 2014)</li> </ul>	<ul> <li>In Malaysia, 2014 (2 weeks, 6 part.)</li> <li>2 weeks / 17 participants (2013)</li> <li>1 day, 20 officials (2012)</li> </ul>	Internat. Consultant (South Africa)
<ul> <li>Two training workshop carried-out on preparation of biosafety rules and regulations</li> <li>Seminar on GMO regulations (2014)</li> </ul>	Two Weeks, 10 participants (Inspectors) BAFRA Officials	
<ul> <li><u>Study Tours:</u></li> <li>Study tour on GMO detection, NBPGR and Genetic Lab at New Delhi, Reliable Lab in Thane, SGS Lab in Ahmadabad</li> <li>Study Tour to see how biosafety is handled in Thailand and India –</li> <li>Study tour to understand the existing biosafety</li> </ul>	4 Days, South Korea (MoAF and BAFRA officials) 9 participants BAFRA,	
<ul> <li>regulations/decisions in India</li> <li>Study tour to Australia and Malaysia for studying the latest development in the area of biosafety –</li> <li><u>Regional workshops, conferences and meetings</u></li> </ul>	2011 5 participants, BAFRA, MoAF, 2011	
BCH Training in Cambodia	4 participants, BAFRA, 2012	

5.2 Strengthened BAFRA laboratories able to detect LMOs.	<ul> <li>%of technical staff trained in LMO detection;</li> <li>% of samples submitted that are processed on time</li> <li>% of LMO detection tests completed as per established procedures.</li> <li>Laboratoria conjunction of the procedures.</li> </ul>	<ul> <li>South Asian Biosafety conference and workshops, New Delhi, India -</li> <li>Workshop on quantification of GMO using PCR, Malaysia -</li> <li>Consultative meeting on biosafety/GMO and agriculture development, South Korea and Thailand – August 2014</li> <li>2<sup>nd</sup> Annual South Asia Biosafety Conference, Colombo, Sri Lanka</li> <li>International Workshop on Strategic Approaches in the Evaluation of the Science Underpinning GMO Regulatory Decision-making, ICGEB Trieste, Italy -</li> <li>A GMO lab has been established in BAFRA lab.</li> <li>Lab is equipped with required equipment and trained laboratory officials for carrying-out GMO detection;</li> <li>Protocol and manual developed for handling and testing of samples for detecting GM content (see 3.2)</li> </ul>	6 participants, BAFRA, MoAF, 2013  2 participants, BAFRA, 2013  6 part. BAFRA, 2013  1 part. BAFRA, 2013  13 participants, BAFRA, MoAF, 2014  2 part. BAFRA, 2014  1 part. BAFRA, 2013  http://www.moaf.gov.bt/wor kshop-on-genetically- modified-organism- detection-techniques/
		<ul> <li>testing of samples for detecting GM content (see 3.2)</li> <li>Laboratory staff trained in GMO detection and quantification (see 5.1)</li> <li>The Lab has interaction with the Malaysian</li> </ul>	
5.3 Emergency	• Procedures for emergency responses for	Quarantine Laboratory and the College of National Resources where the Inspectors are formed ((Royal University of Bhutan). - Not achieved.	

response procedures (ERP) established & made operational by BAFRA, the NEC and relevant Govt agencies.	<ul> <li>LMOs prepared and made available to all relevant agencies;</li> <li>% of staff in relevant agencies trained in handling emergencies to do with LMOs;</li> <li>% of emergencies dealt with as per established procedures.</li> </ul>			
Outcome 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, inter alia through the establishment of a national BCH under the BCH project	<ul> <li>Training materials on information access and sharing made available to all stakeholders;</li> <li>Percentage of stakeholders with access to information on LMOs;</li> <li>Number of times that Bhutanese biosafety website is accessed</li> <li>Percentage of LMO applications receiving submissions or inputs from public;</li> </ul>	<ul> <li>Chapter VI of the Biosafety Bill of Bhutan 2014 clearly indicates the importance of creating public awareness, access to information and education on biosafety;</li> <li>Biosafety Bill uploaded into the Ministry website and BAFRA websites.</li> <li>An user-friendly "Biosafety House" window in BAFRA website, with quick links to BCH, CBD, CPB, FAO Platform on Biosafety, ICGEB</li> </ul>	http://www.bafra.gov.bt/	National BCH issue has to be addressed in order to find more effective solutions (location, responsibility, updating, etc.)
6.2 Strengthened system for public awareness on the safe use of LMOs in place.	<ul> <li>Numbers of campaigns for raising public awareness on biosafety;</li> <li>Numbers of outreach publications on biosafety published and disseminated;</li> <li>Numbers of people participating in public meetings and debates on biosafety;</li> </ul>	<ul> <li>4000 copies of Q+A booklet on biosafety published. The booklet was distributed to:</li> <li>3000 calendars with biosafety messages published. The calendars were distributed to schools, Ministries, Parliament, NGOs and</li> </ul>	Distributed to: > 104 schools; > 10 Ministries; > 20 districts; > 47 members of National	Very successful initiative

	• % of public showing awareness of biosafety in surveys of public opinion.	<ul> <li>Armed forces;</li> <li>Documentary on biosafety/GMO was developed and aired through the national television channel;</li> <li>A cartoon on GMO was developed in local language and was aired through national television channel. The program was also uploaded under relevant websites;</li> <li>Common biosafety forum in social media;</li> <li>Biosafety to be upgraded into the curricula of College of Natural Resources (CNR).</li> </ul>	Assembly; > 25 members of National Council; > 15 NGOs and Commissions > 7. Armed forces including Royal Bhutan Police.	Very nice products. Already shared with other countries
		- BAFRA is member of FAO GM foods platform.	Under three different academic areas namely, Forestry, Agriculture and Animal Science This is a simple online platform to share	
			information on safety assessment of GM foods.	
6.3 Strengthened system for public participation in decision-making on LMOs in place.	<ul> <li>NCA decision making procedures provide guidelines for public representation on their decision making body;</li> <li>Number of people making submissions on applications for LMO release into the environment;</li> <li>Numbers of people attending training workshops;</li> <li>% of staff in NCA trained in public participation;</li> </ul>	The National Bill does not permit any environmental release of GMOs		There is a BIO- BHUTAN Company in the country that exports organic lemon grass oil Bhutan is going to be a 100% Organic Country (see interviews to the Minister of Agr. and Forests, <u>http://www.theguardian.</u> <u>com/sustainable-</u>

				business/bhutan-organic- nation-gross-national- happiness-programme, and http://www.forumforthef uture.org/greenfutures/art icles/bhutan-worlds-first- 100-organic-nation)
Outcome 7: Enhanced regional cooperation on biosafety as well as sharing of experiences with other NBF projects globally				
7.1 Technical expertise, decision-making tools, training activities and materials for training and outreach shared with other countries in SAARC	<ul> <li>Numbers of joint biosafety training activities with SAARC countries;</li> <li>Numbers of regulators and experts from SAARC countries participating in capacity building activities in Bhutan;</li> <li>% of training materials and manuals developed in consultation with SAARC</li> </ul>	<ul> <li>Bhutan hosted four days (May 2014) SAARC Regional Workshop on the theme "Ensuring Biosafety through legal and regulatory instruments: South Asian Perspectives" focus on knowledge and experience sharing about modern biotechnology innovation and its applications towards food security and poverty alleviation, vis-à-vis its regulations.</li> <li>Important papers from the workshop compiled and published.</li> </ul>	http://www.moaf.gov.bt/sout h-asian-regional-workshop- on-biosafety/ http://www.moaf.gov.bt/16t h-npc-meeting-ongoing-in- thimphu/ - 44 participants from six SAARC member countries (Bangladesh, Bhutan, India, Nepal,	The workshop was seen as an initiative to bring in regional experts from SAARC member countries to provide regional perspectives, discourse and potential directions towards building a legal instrument that takes benefit of the
7.2 Alignment of biosafety policies, regional mechanisms and common formats for sharing of information amongst SAARC countries on biosafety.	<ul> <li>Joint meeting of SAARC Working Groups on Environment and on Biotechnology hosted by Bhutan to discuss alignment of biosafety policies;</li> <li>SAARC agreement on mechanisms for sharing biosafety information</li> </ul>		<ul> <li>Pakistan and Sri Lanka), together with representatives from FAO and SAC (SAARC Agriculture Centre) attended the workshop;</li> <li>Some of recommendations and findings from the</li> </ul>	regional/global experiences;

			workshop were discussed during the 2 <sup>nd</sup> Annual South Asia Biosafety Conference in Sri Lanka (September 2014). Two participants from BAFRA participated in the workshop (see Output 5.1)
7.3 Establish networks established with other Implementation project teams for sharing experiences, lessons & best practices.	<ul> <li>Attendance by NCA staff at biosafety meetings organised by UNEP and CPB;</li> <li>Exchange of reports with other NBF projects.</li> </ul>	- The project assisted UNEP in hosting the 16 <sup>th</sup> NPC meeting in Thimphu, Bhutan. Nineteen officials from nine countries including representatives from UNEP attended the meeting, which was funded by UNEP.	

#### 4.3 Effectiveness: Attainment of project objectives and results

- 41. As previously stated (section 3.2), the overall objective of the project is "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". The specific objectives of the project have been formulated as seven (7) direct Outcomes, each of which was intended to be achieved under the project's seven components.
- 42. The Evaluation has assessed to what extent the delivery of the Outputs (see Table 1) has produced the short to medium term institutional changes and systemic effects (Outcomes) designed to achieve higher level of results (Impact). The achievement of the planned Outcomes of the Projects has been analysed and discussed with the National Project Coordinator and the NCA (BAFRA) director and officers during the country visit, by using the Table 2<sup>14</sup> (sub-chapter 4.3.1), which describes in detail the achievements at Outcomes level.
- 43. Sub-chapter 4.3.2 presents a qualitative analysis and interpretation of the Outcomes achieved in the light of the reconstructed Theory of Change (TOC) from Outputs to Outcomes depicted in Diagram 1, whereas Diagram 2 illustrates the TOC from Outcome to Impact and sub-chapter 4.3.3 discusses and makes an assessment of the Likelihood of Impact.
- 46. Overall, based on the assessment contained in the following three sub-chapters (4.3.1, 4.3.2 and 4.3.3), the Evaluation considers that the attainment of project objectives and results (Effectiveness) of the Project has been <u>Highly Satisfactory (HS)</u>.

<sup>&</sup>lt;sup>14</sup> Based on a format that the Consultant had shared with the team of the Project before the country visit

#### 4.3.1 Achievement of direct Outcomes

This section presents in detail the achievements at Outcome level. Achievements of direct Outcomes are considered Highly Satisfactory (HS)

Objective / Outcome	<i>Outcome / objective level indicator</i>	Baseline Conditions	Target Achieved October 2014 (evidence-based) and comments
<b>Project Objective</b> : 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	<ul> <li>Safe use of biotechnology for food security included as a priority in the implementation of the Tenth Plan;</li> <li>NCA able to process all biosafety applications on time in conformity with provision of</li> </ul>	<ul> <li>NBF approved by</li> <li>Government but no action on integration into Tenth Plan;</li> <li>Food security a priority for Bhutan but ban on GMOs;</li> <li>NCA has no capacity for biosafety, only for quarantine</li> </ul>	<ul> <li>Biosafety is integrated in the 11<sup>th</sup> Plan of MoAF (2014-18)</li> <li>BAFRA (NCA) is prepared to implement systems for handling applications, GMOs detection, risk assessment and monitoring.</li> </ul>
the Kingdom. Outcome 1 Baseline established for information on the safe use of biotechnology in Bhutan through a stocktaking analysis.	the CPB. - Stocktaking, review and assessment reports submitted to Government; - Reports made available to stakeholders' - Reports published on nBCH.	and food safety. - Some information (35%) available in NBF.	The baseline survey of national human, technical and institutional capacities has been completed; findings and recommendations have been submitted to the Ministry of Agriculture in 2010, allowing the subsequent, progressive implementation of the National Biosafety Framework
Outcome 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.	- All relevant national action plans and strategies include - biosafety as an issue relevant to their sector - Biosafety policy formally adopted by Government	- Sectoral plans and Tenth Plan stress food security but not biosafety.	Biosafety is one of the main sector of activities, with Outcomes and Indicators, of the Eleventh Plan of the Ministry of Agriculture and Forests (2013-2018)
Outcome 3: A legal and regulatory framework on biosafety in place that is consistent with the CPB, and is workable and responsive	- Biosafety rules and regulation incorporated into Food Act 2005. - Biosafety rules and regulation comply with	- GMO ban in place that is inconsistent with CPB obligations.	<ul> <li>Biosafety is incorporated into the Food Act of 2005</li> <li>"Rules and Regulations" are ready to be approved, just waiting for the promulgation of the National law</li> <li>Main Guidelines prepared (see Output 3.2)</li> </ul>

Table 2: Assessment of Outcomes Achievement (based on App.7 / M&E Framework) Project "Implementation of the National Biosafety Framework of Bhutan"

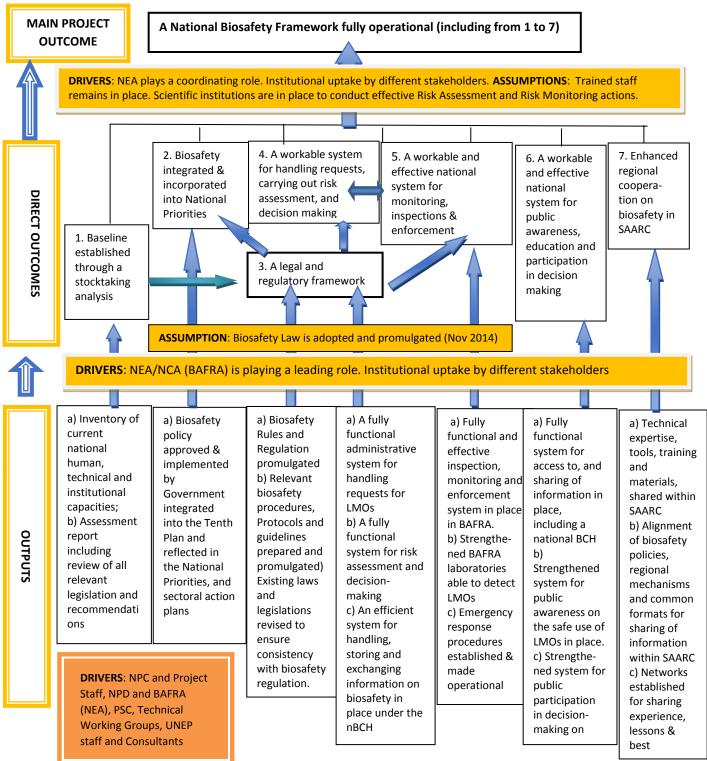
to national needs and the National Priorities of the Tenth Plan.	Cartagena Protocol, ICCP checklist, and trade related obligations.		
Outcome 4: A workable system for handling requests, carrying out risk assessment, and decision making for LMOs in place that reflects the priorities of the Tenth National Plan.	<ul> <li>Percentage of LMO applications processed on time and according to established procedures;</li> <li>Percentage of decisions for LMO applications made with public consultation as defined in Cartagena Protocol Article 23(2);</li> <li>Summaries of all decisions on LMO applications published on BCH;</li> </ul>	- GMO ban in place that is inconsistent with CPB obligations.	<ul> <li>NCA is able to process all biosafety applications (for food and feed import).</li> <li>Environmental release is not permitted by the Law</li> </ul>
Outcome 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.	<ul> <li>Clear guidelines and procedures on M&amp;E published by government and made available to stakeholders;</li> <li>Percentage of monitoring requirements for LMO decisions completed as per established procedures.</li> <li>Clearly defined ERP roles and responsibilities for NCA and other relevant government agencies;</li> </ul>		<ul> <li>All relevant guidelines are ready</li> <li>Role and functions are very clear</li> <li>No applications so far</li> </ul>
Outcome 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	<ul> <li>% of public showing awareness of biosafety in surveys of public opinion;</li> <li>% of applications receiving submissions or inputs from public;</li> <li>Numbers of people participating in public meetings and debates on biosafety;</li> </ul>	- limited awareness through NBF development project.	<ul> <li>Public survey was made at the beginning of the Project (2011)</li> <li>Unfortunately not repeated at the end of the project to assess the difference and the progress on awareness</li> </ul>

Outcome 7:	Biosafety included as a topic	SAARC has working groups on	- Biosafety included as part of agenda for SAARC working
Enhanced regional cooperation	for joint meeting in Bhutan of	environment and on	groups on environment and on biotechnology;
on biosafety in SAARC, as well	SAARC Working Groups on	biotechnology but no regional	- Mechanisms in place for sharing information on biosafety in
as sharing of experiences with	Environment and on	forum for biosafety	SAARC;
other NBF Implementation	Biotechnology;		- Networking between regulators in SAARC and with other
projects globally	Biosafety included in agenda		implementing countries.
	oif future meetings of		
	environment and		
	biotechnology working groups.		

#### 4.3.2 Direct outcomes from reconstructed TOC

- 44. As previously stated (section 3.2), the overall objective of the project is "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". The specific objectives of the project have been formulated as seven (7) direct Outcomes, each of which was intended to be achieved under the project's seven components.
- 45. Diagram 1 maps out the lower part of the reconstructed Theory of Change (from Outputs to Outcome) based on our understanding of the causal logic of the project from the project documents. The final adoption of the Biosafety Law in November 2014 enables the subsequent adoption by the MoAF of the "Rules and Regulations" (already prepared) on Biosafety. All main guidelines have equally been prepared and will be adopted as soon as the Rules and Regulations are promulgated. Overall, the crucial Direct <u>Outcome 3</u> (A legal and regulatory framework) can be considered virtually achieved.
- 46. Direct <u>Outcome 1</u> (Baseline established through stocktaking analysis) has been achieved in 2010 and has been instrumental to the achievement of Outcome 3, permitting to identify needs and gaps in the regulatory framework and respond accordingly.
- 47. Considering that Biosafety is one of the main sectors of activities of the Eleventh Plan of the Ministry of Agriculture and Forests (2013-2018), it will be automatically included in the National Plan to be financed by the Gross National Happiness Commission (GNHC). Direct <u>Outcome 2</u> can therefore be considered as fully achieved.
- 48. The implementation of Biosafety systems for the handling of requests, LMOs risk assessment and decision-making procedures (Direct <u>Outcome 4</u>), and of systems for LMOs monitoring, inspections and enforcement (Direct <u>Outcome 5</u>) has been inserted in the usual routine of work of BAFRA's Inspectors and Officers, through staff Capacity Building, laboratory upgrading, preparation of specific guidelines, laboratory protocols and technical manuals. Nevertheless, the systems cannot be considered operational, since no concrete activity on LMOs detection has started so far. Considering the technical and procedural solidity of BAFRA, the Evaluation does not envisage any major problem for the functioning of the new Biosafety systems. Direct Outcomes 4 and 5 can therefore be considered achieved at 80-90%.
- 49. The information campaigns have enhanced public awareness on Biosafety issue, yet an effective national system for public awareness, education and participation in decision making (Direct <u>Outcome 6</u>) cannot be considered fully achieved so far. Cooperation and networking at SAARC (South Asian Association for Regional Cooperation) level has surely been enhanced (Direct <u>Outcome 7</u>) and Bhutan is playing a proactive role in the regional initiatives.
- 50. As a result of all the above, the Evaluation considers that the <u>main Project Outcome</u> (A National Biosafety Framework fully operational) has been achieved, though not yet consolidated due to the lack of concrete opportunities of application, so far. Moreover, it has to be stressed that one of the Assumptions identified (Scientific institutions are in place to conduct effective Risk Assessment and Risk Monitoring) has to be permanently maintained and upgraded inside BAFRA, yet in absence of a national academic and research system able to play a supporting role. This remark has implications in terms of Sustainability (see 4.4.3), Conclusions (§ 101) and Recommendations (Rec. 2.b).
- 51. The Evaluation has permitted to confirm the driving force of the Project, particularly the National Project Coordinator (NPC), in the achievement of the Project Outcomes. The Project has been highly instrumental to aggregate and network with other key-drivers, namely the staff and managers of BAFRA, the members of the Project Steering Committee and of the so-called Technical Working Groups that have actively participated in the preparation of the Law, Rules and Regulations, Guidelines, etc. As a whole, progress towards the achievement of Outcomes Achievement can be considered <u>"Satisfactory"</u>.

# Diagram 1: Theory of Change Project "Implementation of the National Biosafety Framework of Bhutan": From OUTPUTS TO OUTCOMES

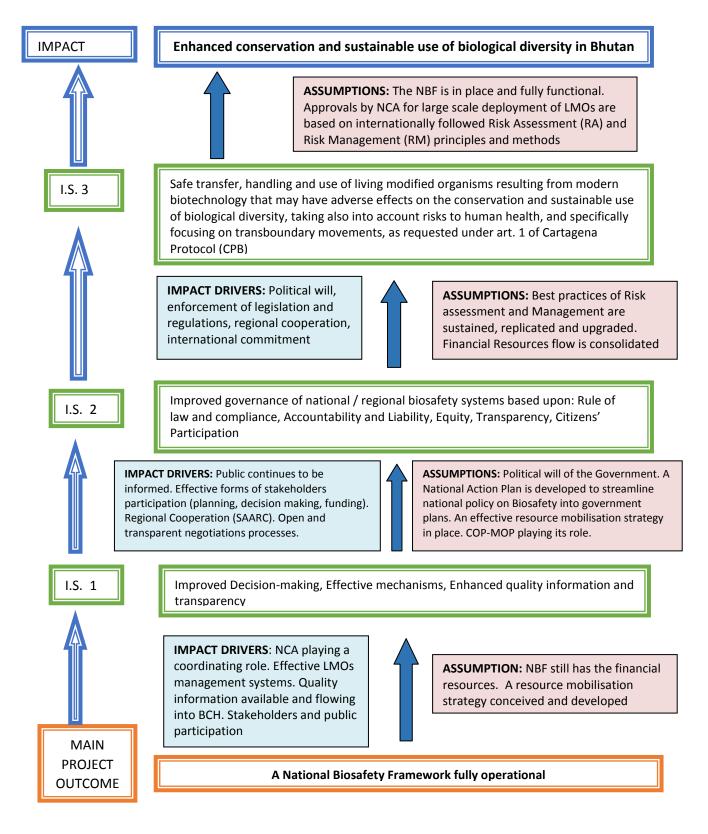


#### 4.3.3 Likelihood of impact using ROtI and based on reconstructed TOC

- 52. The assessment of the likelihood of achieving the expected impact of the Project has been conducted through the so-called "Review of Outcomes to Impacts" (ROtI) approach, which is used to assess the likelihood of impact by building upon the concepts of the Theory of Change (see Section 3.9).
- 53. In other words, it has been appreciated to what extent the project has to date contributed, and is likely in the future to further contribute to changes in stakeholder behaviour as a result of the project's direct outcomes, and the likelihood of those changes in turn leading to environmental benefits (impact). The TOC also depicts any intermediate changes required between project outcomes and impact, called intermediate states. The TOC further defines the external factors that influence change along the pathways, called drivers (when the project has a certain level of control) or assumptions (when the project has no control). Diagram 2 that follows shows the possible pathway from Outcome to Impact
- 54. The overall intended impact of the project is the Global Environmental Benefit to which it contributes: the enhanced conservation and sustainable use of biological diversity in Bhutan. The pathway from the Project Outcome (a fully operational NBF) to the intended Impact is not a straightforward process: transitional conditions (called Intermediate States) have to be fulfilled, as shown in Diagram 2, which presents our understanding of the causal logic and of the pathway from Outcome to Impact.
- 55. Three main Intermediate States (I.S.) have been identified. Under the conditions that, firstly, the NBF has the financial resources to effectively implement its Work Plan and, secondly, a resource mobilisation strategy is conceived and developed (as discussed under Financial sustainability, Chapter 4.4.2), the process will lead to "Improved decision-making processes for LMOs approval, effective implementation mechanisms and enhanced quality information and transparency" (I.S. 1). Key impact drivers in that step are the coordinating role of the National Biosafety Commission (NBC) and of the National Competent Authority/NCA (BAFRA), effective LMOs management systems (e.g. for detection and referral, for handling applications, for risk assessment and monitoring), active stakeholders and public participation, quality information available and timely flowing into BCH and national websites.
- 56. Improved decision-making will lead to "Improved Governance of National/International Biosafety systems based upon: Rule of Law and Compliance, Accountability and Liability, Equity, Transparency and Citizens' Participation" (**LS. 2**), under the assumption that the political will of the Governments is not missing. That should be reflected in the consolidation of NBF Work Plans to streamline national policy on Biosafety into government plans and in an effective strategy of resource mobilisation put in place. Another assumption is that COP-MOP (the Conference of the Parties serving as the Meeting of the Parties to the Protocol) is playing its role of governing body of the Protocol. The main impact drivers at that stage will be effective forms of stakeholders participation (in planning, decision making and funding), conducive to open and transparent information flows and negotiation processes at different levels. Another driver, particularly relevant for the institutional sustainabilty (see 4.4.3), is the Regional Cooperation under SAARC umbrella.
- 57. The Intermediate State 3 (**I.S. 3**) is the Objective of the Protocol itself, as stated in its art. 1: "The safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements". Political will and regional cooperation will act as impact drivers at that level, under the main assumption that the NCA's decision-making persists based on rigorous Risk Assessment and Risk Management best practices, and that financial resources flow into Biosafety programs mechanisms.
- 58. Under the same assumption that internationally followed principles of Risk Assessment and Risk Management are lastingly used by the National Competent Authorities (NCA) for deciding on LMOs

production/use, the **Project Impact** (Enhanced Conservation and Sustainable Use of Biological Diversity in Mongolia) can be achieved.

#### Diagram 2: Theory of Change Project "Implementation of the National Biosafety Framework of Bhutan": From OUTCOME to IMPACT



- 59. According to the TOR of the Evaluation, the Evaluation has to assess the likelihood of the Project to achieve the expected Impact, by using the rating scales of Table 3 and 4 that follow. Based on the analysis presented in this Chapter, the Evaluation deems that the Project deserves an "A" Outcome rating.
- 60. Progress towards Intermediate States has started, with the inclusion of Biosafety into the 11<sup>th</sup> Plan of the MoAF (which guarantees a budget from the Government), the increased ownership of BAFRA, the opening of some extra-budgetary channels of funding, the growing dynamism of SAARC around Biosafety at regional level. Rating of progress towards Intermediate States is "C" and the aggregate rating is "AC". Considering the high level of national appropriation of the results and the solidity of the NCA, a notation "+" is also attributed, producing a final rating "AC+".

Outcome Rating	Rating on progress toward Intermediate States
D: The project's intended outcomes were not	D: No measures taken to move towards intermediate states.
delivered	
C: The project's intended outcomes were	C: The measures designed to move towards intermediate states
delivered, but were not designed to feed into a	have started, but have not produced results.
continuing process after project funding	
B: The project's intended outcomes were	B: The measures designed to move towards intermediate states
delivered, and were designed to feed into a	have started and have produced results, which give no
continuing process, but with no prior allocation of	indication that they can progress towards the intended long
responsibilities after project funding	term impact.
A: The project's intended outcomes were	A: The measures designed to move towards intermediate states
delivered, and were designed to feed into a	have started and have produced results, which clearly indicate
continuing process, with specific allocation of	that they can progress towards the intended long term impact.
responsibilities after project funding.	

61. According to the used methodology, the rating obtained is translated onto the usual six point rating scale used in all UNEP project evaluations, as shown in Table 4 below. The Project, with an aggregated rating of AC+ as described in the paragraph above, can therefore be considered "Likely" to achieve the expected Impact.

Table 4. 'Overall likelihood of impact achievement' on a six point scale.

Highly Likely	Likely	Moderately Likely	Moderately Unlikely	Unlikely	Highly Unlikely
AA AB BA CA BB+ CB+ DA+ DB+	BB CB DA DB AC+ BC+	AC BC CC+ DC+	CC DC AD+ BD+	AD BD CD+ DD+	CD DD

#### 4.4 Sustainability and replication

62. The evaluations has analysed to what extent follow-up work has been initiated and how project results could be sustained and enhanced over time. The reconstructed TOC presented in the previous chapter has assisted in the evaluation of sustainability, by identifying the main driving forces and assumptions influencing Project's achievements. Four aspects of sustainability have been addressed: a) Socio-political sustainability, b) Financial sustainability, c) Institutional sustainability, d) Environmental sustainability.

## 4.4.1 Socio-political sustainability

- 63. As discussed in the previous chapters, the Project has taken substantive steps in putting forward the Biosafety Agenda in the country by incorporating it in Ministerial and Governmental Plans, which represents a major element of socio-political sustainability. The strong and diffuse national attitude of preservation and stewardship of cultural and environmental assets must also be considered a major element of socio-political sustainability for the Biosafety agenda.
- 64. Due to its condition of small and landlocked country, and the tiny national budget, there is a consensual understanding that socio-political sustainability needs to be fostered through stronger alliances with national and regional partners, so as to enable effective forms of stakeholders' participation in planning, decision making and funding (key-drivers from I.S 1 to I.S 2 in Diagram 2). There is also the need to establish stronger links with Civil Society Organizations, particularly those active in environmental and consumers' rights protection, as well as with Private Sector actors, particularly those interested in promoting the environmental and cultural assets of the country (e.g. green tourism, organic products, etc.).
- 65. The fact that, in the Five-year Plan of the Ministry of Agriculture and Forest (MoAF), Biosafety is integrated with Biosecurity, Food Safety and Quality Assurance under the same Programme, is an element of strength and sustainability, which creates synergies, cooperation and socio-political consensus around common themes like imported food's quality control, labelling, etc. Socio-political sustainability is rated <u>"Likely (L).</u>"

## 4.4.2 Financial sustainability

- 66. Financial sustainability is surely an area of concern among the stakeholders. The inclusion of Biosafety in the national Plans gives elements of optimism, since Biosafety will be included in the exercise of budgetisation by the Gross National Happiness Commission (GNHC). However, whether the budget assigned would be enough to carry out the planned activities or not, remains to be seen.
- 67. BAFRA is confident to have access to a portion of GEF 6 allocation to the country, but the need for alternative sources of funding for the implementation of the National Biosafety Framework is recognized. The regional dimension, through SAARC umbrella, could be a promising instrument for increasing funds availability for the Biosafety Agenda in Bhutan.
- 68. The remarkable result obtained by the Project in terms of extra-fund raising (see 4.6.5) from different sources (Bilateral Cooperation Agencies, International Institutions, SAARC) has to be stressed and it represents an element of optimism for future financial support. Overall, Financial sustainability is considered Likely (L).

## 4.4.3 Institutional sustainability

- 69. Institutional sustainability is crucial for the progress of the results achieved so far. The NCA (BAFRA) is a solid and dynamic institution playing a strategic role in the MoAF. Actually, it is responsible for the implementation of all relevant national policies stemming from legal instruments such as the Plant Quarantine Act, Seed Act, Pesticide Act, Livestock Act, Food Act, Forest and Nature Conservation Act, Biodiversity Act and, eventually, the Biosafety Act, and of their secondary and tertiary legislations. It implements sanitary and phytosanitary measures, functions as the National Food Quality and Safety Control agency, regulates and promotes the quality of agriculture inputs (seeds, animal feed, etc.).
- 70. BAFRA is not only the National Competent Authority for CPB, but also the Focal Point for other International Bodies, such as the IPPC (International Plant Protection Convention), CAC (*Codex Alimentarius* Commission), the National Enquiry Point for WTO-SPS Agreement (World Trade Organization-Sanitary and Phytosanitary Agreement) and as the competent authority for Biosecurity of Bhutan.

- 71. The institutional anchorage of Biosafety is therefore strong and the possibility to liaise with other national and international regulatory instruments is equally high. Both are crucial factors of institutional sustainability.
- 72. The on-going transition from a "Project Office" with a full-time, externally hired NPC (though located in BAFRA), to a fully integrated Biosafety Unit within BAFRA under the responsibility of a BAFRA Officer has been discussed. Opportune and gradual measures of "replacement" are already on-going (targeted training, participation to meetings also at regional level, etc.).
- 73. The new Biosafety Law foresees the National Biosafety Commission (NBC), chaired by the Minister of MoAF and with thirteen (13) members from the MoAF (6 members, including BAFRA), Ministry of Health (1), Ministry of Economic Affairs (2), Ministry of Home and Cultural Affairs (1), Office of Attorney General (1), National Environmental Commission (1) and the Bhutan Chamber of Commerce and Industry (1), which is the only Non-State Actor present in the Commission (see also 4.6.3). The Technical Working Groups, also foreseen in the new Biosafety Law, have already been working for years in the framework of the Project.
- 74. As pointed out in Diagram 2, COP-MOP also makes part of the institutional sustainability at national and regional level, through appropriate and effective decisions. A stronger Regional Cooperation under SAARC<sup>15</sup> umbrella could not only contribute to institutional sustainability, but also make national programmes more cost-effective, through cost-sharing and service-sharing, hence also contributing to Financial Sustainability. The workshop organised by the Project and BAFRA in May 2014<sup>16</sup> with the participation of representatives of SAARC countries, has identified possible areas of cooperation on LMOs detection (e.g. regional reference laboratory), harmonized labelling, border inspections (e.g. Green Customs initiative).
- 75. Institutional sustainability also depends on the cooperation and effectiveness of the UN System. It is quite unfortunate to observe, in a country like Bhutan that has adopted the approach "Delivery as One", the fragmentation of initiatives and dispersion of funds within the System. As a result, the GEF Biosafety Project implemented by UNEP is little known at UN House and GEF funded Project on Nagoya Protocol implemented by UNDP has no links with Biosafety Project (see also Lessons Learned, 5.2). As a whole, institutional sustainability is considered Likely (L).

## 4.4.4 Environmental sustainability

- 76. The Precautionary Principle is well reflected in the National Biosafety Law and Biosafety is included in the 11<sup>th</sup> Plan of MoAF under the Sectoral Key Resource Areas:
  - Enhanced conservation of plant and animal genetic resources and natural heritage sites;
  - Enhanced sustainable forest, land, water and biodiversity resources.

Environmental Sustainability is rated Likely (L).

## 4.4.5 <u>Catalytic role and replication</u>

77. The Project has been a strong catalytic factor for the Biosafety Agenda in the country, promoting outstanding behavioural and institutional changes like the preparation of the National Biosafety Law, Rules and Regulations, the setting up of the first national laboratory for GMOs quantitative detection and the diffusion of knowledge and complex scientific concepts to a large public through incisive information campaigns.

<sup>&</sup>lt;sup>15</sup> South Asian Association for Regional Cooperation, members countries: Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka

<sup>&</sup>lt;sup>16</sup> South Asian Regional Workshop on Biosafety "Ensuring Biosafety through legal and regulatory instruments: South Asian Perspectives", Thimphu, 26-29/05/2014

- 78. The Project has also promoted the meaningful participation of a consistent number of national officers and specialists through Technical Working Groups that have advised on several, specific issues regarding Biosafety regulation in the country. The Technical Working Groups have been explicitly recognised by the new Biosafety Law "to advise on technical and scientific issues related to genetically modified organisms, as needed or as prescribed in the Rules and Regulations". This is a major result.
- 79. Eventually, the Project has represented an extraordinary opportunity for motivated individuals to be catalytic of changes in their own country and to substantively upgrade their technical and managerial capacities. Overall, the Catalytic role and replication is considered <u>Highly Satisfactory (HS)</u>.

## 4.5 Efficiency

- 80. The Project has been quite cost-effective in its execution, thanks to its institutional integration within the BAFRA and the use of the existing national expertise within BAFRA and the MoAF. The setting of the GMO laboratory has been done through the upgrading of the existing BAFRA laboratory. Cost-effectiveness has also been enhanced through a successful strategy of fund-raising, which has largely contributed to Capacity Building results without extra-costs for the Project (see 4.6.5).
- 81. Despite some delays in its starting phase and during the implementation, because of Governmental changes in 2013, the Project has also been quite time-effective in its execution, completing all the planned activities and delivering the foreseen outputs with a small no-cost extension of seven months. Efficiency is rated <u>Satisfactory (S)</u>.

## 4.6 Factors affecting performance

## 4.6.1 <u>Preparation and readiness</u>

- 82. The quality of project design was assessed in the Inception Report and rated Satisfactory (S). It is interesting to observe that the project document looked quite critic on the existing (at the time of project elaboration) LMO's banning and, in fact, the assessment of the "Risk identification and Social Safeguards" had scored poorly (Moderately Unsatisfactory), because "Potential negative effects of biotechnologies on the environment and on the socio-economic structure of the rural sector are not discussed". As a matter of fact, the new Biosafety Law prohibits the LMOs environmental release, a possibility not contemplated in the ProDoc.
- 83. The fact that, as pointed out in the previous chapter, the results were achieved in the expected timeframe and the budget has been adequate to the expected results, show that the Project design was actually accurate on those points. Overall, Preparation and readiness are rated <u>Moderately Satisfactory (MS)</u>.

## 4.6.2 <u>Project implementation and management</u>

- 84. The mechanisms of project implementation have followed those outlined in the project document. The guiding /oversight central role of the NCA, also NEA of the Project (BAFRA), was clearly foreseen in the project document and has been effectively implemented. The direct execution responsibility of the NPC, a national expert hired by the Project, proved also to be an effective choice. The Project Steering Committee (PSC) has evolved into the National Biosafety Commission foreseen in the new Biosafety Law, with almost the same component members.
- 85. External and specialised expertise has been taken on board by the Project through the so-called Technical Working Groups that have played a substantive role in project implementation and have been formally contemplated in the new Biosafety Law. Overall, Project Management and implementation are rated <u>Highly Satisfactory (HS)</u>.

## 4.6.3 <u>Stakeholder participation and public awareness</u>

- 86. The Evaluation has received the impression of a meaningful participation of the stakeholders in the Project Steering Committee (now Biosafety National Commission, NBC) and in the Technical Working Groups. The composition of the NBC can, however, raise some concerns regarding the unbalanced representation of the different sectors, as described in 4.4.3. It has to be noticed that in the previous Project Steering Committee, NGOs and Private Sector had a larger representation, with the presence not only of the Bhutan Chamber of Commerce and Industry, but also of Bhutan Association of Women Entrepreneurs and of the Royal Society for Protection of Nature. It would be a pity to lose their participation in the future NBC and the issue will need to be addressed in the future, with the progression of the Biosafety Agenda in the country.
- 87. The public awareness initiatives have been so far directed to convey information to the general public or to certain target groups (e.g. students) and to promote debate within specific audiences (experts, professors, officers, etc.). On this regard, too, the transition to more meaningful forms of participation of groups, associations and citizens in the national Food Safety and Biosafety agenda seems inevitable, particularly in urban areas like the capital city Thimphu. As a whole, stakeholders' participation and public awareness have to be considered <u>Satisfactory (S)</u>.

## 4.6.4 <u>Country ownership and driven-ness</u>

88. Country ownership is surely strong and made effective through the leading role of BAFRA, as previously explained under Sustainability (4.4.3). The NBC has still to prove its effectiveness under the new institutional setting of the Biosafety Law and the concrete implementation of the national systems for handling applications and carrying out the follow up of LMOs management in the country, however there are no particular reasons to believe that it would not play its role of national strategic guidance on Biosafety. Overall, country ownership is strong, rated <u>Highly Satisfactory (HS)</u>.

## 4.6.5 Financial planning and management

- 89. As previously remarked under the chapter of Efficiency (chapter 4.5), the Project has been able to efficiently and timely execute planned activities. That has been possible also due to application of proper standards of transparency and clarity in the financial planning, management and control. Main reasons for that are:
  - The appropriate use of the Anubis platform that allows the update control of disbursements from UNEP to the Project, the quarterly financial reporting from the Project to UNEP and subsequent replenishment by UNEP, as well as the aggregate financial statement at any point in time (updated to the end of the previous trimester).
  - The regular and fast disbursement from UNEP after the Project request (nine instalments in total);
  - Annual audits have been carried out regularly from 2011 on; the last one was carried out in June 2014, concerning the period January-December 2013 and concluded that "the project had maintained reasonably effective internal control in all material respects".
  - The timely procurement of goods, mainly office and laboratory equipment, according to the established procedures (tendering, etc.).
  - 90. The financial statement of the Project provided by the NPC as of 30/09/2014 shows a rate of expenditures of 95% of the total budget of the project (see Annex 3). Five budget revisions have been approved that did not essentially alter the content of the activities and the results. According to data provided by the Project, co-financing from Government contribution was of 655.575 USD on 30/09/2014.

91. The Project has raised supplementary funds for the remarkable amount of USD 106.500, which represents an extra-budget amount of more than 12%. The Netherland Fellowship Program has contributed for 95.000 USD (two weeks of "ad hoc" training for 11 BAFRA officials in the Netherlands), while other sponsors have contributed with lower amounts for trainings and participation to regional meetings (see Annex 5). Overall Financial Planning and Management are Highly Satisfactory (HS).

## 4.6.6 <u>UNEP supervision and backstopping</u>

- 92. National stakeholders consider UNEP supervision and backstopping of high quality, for four main reasons:
  - The technical and administrative backstopping of the Biosafety Unit has been constant and effective, through prompt replies (through skype and email) to any doubt or question on financial issues, on the use of the platform ANUBIS, as well as by providing technical advise on substantive issues related to project execution, such as institutional aspects, definition of priority;
  - The support received through the field missions of UNEP Task and Financial Managers, during the first supervisory visit, the Mid Term Review and the yearly, regional meetings of the National Project Coordinators;
  - The organization of the yearly meetings of the National Project Coordinators, which are considered a valuable moment of exchange and horizontal learning, technical and administrative updating, and of general "empowerment" of the project coordinators.
  - The quality and timeliness of the technical assistance received by UNEP international consultants, direct Technical support/advice provided by Task Manager and/or the possibility to upgrade national capacities through the participation to regional or international meetings, workshops, trainings.
- 93. There is no evidence of any involvement of UNEP Regional Office (Bangkok) in activities of project supervision and backstopping. Overall, UNEP supervision has been rated <u>Highly Satisfactory (HS)</u>.

## 4.6.7 Monitoring and evaluation

- 94. The quality of the logical framework of the Project, as well as its Monitoring system were considered Satisfactory in the assessment of the Project Design presented in the Inception Report, including Results Framework, Milestones and Deliverables Table and a very detailed M&E Framework. Surprisingly enough, yet not differently from other NPCs, the Project Coordinator has never used such instruments. She has, on the contrary, elaborated her own instrument of project monitoring, based on a "home-made" work plan, which has functioned very efficiently to steer project's activities and expenditures. As for the Evaluation component, an internal Mid-Term Review was carried out by UNEP task Manager in August 2013 and a number of key-recommendations were issued on normative activities, training (both with a plan), regional cooperation & networking, follow-up and sustainability. The major part of the recommendations has been implemented.
- 95. The Evaluation has to remark (and not specifically for the case of Bhutan's project) that the information acquired through the UNEP/GEF Monitoring system in place (progress reports, PIR rating, etc.), though timely flowing from the project to UNEP, is not very helpful to really understand (at least, by an outsider view) the progress and problems of project implementation. The formats are not helpful for channelling synthetic data and meaningful information<sup>17</sup>. As a result, the reports are often repetitive, poor and boring; the scoring exercise looks somewhat "standardised" and

<sup>&</sup>lt;sup>17</sup> Reporting format is UNEP's template for reporting

rarely supported by any evidence or value judgement. In sum, the effectiveness of the whole system, in terms of result-based management, is highly questionable. Overall, Monitoring and Evaluation has to be considered <u>Moderately Satisfactory (MS)</u>.

## 4.7 Complementarity with UNEP strategies and programmes

96. The Project relates to two of the cross-cutting areas of UNEP's intervention: Ecosystem Management (EM) and Environmental Governance (EG). Regarding the <u>Sub-programme Ecosystem Management</u>, the Evaluation considers that the Project has been greatly instrumental to the achievement of Expected Accomplishment (EA) 3 in the PoW 2014-15, as showed in the comparative table here below:

EM Expected Accomplishment (EA) 3	Project contribution (how)
"Outputs will focus on the collaborative efforts aimed at strengthening the science-policy interface at global, regional and national levels	<ul> <li>Setting up and implementation of Technical Working Groups of specialists to support the development of regulatory instruments;</li> <li>Organizing the regional (SAARC) workshop "Ensuring Biosafety through legal and regulatory instruments: South Asian Perspectives"</li> </ul>
and assisting countries to create the necessary institutional, legal and policy conditions to integrate goods and services into their development planning, decision making and poverty reduction measures.	<ul> <li>Supporting the preparation of the Biosafety Law, Rules and Regulations, Guidelines;</li> <li>Integrating Biosafety into the 5-year planning of the MoAF, hence into National Plans.</li> </ul>
In particular, support will be provided to countries in creating the enabling environment for the implementation of biodiversity-related MEAs, with a particular emphasis on the achievement of the Aichi biodiversity targets"	<ul> <li>Supporting NBF implementation, hence enabling the country to establish and further develop effective biosafety systems for the implementation of the Cartagena Protocol;</li> <li>Contributing to Aichi Target 13 (minimizing genetic erosion and safeguarding genetic diversity), to Aichi Target 17 (effective, participatory and updated national biodiversity strategy and action plan) and to Aichi Target 19 (improving and sharing knowledge and science- based technologies relating to biodiversity)</li> </ul>

97. Regarding <u>Sub-programme Environmental Governance</u>, the Project has been highly instrumental to the achievement of Expected Accomplishment (EA) b in PoW 2014-15, as showed in the comparative table here below:

EG Expected Accomplishment (EA) b	Project contribution (how)
"The capacity of countries to develop and enforce laws and strengthen institutions to achieve internationally agreed environmental objectives and goals and comply with related obligations is enhanced	Supporting NBF implementation through new Biosafety Law and other regulations, as well as institution and capacity building to comply with CPB
a particular focus will be placed on supporting efforts of Governments to achieve internationally agreed environmental objectives and goals through strengthened law and institutions."	The focus on National Biosafety Law adoption and implementation also enables the country's meaningful participation in the fourth Programme for the Development and Periodic Review of Environmental Law, known as the Montevideo Programme IV

98. Given its strong focus on Capacity Building and, to some extent, on Technology Support (for instance training in Risk Assessment, Risk Monitoring, Laboratory upgrading) the Project is surely aligned with Bali Strategic Plan (BSP). Actually, the project has been active in addressing many of the cross-cutting issues listed in Section D of the Plan, such as the Strengthening of national institutions, the Development of national law and regulations, the Compliance with obligations under multilateral environmental agreements, the Development of national research, monitoring and assessment capacity, including training. The Project did not have a particular focus on Gender. As far as South-South cooperation is concerned, there are interesting regional on-going and planned activities in the framework of the SAARC, as well as the USAID Supported South Asia Biosafety Program, which, though not initially targeting Bhutan, has allowed for Bhutan's participation in the annual conferences and training workshops (see Outcome 7 in Table 1, Chapter 4.2).

## 5 Conclusions and Recommendations

## 5.1 Conclusions

- 99. The project "Implementation of the National Biosafety Framework of Bhutan" has been highly instrumental in supporting the country in the implementation of the National Biosafety Framework (NBF). Biosafety is now regulated by a National Law approved in 2014 and the Secondary Law (Rule and Regulations) are ready for approval, too. The integration of Biosafety, Biosecurity, Food Safety and Quality Assurance under a single, coordinated Programme of the 11th Plan of the Ministry of Agriculture and Forests provides strength and sustainability to the Biosafety agenda in the country, as well as enabling its inclusion in the National Budget, hence contributing to financial sustainability.
- 100. The two main bodies established by the new Biosafety Law (the National Biosafety Commission with responsibility for strategic guidance and coordination, and the Technical Working Groups with advisory function) are, in fact, the natural evolution of implementing mechanisms set by the Project and have already given evidence of meaningful participation and of strategic and technical capacities. The wider membership of the NBC, by incorporating more representatives from the Civil Society and Private Sectors, remains an open question.
- 101. The NCA (BAFRA) is a solid and dynamic institution playing a strategic role at national level, being responsible for the application of relevant national policies and legal instruments such as the Plant Quarantine Act, Seed Act, Pesticide Act, Livestock Act, Food Act, Forest and Nature Conservation Act, Biodiversity Act and, eventually, the Biosafety Act. It functions as the National Food Quality and Safety Control agency and is the National Competent Authority not only for the CPB, but also the IPPC (International Plant Protection Convention), CAC (*Codex Alimentarius* Commission), the WTO-SPS Agreement (World Trade Organization-Sanitary and Phytosanitary Agreement). Biosafety can therefore take profit from a robust and polyvalent institutional anchorage, which offers large guarantees of institutional and socio-political sustainability.
- 102. Biosafety has already been inserted in the plan of work of BAFRA's Inspectors and Officers, through staff capacity building, laboratory upgrading, LMOs specific guidelines, laboratory protocols and technical manuals. Key human resources have been exposed to a variety of training activities in the country, conducted by international consultants in the framework of the Project, as well as abroad, through tailored training in the Netherlands (financed by the Netherlands Fellowship Programme), study tours in Thailand, India, Australia, Malaysia and Italy, regional conferences and workshops in the SAARC region. Actually, the country, which has a very young and limited academic system, has to be proactive in finding external sources and resources for knowledge and training.
- 103. Bhutan is investing in regional cooperation, not only for the Biosafety sector, in order to minimise the shortcomings of its condition of small and landlocked country. It is a dynamic actor in creating

Biosafety partnerships within the SAARC umbrella, which seems to be leading to interesting opportunities that have to be fostered and followed up, also with the support of UNEP.

104. The Evaluation has therefore concluded that relevant factors exist for believing that the National Biosafety Framework in place can move forward and consolidate in Bhutan. However, the systems for handling and managing LMOs have to prove efficient and effective to the test of daily reality and it must not be omitted that Biosafety is still a very young subject in Bhutan. Existing material, financial and human resources are not only to be maintained at a suitable level, but also upgraded and improved. Key human resources at central level, as well as the inspectors at the border points, need to consolidate their "know how" on Biosafety, through specific, tailored trainings enabling them to continuously update and improve their capability of inspection, detection, risk assessment and risk monitoring.

104. As requested by the TOR of the Evaluation, the overall ratings table for the different evaluation criteria is presented hereafter. As a whole, the Project can be rated largely Satisfactory (S).

Criterion	Summary Assessment	Rating
A. Strategic relevance	The Project confirms all its relevance in addressing challenging and crucial issues and needs in the area of biodiversity's sustainable use, in achieving internationally agreed environmental objectives and goals and in contributing to fulfil UNEP's mandate and policy, as well as GEF priorities and strategies.(see 4.1)	S
B. Achievement of outputs	The Project has very satisfactorily delivered the expected outputs.(see 4.2 and Table 1)	HS
C. Effectiveness: Attainment of project objectives and results	Virtually all the direct Outcomes have been achieved, as well as the main Project Outcome (A National Biosafety Framework fully operational), though not yet consolidated due to the lack of concrete opportunities of application. (see 4.3.2)	S
1. Achievement of direct outcomes	Fully or to a very large extent achieved (see 4.3.1, Table 2)	HS
2. Likelihood of impact	Likely to occur through existing Driving Forces and under certain Assumptions (see 4.3.3, Diagram 2, Tables 3 and 4)	L
D. Sustainability and replication	Sustainability is overall likely to occur, but Financial Sustainability rises some concerns	L
1. Financial	Inclusion of Biosafety in the national Plans and Budget gives elements of optimism, yet the budget allocated to Biosafety is currently unknown. Possible access to a portion of GEF 6 allocation to the country. Regional cooperation (SAARC) can improve funds availability for Biosafety. Remarkable results obtained by the Project in terms of extra-fund raising (see 4.6.5) represent an element of optimism for future financial support. (see 4.4.2)	L
2. Socio-political	Five-year Plan of the MoAF integrates Biosafety with Biosecurity, Food Safety and Quality Assurance under the same Programme, which enables synergies, cooperation and socio-political consensus. Strong and diffuse national attitude of preservation and stewardship of cultural and environmental assets. (see 4.4.1)	L
3. Institutional framework	The NCA (BAFRA) is a solid and dynamic institution playing a strategic role at national level, functioning as the National Food Quality and Safety Control agency, as well as National Focal Point for several international agreements. The NBC and the Technical Working Groups have been actively working for years in the framework of the Project. Regional cooperation can strengthen institutional sustainability. Poor cooperation at UN level, despite the "Delivery as One" framework operating in Bhutan.(see 4.4.3)	L
4. Environmental	The Precautionary Principle is one of the underpinning principles of the CPB and it is well reflected in the National Biosafety Law and in the Plan of the MoAF (see 4.4.4)	L
5. Catalytic role and replication	The Project has catalysed outstanding behavioural and institutional changes in the country, promoted meaningful participation of national experts and stakeholders, given opportunities to national "champions" (see 4.4.5)	HS
E. Efficiency	Project quite cost-effective in its execution, thanks to its institutional integration within the BAFRA and the MoAF. Cost-effectiveness also enhanced through a successful strategy of fund-raising. Some	S

	delays in its starting phase and during the implementation, due to Governmental changes in 2013.	
F. Factors affecting project performance	Governmentar changes in 2013.	
1. Preparation and readiness	Project Design Satisfactory, but the prohibition by Law of the environmental release of LMOs was not contemplated, which raises questions on the methodology of elaboration of the Project Document. (see 4.6.1)	MS
2. Project implementation and management	Mechanisms of project implementation have followed those outlined in the project document. The Project Steering Committee (PSC) has evolved into the National Biosafety Commission foreseen in the new Biosafety Law. Specialised expertise has been taken on board by the Project through the so-called Technical Working Groups (see 4.6.2)	HS
3. Stakeholders participation and public awareness	Meaningful participation of stakeholders, yet unbalanced representation of the different sectors in the NBC. Public awareness initiatives have successfully conveyed information to the general public or to target groups (see 4.6.3)	S
4. Country ownership and driven-ness	Country ownership is surely strong and undeniable factor of sustainability. (see 4.6.4)	HS
5. Financial planning and management	Proper standards applied in the financial planning, management and control. Good use of financial monitoring tools (Anubis, etc.). Rate of expenditure near 100%. Remarkable external fund raising (see 4.6.5)	HS
6. UNEP supervision and backstopping	High quality, through constant coaching, in-country mission, mid- term review, NPC meetings, quality of consultants (see 4.6.6)	HS
7. Monitoring and evaluation	Monitoring tools timely used but not very helpful to really monitor progress and problems, formats not helpful for channelling synthetic data and meaningful information, repetitive and poor, scoring not explained or justified. (see 4.6.7)	MS
a. M&E Design	Good Project Design, with Results Framework, Milestones and Deliverables Table and a very detailed M&E Framework.	S
b. Budgeting and funding for M&E activities	Foreseen, but quite inappropriate	MS
c. M&E Plan Implementation	Mid-term review has been useful and Recommendations have been followed. The NPC has created her own system for M&E, because the "official" one was not helpful, see above.	MS
Overall project rating		S

## 5.2 Lessons Learned

- 105. The institutional setting of Biosafety within the BAFRA is conducive to a tight linkage between Biosafety, Food Safety and Quality Control, increasing cost effectiveness of detection, inspection and monitoring activities, good coordination and a stronger institutional presence in socio-political arena.
- 106. Due to the limited quantity of the material needed for the GMOs laboratory, the country has difficulty in purchasing primers and other material for GMOs detection, because companies do not consider the tenders attractive and do not participate. Aggregate purchasing among small neighbouring countries could be a solution.
- 107. Though sub regional and regional networking and cooperation are cost effective for geographical and socio-cultural reasons, the different policies of the countries within the region have also to be taken into account. Bhutan, for instance, feels more comfortable to build capacities and develop training through partnerships with countries where the Precautionary Approach is strategically adopted and largely fostered (e.g. E.U)
- 108. The Consultant believes that the lack of coordination between UN agencies tends to create competition rather than cooperation among the national stakeholders. This is the case of UNDP (implementing a Project on Nagoya Protocol on Access and Benefit Sharing of genetic resources with

the Min. of Environment) and UNEP (implementing Cartagena Protocol with BAFRA, Min Agriculture and Forests).

109. The dynamism of the Project Coordinator can be determinant to leverage extra funds (Bhutan project has increased its budget of more than 12% through extra funding).

## 5.3 Recommendations

110. Based on the main Conclusions and Lessons Learned, the recommendations are the following:

Recommendation 1: to UNEP, NCA (BAFRA), NBC

#### Findings / Conclusions (§ 104):

Key human resources at central level, as well as the inspectors at the border points, need to consolidate their "know how" on Biosafety, through specific, tailored trainings enabling them to continuously update and improve their capability of inspection, detection, risk assessment and risk monitoring.

#### **Recommendation 1:**

In order to consolidate the positive achievements obtained so far and considering the challenges of the implementation of the National Biosafety Programme, it is recommended to give continuity to GEF/UNEP assistance through a follow-up phase or project focused on:

a) Training needs assessment and targeted, intensive training to key human resources responsible for and/or directly involved in LMOs Inspection, Detection, Risk Assessment and Monitoring.

#### 111. <u>Recommendation 2</u>: to UNEP, NCA (BAFRA), NBC

#### Findings / Conclusions (§ 74, § 103):

Bhutan is investing in regional cooperation, not only for the Biosafety sector, in order to minimise the shortcomings of its condition of small and landlocked country. It is a dynamic actor in creating Biosafety partnerships within the SAARC umbrella, which seems to be leading to interesting opportunities that have to be fostered and followed up, also with the support of UNEP.

#### **Recommendation 2:**

It is recommended that Bhutan keeps on playing a dynamic role in enhancing SAARC cooperation in order to improve areas of particular relevance for the country, possibly through a sub-regional project aiming at implementing:

a) shared services in the area of LMOs detection (e.g. regional reference laboratory), harmonized labelling, border inspections (e.g. Green Customs initiative), aggregate purchasing of laboratory material;

b) regional capacity building programme, particularly in the area of Risk Assessment and Risk Monitoring.c) additional Biosafety and Food Safety capacity building through bilateral or multilateral cooperative agreements with key trading partners in the region (e.g. Japan, India, Netherlands, EU).

#### Annexes

1. Response to stakeholder comments received but not (fully) accepted by the evaluators

- 2. Evaluation TORs (without annexes)
- 3. List of people met
- 4. Bibliography
- 5. Summary co-finance information and a statement of project expenditure by activity
- 6. Brief CV of the consultant

7. Notes of the Consultant: "The UNEP/GEF projects of NBF implementation in Mongolia, Bhutan, Lao PDR : elements for a comparative analysis"

Response to stakeholder comments received but not (fully) accepted by the evaluators

NA

#### **Evaluation TORs (without annexes)**

## Terminal Evaluation of the UNEP/GEF projects

- "Implementation of Bhutan National Biosafety Framework"
- "Support the implementation of National Biosafety for Lao PDR"
- "Capacity Building for Biosafety Implementation for Mongolia"

## 1. PROJECT BACKGROUND AND OVERVIEW

### 2. Project General Information

#### Table 1. Project summary

GEF project ID:	3850 3642 4010	IMIS number:	GFL/2328-2716-4B22 GFL/2328-2716-4A85 GFL/2328-2716-4B95
Focal Area(s):	BD3 – SP6 (Biosafety)	GEF OP #:	
GEF Strategic Priority/Objective:	Environmental governance	GEF approval date:	08/01/2010 22/06/2009 06/04/2011
UNEP approval date:	19/03/2010 08/09/2009 27/04/2011	First Disbursement:	22/03/2010 17/09/2009 15/05/2011
Actual start date:	01/07/2010 01/10/2009 01/05/2011	Planned duration:	48 months 48 months 36 months
Intended completion date:	06/30/2014 07/09/2014 26/04/2014	Actual or Expected completion date:	06/30/2014 07/09/2014 26/04/2014
Project Type:	MSP	GEF Allocation:	\$869,000 \$995,000 \$379,300
PDF GEF cost:		PDF co-financing*:	
Expected MSP/FSP Co- financing:	\$854,000 \$505,000 \$335,000	Total Cost:	\$1,723,000 \$1,500,000 \$753,300
Mid-term review/eval. (planned date):	30/06/2012 30/09/2011 30/01/2013	Terminal Evaluation (actual date):	August 2014
Mid-term review/eval. (actual date):	23/08/2012 30/09/2012 30/01/2013	No. of revisions:	5 6 3
Date of last Steering Committee meeting:	17/04/2013 02/04/2013	Date of last Revision:	01/01/2014 01/04/2014 01/01/2014
Disbursement as:	\$731,610.00 (Bhutan, 27/01/2014)	Date of financial closure:	Financial closure will be done in IMIS when the Terminal Evaluation is done.

	\$944,265.00 (Laos PDR, 25/02/2014) \$379,300.00 Mongolia, 30/03/2014)		
Date of Completion:	N/A	Actual expenditures reported as of:	
	\$492,150.83 (Bhutan, 31/03/2014)		
Total co-financing realized	\$444,658.41 (Laos PDR, 31/03/2014) \$336,670 (Mongolia, 26/04/2014)	Actual expenditures entered in IMIS as 30 June 2013:	
Leveraged financing:			

## **3. Project rationale**

**Bhutan:** Bhutan ratified the Convention on Biological Diversity on August 25, 1995, the Cartagena Protocol on August 26, 2002 and completed its National Biodiversity Strategy and Action Plan in 2002; the NBSAP recognized the potential contribution of modern biotechnology to development and conservation of biodiversity. Bhutan started its project on the development of a National Biosafety Framework in April 2004. The final draft of the NBF project was completed in June 2006; this draft included 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. This project intended to 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 exchanges relating to biosafety both at the national and BCH level;
- The development of systems for strengthening public awareness, education and participation in decision making on LMOs.
- Enhancing regional cooperation on biosafety and biotechnology in the SAARC subregion that would 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.

Bhutan's major concern at the time of project development was the safety of its citizens and its almost pristine environment. At the same time, increasing food security and food self-sufficiency were critical objectives. The use of biotechnology to achieve these objectives seemed a likely course of action for the country.

Lao PDR: The government of Lao PDR acceded to the Convention on Biological Diversity (CBD) on September 20, 1996 and completed its National Strategy on Environment to the year 2020 and Action Plan (2006 – 2014) by Prime Minister's Decree No. 120 / PM on August 27, 2004. This was followed by accession to the Cartegena Protocol on Biosafety (CPB) on November 1, 2004. Lao PDR participated in the UNEP/GEF National Biosafety Framework Development (NBF) project and completed it successfully in December 2004. This project aimed to assist Lao PDR to implement the draft Biosafety Law, which was based on the draft NBF, into a workable and transparent NBF by 2014, to fulfill its National Socio-economic Development Plan and implement its obligations as a Party to the Cartagena Protocol on Biosafety. Expected Project Outcomes included:

- Updated needs analysis of the country;
- The integration of Biosafety into National development plans;
- A workable regulatory regime for biosafety supported by regulations;
- An efficient administrative system for handling requests;
- Increased public awareness and education in biotechnology and biosafety and participation in decision making.

Lao PDR is a landlocked country where modern biotechnology R&D activities were still nascent in its national R&D institutions at the time of the project development. No biotechnology products from its national research laoboratories were expected to be released in the immediate future. However, since Lao PDR was considered a potential net importer of biotechnology products, it appeared imperative that the country be prepared to handle import of LMOs. Additionally, with its porous borders, farmers may have unknowingly planted GM-crops like rice, without due risk management in place to reduce the potential negative impact of gene flow from the transgenics to the thousands of wild and other cultivated varieties. Additionally, information received at the time of the project development suggested that farmers, financed by foreign companies, were already cultivating GM-crops (soybean, cotton, papaya). Without the setting up of proper risk management procedures, the potential for dispersal of pollen from these transgenic crops to wild and cultivated conventional crops was deemed high.

**Mongolia:** Mongolia is a Party to the Convention on Biological Diversity since September 30, 1993 and Party to the Cartagena Protocol on Biosafety since October 20, 2003. The Ministry of Nature, Environment and Tourism (MNET) is the appointed National Focal Point for the Protocol. From 2002 to 2005, Mongolia successfully completed a draft NBF under the UNEP/GEF funded global project on "Development of National Biosafety Frameworks". The project aimed to develop the National Biosafety Framework in agreement with the provisions of the CPB. The draft NBF formed the basis of a new law, which was enacted in November 2007.

However, Mongolia had very limited capacity to implement this new law. In order to operationalize it, supporting implementing activities were deemed necessary. This project intended to enable Mongolia to adopt essential regulations to help make the Law on LMOs workable and consistent with its international obligations. In addition, Mongolia did not have the technical capacity to detect LMOs, and LMOs could therefore enter the country without detection and prior risk assessment. Mongolia also lacked the capacity to perform any safety assessment of modern biotechnology applications, which might benefit the country's food security through maintaining yields in the face of pest pressure (insects and weeds) and abiotic stress (temperature, drought and salt tolerance).

The project aimed to establish and operationalise Mongolia's National Biosafety Framework and to assist Mongolia to comply with its obligations as a Party to the Cartagena Protocol on Biosafety so that Mongolia may make a safe use of modern biotechnology for sustainable development.ù

## 4. **Project objectives and components**

The overall goal of the projects was to put in place a workable and transparent national biosafety framework, in line with respective national development priorities and international obligations.

The projects' objective was to develop the national biosafety capacities required to establish functional, workable and transparent national biosafety frameworks in accordance with national development priorities and international obligations.

The project purpose was to contribute to the safe use of biotechnology and reduce the potential risk associated to LMO use on biodiversity and human and animal health.

The structure of these projects comprised seven components in Bhutan, eight in Lao PDR and six in Mongolia. Table 2, 3 and 4 summarize the components per country and list the outcome and/or outputs the projects intended to achieve.

Project Component	Outputs
Baseline established for information on	Inventory of current national human, technical and institutional capacities to implement a
the safe use of biotechnology in Bhutan	comprehensive biosafety management system.
through a stocktaking analysis.	Accurate information on how Biosafety can be harmonized with National Laws, policies and
	plans, and built into existing Monitoring and Enforcement systems.
	Biosafety systems are consistent with national priorities on gender mainstreaming, and
	human rights, including participation by all sectors in decision-making.
Biosafety integrated and incorporated	Biosafety policy approved & implemented by Government by end of 2010.
into National Priorities on poverty	Biosafety policy integrated into the Tenth Plan and reflected in the National Priorities, and
reduction and environment, as well as	sectoral action plans by end-2011.
sectoral action plans and strategies, in	
conformity with Bhutan's Tenth Plan.	
A legal and regulatory framework on	Biosafety Rules and Regulation promulgated by the Minister of Agriculture under the Food
biosafety in place that is consistent with	Act of Bhutan, 2005 to replace the existing Moratorium on import of LMOs.
the CPB, and is workable and responsive	Relevant biosafety procedures, protocols and guidelines prepared and promulgated by
to national needs and the National	relevant Government agencies.
Priorities of the Tenth Plan.	Existing laws and legislations revised to ensure consistency with biosafety regulation and
	CBP by end of 2012.
A workable system for handling requests,	A fully functional administrative system for handling requests for LMOs.
carrying out risk assessment, and decision	A fully functional system for risk assessment and decision-making.
making for LMOs in place that reflects the	An efficient system for handling, storing and exchanging information on biosafety in place
priorities of the Tenth National Plan.	under the nBCH.
A workable and effective national system	Fully functional and effective inspection, monitoring and enforcement system in place in
for monitoring, inspections &	BAFRA.
enforcement in place, including	Strengthened BAFRA laboratories able to detect LMOs.
monitoring of socio-economic impacts,	Emergency response procedures (ERP) established & made operational by BAFRA, the NEC
that is consistent with National Priority on	and relevant Govt agencies.
environment and disaster management.	
A workable and effective national system	Fully functional system for access to, and sharing of information in place in Bhutan by end o
for public awareness, education and	2011, inter alia through the establishment of a national BCH under the BCH project.
participation in decision making for LMOs	Strengthened system for public awareness on the safe use of LMOs in place.
in place, in support of the National Priority	Strengthened system for public participation in decision-making on LMOs in place.
on good governance:	
Enhanced regional cooperation on	Technical expertise, decision-making tools, training activities and materials for training and
biosafety in SAARC, as well as sharing of	outreach with other countries in SAARC.
experiences with other NBF	Alignment of biosafety policies, regional mechanisms and common formats for sharing of
Implementation projects globally:	information amongst SAARC countries on biosafety.
······································	Establish networks established with other Implementation project teams for sharing
	experiences, lessons & best practices.

Table 2 – Projects components/outcomes and outputs – Bhutan

#### Table 3 – Projects components and expected outcomes and outputs – Lao PDR

Project Component	Expected Outcomes	Outputs	
1. Stocktaking	Updated information on	A clear national policy encompassing biotechnology, biosafety and national	
analysis	status and capacity for	development is developed within the first year of project initiation by the NEA and	
	biotechnology & biosafety	line agencies.	
	management in the country	A status and strategy paper on biosafety cum biotech. R&D in Lao PDR prepared by	
		the National Coordination Committee (NCC) and NEA, within 6 months after	
		completion of stocktaking exercise.	
<ol><li>National plan</li></ol>	Biosafety intergrated into	A National Biotechnology Strategy and Action Plan (NBSAP) for 2011-2015 is jointly	
(policy)	national development policy	developed by NEA and partners to implement the Biotech. & Biosafety policy by	
implementation	and plans	2010.	
		Biosafety & biotech. are executed in national and sectoral plans and strategies by line	

3. Regulatory	Regulatory regime to	agencies by 2011. Biosafety Law which is supported by other national Laws and is compliant with CPB is adopted by 2012. Legal personnel are trained in the operation of the Biosafety regulatory regime by 2010. By 2012, the Prime Minister's Decree will ensure that the legally-binding Biosafety
regime	complement other national laws and compliant with CPB Regulatory regime strengthened and consolidated	Regulations will come into force. By 2011, voluntary instruments like guidelines and manuals are developed by NEA and relevant agencies. By 2010, legal personnel are trained in at least 2 workshops organized by the NPC and NEA on drafting secondary and tertiary legislations.
4. Handling requests	An efficient administrative structure for biosafety Enhanced institutional arrangement for handling requests.	<ul> <li>By 2009, institutional arrangement for handling requests is made functional by NCC/NEA and relevant line agencies.</li> <li>By 2009, the Scientific Advisory Committee (SAC) for RA and RM is appointed with trained members by NEA.</li> <li>By 2009, technical tools &amp; documents to assist decision making are developed by NCA.</li> <li>By 2009, responsibilities of various agencies are clearly defined by NCA and National Authorities on Biosafety.</li> <li>A functional and integrated administrative system at institutional level is in place for handling requests within first 12 months of project life.</li> <li>Members of all SACs are appointed by NCA/NEA and trained by 2009.</li> <li>A transparent decision making process is established within first year of project by NEA/NCA.</li> <li>By 2009, tools, training manual and technical documents are developed by NEA/NCA.</li> <li>By 2009, a mechanism for public participation in decision making is established within the NEA/NCA.</li> </ul>
5. System for 'follow-up' activities	Strengthened capacity for monitoring, enforcement and inspection Better enforcement and compliance to national regulatory regime.	By 2011, human and infrastructural resources for monitoring, inspection, enforcement and LMO detection are strengthened in Lao PDR by NCAs. By 2010, an effective monitoring strategy comprising methodology, workflow and schedule is set up by NCAs. By 2011, relevant staff are trained and equipped with appropriate tools by NCAs. Technical guidelines and checklists are developed by NEA/NCAs and distributed to relevant personnel by 2010. By 2010, information is compiled on the biology and distribution of rice and other important crops in Lao PDR by NEA/NCAs. By 2011, indicator organisms and parameters are identified for monitoring environmental impact caused by planting GM-rice by SAC. Strategy to apply GM-rice with minimal negative impact on the environment is devised by SAC by 2011. By 2010, emergency response plan (ERP) is developed by SAC/NCA for accidental or unauthorized release.
6. Public education, awareness and participation	Enhanced public awareness in biotechnology and biosafety matters Active public participation in decision making	By 2009, a public-friendly information access system is set up by NEA. By 2010, bosafety education and awareness materials are developed by NEA and partners. By 2011, secondary and tertiary educational curricula contain biosafety. By 2010, a platform for 2-way public participation is set up by NEA/NCAs. By 2010, strategy for public awareness, education and participation is developed by NEA/NCAs. By 2010, platform for public participation in decision-making is developed by NEA. By 2010, entry points are identified by NCC/NEA/SAC for feedback from the public in decision making. By 2010, decisions on LMOs are publicized and accessible to the public by NEA via the BCH.
<ol> <li>Project Review</li> <li>Evaluation, and</li> <li>Audit</li> <li>Regional</li> <li>Networking</li> </ol>	Checks and balance for project implementation Enhanced Regional cooperation	By 2010, formats for info exchange on RA&RM will be agreed between ASEAN countries.
		Lessons and best practices will be identified and shared between ASEAN countries throughout project cycle and beyond.

## Table 4 – project components, expected outcomes and outputs - Mongolia

Project Components	Expected Outcomes	Expected Outputs
1.Policy and legal	1.1 Review of Mongolian	1.1.1 An analysis of what implementing regulations are needed to make the Law on
aspects for	policy and legal framework	LMO (2007) operational.

development of a National Biosafety	with respect to implementation of the Law	1.2.1 Regulations to implement the Law on LMOs are prepared and linked to
Program	on LMO.	environmental governance.
	1.2 Gaps in national laws in	
	relation to biosafety are identified and addressed	1.2.2 Biosafety Program is developed and integrated into the Environmental Framework Law and NBF within national strategies.
2.Capacity building	2.1 Strengthened human	2.1.1 Training organized for decision makers. Staff trained in administrative aspect o
in human resource	resource in administration	Biosafety implementation, including risk assessment and risk management, decision
for implementation	and decision making for	making and risk communication.
of a Biosafety	implementation of biosafety	
Program	program.	
	2.2 Coordinated decision	2.2.1 Technical manuals on decision making procedure are prepared.
	making on LMOs	
	2.3 An effective mechanism	2.3.1 Organizing training for enforcement and monitoring officials.
	for monitoring and	
	inspection to ensure compliance to Law on LMOs	
3.Capacity	3.1 Strengthened	3.1.1 Key professional institutions to be strengthened are identified.
strengthening at	institutional arrangement	3.1.2 Strengthening the reference laboratory
institutions for	for effective	
implementation of	implementation of a	
a Biosafety Program	Biosafety Program	
	3.2 Enhanced institutional	3.2.1 Training for technicians and researchers in LMO detection and verification of
	infrastructure to facilitate	LMOs for regulatory compliance.
	operation of the Biosafety	
	Program	
	3.3 Improved coordination	3.3.1 Setting clear roles and responsibilities by MOU between collaborating
	between institutions for Biosafety implementation	institutions
4.Public awareness	4.1 A comprehensive public	4.1.1 A strategy for public awareness and participation in decision making related to
and public	awareness and participation	LMOs.
participation in	strategy on biosafety that is	
matters related to	linked to the national	
Living Modified	environmental	
Organisms (LMOs)	policy/program and Law on LMOs.	
	4.2 Publishing materials on	4.2.1 Special educational materials for schools and colleges.
	biosafety in different media	4.2.2 Outreach materials for target groups.
		4.2.3 A regularly updated nBCH as a platform for public communication and
		participation.
	4.3 Trainings, lectures, info days, public debates	4.3.1 Organizing public lectures and trainings
5.Establishment of a National and	5.1 Cost effective pooling of regional experts and	5.1.1 A database on national experts in crop science and biotechnology.
	regional experts and resources, cooperation	5.1.2 A natwork among national and regional error science and histofety everyte
Regional networking system	between R & D institutions	5.1.2 A network among national and regional crop science and biosafety experts.
for Biosafety		
6.Project audit,	and regulatory bodies 6.1 Checks are in place to	6.1.1 Annual audit reports
Monitoring and	ensure that project	6.1.2 Mid-term review
Evaluation cost	implementation is according	6.1.3 End of project evaluation

Source: project documents and result framework

## 4. Executing Arrangements

The *Implementing Agency* for the three projects was the United Nations Environment Programme (UNEP). In this capacity, UNEP had overall responsibility for the implementation of the projects, project oversight, technical support and co-ordination with other GEF projects.

In Bhutan, the Bhutan Agriculture and Food Regulation Authority (BAFRA), designated as the National Competent Authority by the Government of Bhutan under the NBF, was the National Executing Agency for this project. In implementing the project, BAFRA was supposed to work closely with the National Environment Commission (NEC),

which is the focal point for Bhutan to the Cartagena protocol on Biosafety. In Lao PDR, the National Authority for Science and Technology (NAST), the focal point to the CPB, was the National Competent Authority (NCA) as well as the National Executing Agency (NEA) for this project. The Ministry of Nature, Environment and Tourism, the focal point to the CPB, was the National Competent Authority (NCA) as well as the National Executing Agency (NEA) for this project. The NEAs were responsible for working on behalf of the respective governments to manage the project, ensuring that the objectives would be met by the end of the project. The NCA were also responsible to provide the necessary scientific, technical, financial and administrative support to the project, working in close cooperation with relevant government agencies, the scientific community and the public.

The National Project Coordinator was responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she had to report to the National Co-ordinating 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 was responsible for all substantive, managerial and financial reports from the National Project. He/she had to 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. Bhutan and Mongolia also appointed a National Project Director, a government employee with the responsibility to provide policy advice and overall direction to the project, as well as coordinating project activities with relevant government agencies.

Bhutan established a Project Steering Committee, while Lao PDR and Mongolia established a National Co-ordinating Committee (NCC). These bodies were established by the National Executing Agencies (NEAs) to advise and guide the implementation of the projects. These committees should have included representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and representations from the private and public sectors. They were intended to be multi-disciplinary and multi-sectoral, covering all fields relevant to the Cartagena Protocol on Biosafety.

#### 5. Project Cost and Financing

The three projects fall in the Middle-size Project (MSP) category. They were expected to mobilize \$854,000

(Bhutan), \$505,000 (Lao PDR) and \$335,000 (Mongolia) in co-financing, mostly from government sources. The estimated projects costs at design stage and associated funding sources are presented in Table 5, 6 and 7.

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

#### Table 5. Estimated project cost in Bhutan (US \$)

Source: project document, agency fee of \$86,900 not included

#### Table 6. Estimated project cost in Lao PDR

Component	GEF Financing	Government contribution	Total
1. Stocktaking analysis	12,5000	3,000	15,500
2. National plan (policy) implementation	70,000	49,000	119,000
3. Regulatory regime	140,500	110,000	250,500

4. Handling requests	144,000	50,000	194,000
5. System for 'follow-up' activities	350,000	123,000	473,000
6. Public education, awareness and participation	106,000	56,000	162,000
7. Regional Networking and meetings	63,000	3,600	66,600
8. Project Management, Review & Evaluation,	109,000	110,400	219,400
and Audit			
Total	995,000	505,000	1,500,000

Source: project document (appendices 1 - 2), agency fee of \$99,500 not included

#### Table 7. Estimated project cost in Mongolia

Component	GEF Financing	Government contribution	Total
1.Policy and legal aspects for development of a National Biosafety Program	38,000	10,000	48,000
2.Capacity building in human resource for implementation of a Biosafety Program	108,000	60,000	168,000
3.Capacity strengthening at institutions for implementation of a Biosafety Program	165,000	125,000	290,000
4.Public awareness and public participation in matters related to Living Modified Organisms (LMOs)	0	100,000	100,000
5.Establishment of a National and Regional networking system for Biosafety	14,000	10,000	24,000
6.Project Management, audit, Monitoring and Evaluation cost	53,000	30,000	83,000
Total	379,300	335,000	714,300

Source: project document (appendices 1 - 2), agency fee of \$37,930 not included

#### 6. Implementation Issues

The Mid Term Reviews (MTRs) were originally scheduled for September 2011 in Lao PDR, June 2012 in Bhutan and January 2013 in Mongolia. Internal reviews were carried out by the UNEP Task Manager in September 2012 in Lao PDR and August 2013 in Bhutan. No review was carried out in Mongolia as it was considered that the project was progressing well and monitoring tools like the PIRs were providing sufficient guidance. The evaluation should consider the extent to which the MTR recommendations for Bhutan and Lao PDR were taken into account and acted upon by the relevant stakeholders.

In Bhutan, the project was developed in 2006. However, it was only submitted under the GEF 4 portfolio and it started being implemented in 2010, after receiving the necessary approvals. Many changes occurred during this period. The project could therefore not follow the work plan as described in the document. The change in some development policies of the government also affected the outcome of the project. For example, the project was supposed to implement the 2006 biosafety draft, however, the changes created a need to have a biosafety act that could bring other related rules and regulations under one umbrella. The evaluation should assess the extent suitable adaptive management practices were put in place once the project implementation got underway.

In Mongolia, the implementation of the project seems to have run smoothly. However, changes in government officials posed some challenges while the fluctuation of the US dollar, which caused an increase in costs, reduced the project budget. The evaluation should assess the extent to which the project was successful in maintaining a high level of country ownership notwithstanding the changes in government officials and whether all outcomes could be delivered as required but with a reduced budget.

In Lao PDR, the project suffered a one year delay, after a satisfactory first year of execution, due to unplanned institutional changes including setting up a new Ministry with new implementing agency. The MTR highlighted a general need to fast track activities. In particular, it stressed the need to use the available draft legislation as a basis for implementation, instead of waiting for formal approval. It also highlighted the need to quickly roll out the public

awareness campaign. The evaluation should assess the extent to which activities were expedited and whether suitable adaptive management measures were introduced.

### **Objective and Scope of the Evaluations**

In line with the UNEP Evaluation Policy<sup>18</sup>, the UNEP Evaluation Manual<sup>19</sup> and the Guidelines for GEF Agencies on Conducting Terminal Evaluations<sup>20</sup>, the Terminal Evaluations of the Projects "Implementation of Bhutan National Biosafety Framework", "Support the implementation of National Biosafety for Lao PDR", "Capacity Building for Biosafety Implementation for Mongolia" will be undertaken upon completion of the project (Bhutan, Mongolia) or immediately before the completion of the project (Lao PDR) to assess project performance (in terms of relevance, effectiveness and efficiency), and determine outcomes and impacts (actual and potential) stemming from the project, including their sustainability. The evaluations have two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP, the GEF and their executing partners – the National Executing Agencies and the national partners in particular. Therefore, the evaluation will identify lessons of operational relevance for future project formulation and implementation. It will focus on the following sets of key questions, based on the projects' expected outcomes, which may be expanded by the consultants as deemed appropriate:

- To what extent were the projects able to support Bhutan, Mongolia and Lao PDR in establishing a national biosafety framework in accordance with national development priorities and international obligations?
- To what extent were the projects able to assist Bhutan, Mongolia and Lao PDR to establish and consolidate a fully functional and responsive regulatory regime in line with the Cartagena Protocol and national needs and priorities?
- To what extent were the projects able to assist Bhutan, Mongolia and Lao PDR to establish and consolidate a functional national system for handling requests, perform risk assessments, testing of GMOs, decision-making and performing administrative tasks?
- To what extent were the projects able to assist Bhutan, Mongolia and Lao PDR to establish and consolidate a functional national system for "follow-up", namely monitoring of environmental effects and enforcement?
- To what extent were the projects able to assist Bhutan, Mongolia and Lao PDR to establish and consolidate a functional national system for public awareness, education, participation and access to information?

#### **Overall Approach and Methods**

The Terminal Evaluations of the Projects "Implementation of Bhutan National Biosafety Framework", "Support the implementation of National Biosafety for Lao PDR", "Capacity Building for Biosafety Implementation for Mongolia" will be conducted by an independent consultant under the overall responsibility and management of the UNEP Evaluation Office (Nairobi), in consultation with the UNEP Task Manager (Nairobi), and the UNEP Fund Management Officer at UNEP/DEPI (Nairobi).

They will be in-depth evaluations using a participatory approach whereby key stakeholders are kept informed and consulted throughout the evaluation process. Both quantitative and qualitative evaluation methods will be used to determine project achievements against the expected outputs, outcomes and impacts.

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

• A desk review of project documents and others including, but not limited to:

<sup>19</sup> http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationManual/tabid/2314/language/en-US/Default.aspx

<sup>&</sup>lt;sup>18</sup> http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationPolicy/tabid/3050/language/en-US/Default.aspx

<sup>&</sup>lt;sup>20</sup> http://www.thegef.org/gef/sites/thegef.org/files/documents/TE\_guidelines7-31.pdf

- Relevant background documentation, inter alia UNEP and GEF-4 policies, strategies and programmes pertaining to biosafety at the time of the project's approval;
- Project design documents; annual Work Plans and Budgets or equivalent, revisions to the logical framework and project financing;
- Project reports such as progress and financial reports from the executing partners; National Coordination Committee meeting minutes; annual Project Implementation Reviews and relevant correspondence;
- Documentation related to project outputs;
- Relevant material published, e.g. in journals and books
- Interviews with:
  - UNEP Task Manager and Fund Management Officer and other relevant staff in UNEP as necessary;
  - Interviews with project management, National Coordination Committee and key partners to the extent possible;
  - Stakeholders involved with this project, including NGOs, private sector, academia, national organizations and institutes, including National Competent Authorities, regional and international organizations and civil society representatives to the extent possible;
  - Relevant staff of GEF Secretariat and
  - Representatives of the government and other organisations (if deemed necessary by the consultant).
- Country visits. The evaluation consultant will schedule a visit to each country to interview relevant stakeholders and the project team. To the extent possible, the visits should take place back to back to limit the amount of travel required.

## **Key Evaluation principles**

Evaluation findings and judgements should be based on sound evidence and analysis, clearly documented in the evaluation report. Information will be triangulated (i.e. verified from different sources) to the extent possible, and when verification was not possible, the single source will be mentioned. Analysis leading to evaluative judgements should always be clearly spelled out.

The evaluation will assess the project with respect to a minimum set of evaluation criteria grouped in six categories: (1) <u>Strategic Relevance</u>; (2) <u>Attainment of objectives and planned result</u>, which comprises the assessment of outputs achieved, effectiveness and likelihood of impact; (3) <u>Sustainability and replication</u>; (4) <u>Efficiency</u>; (5) <u>Factors and processes affecting project performance</u>, including preparation and readiness, implementation and management, stakeholder participation and public awareness, country ownership and driven-ness, financial planning and management, UNEP supervision and backstopping, and project monitoring and evaluation; and <u>(6) Complementarity with the UNEP strategies and programmes</u>. The evaluation consultants can propose other evaluation criteria as deemed appropriate.

Ratings. All evaluation criteria will be rated on a six-point scale. However, complementarity of the project with the UNEP strategies and programmes is not rated. Annex 3 provides detailed guidance on how the different criteria should be rated and how ratings should be aggregated for the different evaluation criterion categories.

In attempting to attribute any outcomes and impacts to the project, the evaluator should consider the difference between *what has happened with and what would have happened without the project*. This implies that there should be consideration of the baseline conditions and trends in relation to the intended project outcomes and impacts. This also means that there should be plausible evidence to attribute such outcomes and impacts to the actions of the project. Sometimes, adequate information on baseline conditions and trends is lacking. In such cases this should be clearly highlighted by the evaluators, along with any simplifying assumptions that were taken to enable the evaluator to make informed judgements about project performance.

As these are terminal evaluations, particular attention should be given to learning from the experience. Therefore, the "*Why?*" question should be at front of the consultant's minds all through the evaluation exercise. This means that the consultant needs to go beyond the assessment of "*what*" the project performance was, and make a serious effort to provide a deeper understanding of "*why*" the performance was as it was, i.e. of processes affecting attainment of project results (criteria under category 3). This should provide the basis for the lessons that can be drawn from the project. In fact, the usefulness of the evaluation will be determined to a large extent by the capacity of the consultants to explain "*why things happened*" as they happened and are likely to evolve in this or that direction, which goes well beyond the mere review of "*where things stand*" today.

#### **Evaluation criteria**

#### Strategic relevance

The evaluations will assess, in retrospect, whether the projects' objectives and implementation strategies were consistent with: i) Sub-regional environmental issues and needs; ii) the UNEP mandate and policies at the time of design and implementation; and iii) the GEF Biodiversity focal area, strategic priorities and operational programme(s).

The evaluations will also assess whether the projects' objectives were realistic, given the time and budget allocated to the project, the baseline situation and the institutional context in which the project was to operate.

#### **Achievement of Outputs**

The evaluation will assess, for each component, the project's success in producing the programmed results as presented in Table 2, 3 and 4 above, both in quantity and quality, as well as their usefulness and timeliness. The evaluation should briefly explain the degree of success of the projects in achieving their different outputs, cross-referencing as needed to more detailed explanations provided under Section F (which covers the processes affecting attainment of project objectives).

#### Effectiveness: Attainment of Objectives and Planned Results

The evaluations will assess the extent to which the project's objectives were effectively achieved or are expected to be achieved.

The evaluations will reconstruct the Theory of Change (ToC) of the projects based on a review of project documentation and stakeholder interviews. The ToC of a project depicts the causal pathways from project outputs (goods and services delivered by the project) over outcomes (changes resulting from the use made by key stakeholders of project outputs) towards impact (changes in environmental benefits and living conditions). The ToC will also depict any intermediate changes required between project outcomes and impact, called intermediate states. The ToC further defines the external factors that influence change along the pathways, whether one result can lead to the next. These external factors are either drivers (when the project has a certain level of control) or assumptions (when the project has no control).

The assessment of effectiveness will be structured in three sub-sections:

- 1. Evaluation of the achievement of direct outcomes as defined in the reconstructed ToC. These are the first-level outcomes expected to be achieved as an immediate result of project outputs.
- 2. Assessment of the likelihood of impact using a *Review of Outcomes to Impacts* (ROtI) approach as summarized in Annex 6 of the TORs. Appreciate to what extent the project has to date contributed, and is likely in the future to further contribute to changes in stakeholder behaviour as a result of the project's direct outcomes, and the likelihood of those changes in turn leading to changes in the natural resource base, benefits derived from the environment and human living conditions.

3. Evaluation of the achievement of the formal project overall objective, overall purpose, goals and component outcomes using the project's own results statements as presented in original logframe <u>and</u> any later versions of the logframe. This sub-section will refer back where applicable to sub-sections (a) and (b) to avoid repetition in the report. To measure achievement, the evaluation will use as much as appropriate the indicators for achievement proposed in the Logical Framework Matrix (Logframe) of the project, adding other relevant indicators as appropriate. Briefly explain what factors affected the project's success in achieving its objectives, cross-referencing as needed to more detailed explanations provided under Section F.

#### Sustainability and replication

Sustainability is understood as the probability of continued long-term project-derived results and impacts after the external project funding and assistance ends. The evaluation will identify and assess the key conditions or factors that are likely to undermine or contribute to the persistence of benefits. Some of these factors might be direct results of the project while others will include contextual circumstances or developments that are not under control of the project but that may condition sustainability of benefits. The evaluations should ascertain to what extent follow-up work has been initiated and how project results will be sustained and enhanced over time. The reconstructed ToC will assist in the evaluation of sustainability.

Four aspects of sustainability will be addressed:

- Socio-political sustainability. Are there any social or political factors that may influence positively or negatively the sustenance of project results and progress towards impacts? Is the level of ownership by the main national and regional stakeholders sufficient to allow for the project results to be sustained? Are there sufficient government and stakeholder awareness, interests, commitment and incentives to execute, enforce and pursue the programmes, plans, agreements, monitoring systems etc. prepared and agreed upon under the project? To what extent was the project able to reach out to the stakeholders identified in the design phase (academia, private sector, civil society etc)?
- *Financial resources.* To what extent are the continuation of project results and the eventual impact of the project dependent on continued financial support? What is the likelihood that adequate financial resources<sup>21</sup> will be or will become available to implement the programmes, plans, agreements, monitoring systems etc. prepared and agreed upon under the project? Are there any financial risks that may jeopardize sustenance of project results and onward progress towards impact?
- Institutional framework. To what extent is the sustenance of the results and onward progress towards impact dependent on issues relating to institutional frameworks and governance? How robust are the institutional achievements such as governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. required to sustaining project results and to lead those to impact on human behaviour and environmental resources?
- Environmental sustainability. Are there any environmental factors, positive or negative, that can influence the future flow of project benefits? Are there any project outputs or higher level results that are likely to affect the environment, which, in turn, might affect sustainability of project benefits? Are there any foreseeable negative environmental impacts that may occur as the project results are being up-scaled?

**Catalytic role and replication.** The *catalytic role* of GEF-funded interventions is embodied in their approach of supporting the creation of an enabling environment and of investing in pilot activities which are innovative and showing how new approaches can work. UNEP and the GEF also aim to support activities that upscale new approaches to a national, regional or global level, with a view to achieve sustainable global environmental benefits. The evaluations will assess the catalytic role played by these projects, namely to what extent the projects have:

<sup>&</sup>lt;sup>21</sup> Those resources can be from multiple sources, such as the public and private sectors, income generating activities, other development projects etc.

- *catalyzed behavioural changes* in terms of use and application by the relevant stakeholders of: i) technologies and approaches show-cased by the demonstration projects; ii) strategic programmes and plans developed; and iii) assessment, monitoring and management systems established at national and regional level;
- provided *incentives* (social, economic, market based, competencies etc.) to contribute to catalyzing changes in stakeholder behaviour;
- contributed to *institutional changes*. An important aspect of the catalytic role of the project is its contribution to institutional uptake or mainstreaming of project-piloted approaches in the regional and national demonstration projects;
- contributed to *policy changes* (on paper and in implementation of policy);
- contributed to sustained follow-on financing (*catalytic financing*) from Governments, the GEF or other donors;
- created opportunities for particular individuals or institutions ("*champions*") to catalyze change (without which the project would not have achieved all of its results).

**Replication**, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated (experiences are repeated and lessons applied in different geographic areas) or scaled up (experiences are repeated and lessons applied in the same geographic area but on a much larger scale and funded by other sources). The evaluations will assess the approach adopted by the projects to promote replication effects and appreciate to what extent actual replication has already occurred or is likely to occur in the near future. What are the factors that may influence replication and scaling up of project experiences and lessons?

## Efficiency

The evaluations will assess the cost-effectiveness and timeliness of project execution. They will describe any cost- or time-saving measures put in place in attempting to bring the project as far as possible in achieving its results within its programmed budget and (extended) time. They will also analyse how delays have affected project execution, costs and effectiveness. Wherever possible, costs and time over results ratios of the projects will be compared with that of other similar interventions and to each other's. The evaluations will give special attention to efforts by the project teams to make use of/build upon pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. to increase project efficiency, all within the context of project execution.

To what extent were the projects efficiently managed and what lessons can be learnt for future projects? To what extent did any challenges have an impact on the delivery of project outcomes and the achievement of the project objective?

## Factors and processes affecting project performance

**Preparation and readiness.** This criterion focusses on the quality of project design and preparation. Were project stakeholders<sup>22</sup> adequately identified? Were the project's objectives and components clear, practicable and feasible within its timeframe? Were the capacities of executing agencies properly considered when the project was designed? Was the project document clear and realistic to enable effective and efficient implementation? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities) and enabling legislation assured? Were adequate project management arrangements in place? Were lessons from other relevant projects properly incorporated in the project design? What factors influenced the quality-at-entry of the project design, choice of partners, allocation of financial resources etc.? Were GEF environmental and social safeguards considered when the project was designed<sup>23</sup>? Were

<sup>&</sup>lt;sup>22</sup> Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the project. The term also applies to those potentially adversely affected by the project.

<sup>&</sup>lt;sup>23</sup> http://www.thegef.org/gef/node/4562

sufficient components integrated into the project design to ensure the obtaining of commitment of government representatives? Were sufficient provisions integrated into project design to minimise delays in implementation? Were the projects designed with the needs of the countries in mind and to what extent where they aligned to national priorities?

**Project implementation and management**. This includes an analysis of implementation approaches used by the project, its management framework, the project's adaptation to changing conditions (adaptive management), the performance of the implementation arrangements and partnerships, relevance of changes in project design, and overall performance of project management. The evaluations will:

- Ascertain to what extent the project implementation mechanisms outlined in the project document have been followed and were effective in delivering project outputs and outcomes. Were pertinent adaptations made to the approaches originally proposed?
- Evaluate the effectiveness and efficiency of project management by the National Executing Agencies and how well the management was able to adapt to changes during the life of the project.
- Assess the role and performance of the units and committees established and the project execution arrangements at all levels.
- Assess the extent to which project management, as well as national partners, responded to direction and guidance provided by the National Coordination Committee and UNEP supervision recommendations.
- Identify operational and political / institutional problems and constraints that influenced the effective implementation of the project, and how the project partners tried to overcome these problems. How did the relationship between the project management team and the national coordinators develop?
- Assess the extent to which MTR recommendations were followed in a timely manner.
- Assess the extent to which the project implementation met GEF environmental and social safeguards requirements.

**Stakeholder participation and public awareness.** The term stakeholder should be considered in the broadest sense, encompassing project partners, government institutions, private interest groups, local communities etc. The TOC analysis should assist the evaluators in identifying the key stakeholders and their respective roles, capabilities and motivations in each step of the causal pathway from activities to achievement of outputs and outcomes to impact. The assessments will look at three related and often overlapping processes: (1) information dissemination between stakeholders, (2) consultation between stakeholders, and (3) active engagement of stakeholders in project decision making and activities. The evaluations will specifically assess:

- the approach(es) used to identify and engage stakeholders in project design and implementation. What were the strengths and weaknesses of these approaches with respect to the project's objectives and the stakeholders' motivations and capacities? What was the achieved degree and effectiveness of collaboration and interactions between the various project partners and stakeholders during design and implementation of the project?
- the degree and effectiveness of any public awareness activities that were undertaken during the course of implementation of the project; or that are built into the assessment methods so that public awareness can be raised at the time the assessments will be conducted;
- how the results of the project (strategic programmes and plans, monitoring and management systems, subregional agreements etc.) promote participation of stakeholders in decision making.
- Country ownership and driven-ness. The evaluation will assess the performance of national partners involved in the project, as relevant:

- In how far has the national partner assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project and the timeliness of provision of counter-part funding to project activities?
- To what extent has the national and regional political and institutional framework been conducive to project performance?
- How responsive were the national partners to the National Executing Agencies coordination and guidance, and to UNEP supervision?

**Financial planning and management**. Evaluation of financial planning requires an assessment of the quality and effectiveness of financial planning and control of financial resources throughout the project's lifetime. The assessment will look at actual project costs by activities compared to budget (variances), financial management (including disbursement issues), and co-financing. The evaluations will:

- Verify the application of proper standards (clarity, transparency, audit etc.) and timeliness of financial planning, management and reporting to ensure that sufficient and timely financial resources were available to the project and its partners;
- Appreciate other administrative processes such as recruitment of staff, procurement of goods and services (including consultants), preparation and negotiation of cooperation agreements etc. to the extent that these might have influenced project performance;
- Present to what extent co-financing has materialized as expected at project approval (see Table 1, 4, 5 and 6). Report country co-financing to the project overall, and to support project activities at the national level in particular. The evaluations will provide a breakdown of final actual costs and co-financing for the different project components (see tables in Annex 4).
- Describe the resources the projects have leveraged since inception and indicate how these resources are contributing to the projects' ultimate objective. Leveraged resources are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector.
- Analyse the effects on project performance of irregularities (if any) in procurement, use of financial resources and human resource management, and the measures taken by the National Executing Agencies or UNEP to prevent such irregularities in the future. Appreciate whether the measures taken were adequate.

**UNEP supervision and backstopping.** The purpose of supervision is to verify the quality and timeliness of project execution in terms of finances, administration and achievement of outputs and outcomes, in order to identify and recommend ways to deal with problems which arise during project execution. Such problems may be related to project management but may also involve technical/institutional substantive issues in which UNEP has a major contribution to make. The evaluators should assess the effectiveness of supervision and administrative and financial support provided by UNEP including:

- The adequacy of project supervision plans, inputs and processes;
- The emphasis given to outcome monitoring (results-based project management);
- The realism and candour of project reporting and ratings (i.e. are PIR ratings an accurate reflection of the project realities and risks);
- The quality of documentation of project supervision activities; and
- Financial, administrative and other fiduciary aspects of project implementation supervision.

**Monitoring and evaluation**. The evaluations will include an assessment of the quality, application and effectiveness of project monitoring and evaluation plans and tools, including an assessment of risk management based on the assumptions and risks identified in the project document. The evaluations will appreciate how information generated by the M&E system during project implementation was used to adapt and improve project execution, achievement of outcomes and ensuring sustainability. M&E is assessed on three levels:

- *M&E Design*. Projects should have sound M&E plans to monitor results and track progress towards achieving project objectives. An M&E plan should include a baseline (including data, methodology, etc.), SMART indicators and data analysis systems, and evaluation studies at specific times to assess results. The time frame for various M&E activities and standards for outputs should have been specified. The evaluators should use the following questions to help assess the M&E design aspects:
- Quality of the project logframe (original and possible updates) as a planning and monitoring instrument; analyse, compare and verify correspondence between the original logframe in the Project Document, possible revised logframes and the logframe used in Project Implementation Review reports to report progress towards achieving project objectives;
- SMART-ness of indicators: Are there specific indicators in the logframe for each of the project objectives? Are the indicators measurable, attainable (realistic) and relevant to the objectives? Are the indicators time-bound?
- Adequacy of baseline information: To what extent has baseline information on performance indicators been collected and presented in a clear manner? Was the methodology for the baseline data collection explicit and reliable?
- Arrangements for monitoring: Have the responsibilities for M&E activities been clearly defined? Were the data sources and data collection instruments appropriate? Was the frequency of various monitoring activities specified and adequate? In how far were project users involved in monitoring?
- Arrangements for evaluation: Have specific targets been specified for project outputs? Has the desired level of achievement been specified for all indicators of objectives and outcomes? Were there adequate provisions in the legal instruments binding project partners to fully collaborate in evaluations?
- Budgeting and funding for M&E activities: Determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

M&E Plan Implementation. The evaluation will verify that:

- the M&E system was operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period;
- annual project reports and Progress Implementation Review (PIR) reports were complete, accurate and with well justified ratings;
- the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs.

**Use of GEF Tracking Tools**. These are portfolio monitoring tools intended to roll up indicators from the individual project level to the portfolio level and track overall portfolio performance in focal areas. Each focal area has developed its own tracking tool<sup>24</sup> to meet its unique needs. Agencies are requested to fill out these forms at CEO Endorsement (or CEO approval for MSPs) and submit these tools again for projects at mid-term and project completion. The evaluation will verify whether UNEP has duly completed the relevant tracking tool for this project, and whether the information provided is accurate.

<sup>&</sup>lt;sup>24</sup> http://www.thegef.org/gef/tracking\_tools

#### Complementarities with UNEP strategies and programmes

UNEP aims to undertake GEF funded projects that are aligned with its own strategies. The evaluations should present a brief narrative on the following issues:

- Linkage to UNEP's Expected Accomplishments and POW 2010-2011 and 2012-2013. The UNEP MTS specifies desired results in six thematic focal areas. The desired results are termed Expected Accomplishments. Using the completed ToC/ROtI analysis, the evaluation should comment on whether the project makes a tangible contribution to any of the Expected Accomplishments specified in the UNEP MTS. The magnitude and extent of any contributions and the causal linkages should be fully described. Whilst it is recognised that UNEP GEF projects designed prior to the production of the UNEP Medium Term Strategy 2010-2013 (MTS)<sup>25</sup> would not necessarily be aligned with the Expected Accomplishments articulated in those documents, complementarities may still exist and it is still useful to know whether these projects remain aligned to the current MTS.
- Alignment with the Bali Strategic Plan (BSP)<sup>26</sup>. The outcomes and achievements of the project should be briefly discussed in relation to the objectives of the UNEP BSP.
- Gender. Ascertain to what extent project design, implementation and monitoring have taken into
  consideration: (i) possible gender inequalities in access to and the control over natural resources; (ii) specific
  vulnerabilities of women and children to environmental degradation or disasters; and (iii) the role of women
  in mitigating or adapting to environmental changes and engaging in environmental protection and
  rehabilitation. Appreciate whether the intervention is likely to have any lasting differential impacts on gender
  equality and the relationship between women and the environment. To what extent do unresolved gender
  inequalities affect sustainability of project benefits?
- South-South Cooperation. This is regarded as the exchange of resources, technology, and knowledge between developing countries. Briefly describe any aspects of the project that could be considered as examples of South-South Cooperation.

## The Consultants' Team

For these evaluations, the evaluation team will consist of one consultant. The consultant should have experience in project evaluation. A Master's degree or higher in the area of environmental sciences or a related field and at least 15 years' experience in environmental management, with a preference for specific expertise in the area of biosafety and biodiversity is required.

By undersigning the service contract with UNEP/UNON, the consultant certifies that they have not been associated with the design and implementation of the project in any way which may jeopardize their independence and impartiality towards project achievements and project partner performance. In addition, s/he will not have any future interests (within six months after completion of the contract) with the project's executing or implementing units.

#### **Evaluation Deliverables and Review Procedures**

The evaluation consultant will prepare an evaluation for each country. The evaluator will start by preparing three inception reports (see Annex 2(a) of TORs for Inception Report outline) containing a thorough review of the project context, project design quality, a draft reconstructed Theory of Change of the project, the evaluation framework and a tentative evaluation schedule.

The review of design quality will cover the following aspects (see Annex 7 for the detailed project design assessment matrix):

• Strategic relevance of the project

<sup>&</sup>lt;sup>25</sup> <u>http://www.unep.org/PDF/FinalMTSGCSS-X-8.pdf</u>

<sup>&</sup>lt;sup>26</sup> http://www.unep.org/GC/GC23/documents/GC23-6-add-1.pdf

- Preparation and readiness (see paragraph 25);
- Financial planning (see paragraph 30);
- M&E design (see paragraph 33(a));
- Complementarities with UNEP strategies and programmes (see paragraph 34);
- Sustainability considerations and measures planned to promote replication and upscaling (see paragraph 23).

The inception reports will also present a draft, desk-based reconstructed Theory of Change of the project. It is vital to reconstruct the ToC *before* the most of the data collection (review of reports, in-depth interviews, observations on the ground etc.) is done, because the ToC will define which direct outcomes, drivers and assumptions of the project need to be assessed and measured to allow adequate data collection for the evaluation of project effectiveness, likelihood of impact and sustainability.

The evaluation framework will present in further detail the evaluation questions under each criterion with their respective indicators and data sources. The evaluation framework should summarize the information available from project documentation against each of the main evaluation parameters. Any gaps in information should be identified and methods for additional data collection, verification and analysis should be specified.

The inception reports will also present a tentative schedule for the overall evaluation process, including a draft programme for the country visit and tentative list of people/institutions to be interviewed.

The inception reports will be submitted for review and approval by the Evaluation Office before the consultant travels to the field.

The main evaluation reports should be brief (no longer than 35 pages – excluding the executive summary and annexes), to the point and written in plain English. The evaluator will deliver high quality reports in English by the end of the assignment. The reports will follow the annotated Table of Contents outlined in Annex 1. It must explain the purpose of the evaluation, exactly what was evaluated and the methods used (with their limitations). The reports will present evidence-based and balanced findings, consequent conclusions, lessons and recommendations, which will be cross-referenced to each other. The reports should be presented in a way that makes the information accessible and comprehensible. Any dissident views in response to evaluation findings will be appended in a footnote or annex as appropriate. To avoid repetitions in the reports, the author will use numbered paragraphs and make cross-references where possible.

Review of the draft evaluation reports. The evaluation consultant will submit the zero draft reports latest three weeks after conducting the field visits to the UNEP EO and revise the drafts following the comments and suggestions made by the EO. Once a draft of adequate quality has been accepted, the EO will share this first draft reports with the UNEP Task Manager, who will ensure that the report does not contain any blatant factual errors. The UNEP Task Manager will then forward the first draft report to the other project stakeholders, in particular the national partners, for review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. It is also very important that stakeholders provide feedback on the proposed recommendations and lessons. Comments would be expected within two weeks after the draft report has been shared. Any comments or responses to the draft report will be sent to the UNEP EO for collation. The EO will provide the comments to the evaluation team for consideration in preparing the final draft report.

The evaluation consultant will submit the final draft report no later than 2 weeks after reception of stakeholder comments. The consultant will prepare a response to comments, listing those comments not or only partially accepted that could therefore not or only partially be accommodated in the final report. The consultant will explain why those comments have not or only partially been accepted, providing evidence as required. This response to comments will be shared by the EO with the interested stakeholders to ensure full transparency.

**Submission of the final Terminal Evaluation report.** The final report shall be submitted by email to the Head of the Evaluation Office, who will share the report with the Director, UNEP/GEF Coordination Office and the UNEP/DEPI Task Manager. The Evaluation Office will also transmit the final report to the GEF Evaluation Office.

The final evaluation report will be published on the UNEP Evaluation Office web-site www.unep.org/eou. Subsequently, the report will be sent to the GEF Office of Evaluation for their review, appraisal and inclusion on the GEF website.

As per usual practice, the UNEP EO will prepare a quality assessment of the first draft and final draft report, which is a tool for providing structured feedback to the evaluation consultants. The quality of the report will be assessed and rated against the criteria specified in Annex 4.

The UNEP Evaluation Office will assess the ratings in the final evaluation report based on a careful review of the evidence collated by the evaluation consultant and the internal consistency of the report. Where there are differences of opinion between the evaluator and UNEP Evaluation Office on project ratings, both viewpoints will be clearly presented in the final report. The UNEP Evaluation Office ratings are the final ratings that will be submitted to the GEF Office of Evaluation.

#### Logistical arrangement

These Terminal Evaluations will be undertaken by an independent evaluation consultant contracted by the UNEP Evaluation Office. The consultant will work under the overall responsibility of the UNEP Evaluation Office and will consult with the EO on any procedural and methodological matters related to the evaluation. It is, however, the consultants' individual responsibility to arrange for their travel, visa, obtain documentary evidence, plan meetings with stakeholders, organize field visits (if any), and any other logistical matters related to the assignment. The UNEP Task Manager and local partners will, where possible, provide logistical support (introductions, meetings, transport etc.) for the country visit, allowing the consultants to conduct the evaluation as efficiently and independently as possible.

#### Schedule of the evaluation (tentative)

Activity	Date (s)
Start of the evaluation	1 September 2014
Inception reports	30 September 2014
Comments from Evaluation Office	10 October 2014
Field visits	20 October – 31
	October 2014
Zero Draft reports	21 November 2014
Comments from Evaluation Office	29 November 2014
First draft reports	12 December 2014
Comments from stakeholders	5 January 2014
Final reports	17 January 2015

The consultant will be hired under an individual Special Service Agreement (SSA). There are two options for contract and payment: lumpsum or "fees only".

Lumpsum: The contract covers both fees and expenses such as travel, per diem (DSA) and incidental expenses which are estimated in advance. The consultants will receive an initial payment covering estimated expenses upon signature of the contract.

Fee only: The contract stipulates consultant fees only. Air tickets will be purchased by UNEP and 75% of the DSA for each authorised travel mission will be paid up front. Local in-country travel and communication costs will be reimbursed on the production of acceptable receipts. Terminal expenses and residual DSA entitlements (25%) will be paid after mission completion.

The payment schedule for the consultant will be linked to the acceptance of the key evaluation deliverables by the Evaluation Office:

Final inception report:	20 percent of agreed total fee
First draft main evaluation report:	40 percent of agreed total fee
Final main evaluation report:	40 percent of agreed total fee

In case the consultant is not able to provide the deliverables in accordance with these TORs, in line with the expected quality standards by the UNEP Evaluation Office, payment may be withheld at the discretion of the Head of the Evaluation Office until the consultant has improved the deliverables to meet UNEP's quality standards. If the consultant fails to submit a satisfactory final product to UNEP in a timely manner, i.e. within one month after the end date of their contract, the Evaluation Office reserves the right to employ additional human resources to finalize the report, and to reduce the consultant's fees by an amount equal to the additional costs borne by the Evaluation Office to bring the report up to standard.

#### Submission of the final evaluation report:

The final report shall be submitted by email to: Mr. Michael Spilsbury, Chief UNEP Evaluation Office Email: michael.spilsbury@unep.org

> The Head of Evaluation will share the report with the following persons: Brennan Van Dyke Director UNEP/ GEF Coordination Office Email: <u>brennan.vandyke@unep.org</u>

Shakira Khawaja Fund Management Officer UNEP/DEPI Email: shakira.khawaja@unep.org

Alex Owusu Biney Task Manager UNEP/DEPI Email: <u>alex.owusu-biney@unep.org</u>

The final evaluation report will be published on the UNEP Evaluation Office web-site <u>www.unep.org/eou</u> and may be printed in hard copy.

# BHUTAN - LIST OF PEOPLE MET (29/10-03/11)

NAME	POSITION & INSTITUTION
Mr. Karma Dorji <u>karmadorji@moa.gov.bt</u>	Director General Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Kinley Pelden	Chief Regulatory and Quarantine Officer/Project Director Quality and Control Division Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Mr. Jamyang Phuntsho	Head Analytical and Certification Division Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Dr. N.B. Tamang <u>Nbtamang1967@gmail.com</u>	Specialist/Member of Biosafety Technical Working Group Department of Livestock Ministry of Agriculture and Forests
Mr. Karma Rapten	Portfolio Manager (Environment) UNDP (UN House)
Mr. Karma C. Nyedrup	Joint Director/CBP Focal Point, BCH Focal Point National Environnent Commission
Ms. Kesang Tshomo	National Coordinator National Organic Programme Ministry of Agriculture and Forests
Mr. Jambay Dorji	Chief Laboratory Officer National Food Testing Laboratory Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Tashi Yangzom tashiyanz@gmail.com	Regulatory and Quarantine Officer/ Focal for biosafety Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Tshering Yangzom	Sr. Regulatory and Quarantine Inspector Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Sonam Chuki	Sr. Regulatory and Quarantine Inspector Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Karma Yangzom	Sr. Regulatory and Quarantine Inspector Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Mr. Passang Wangdi	Sr. Regulatory and Quarantine Inspector Bhutan Agriculture and Food Regulatory Authority (BAFRA) Ministry of Agriculture and Forests
Ms. Pema Deki	National Project Coordinator (NPC)

pemdixx@gmail.com	National Biosafety Framework Project Bhutan Agriculture and Food Regulatory Authority (BAFRA)	
	Ministry of Agriculture and Forests	
Ms. Pema Choden	Project Assistant	
	National Biosafety Framework Project	
	Bhutan Agriculture and Food Regulatory Authority (BAFRA)	
	Ministry of Agriculture and Forests	

## **BIBLIOGRAPHY**

#### Documents consulted during the main evaluation phase

#### Bhutan:

- Terms of Reference of the Terminal Evaluation
- Project Document "Implementation of Bhutan National Biosafety Framework" (GFL/2328-2716-4B22)
- "Draft National Biosafety Framework of the Kingdom of Bhutan", Nat. Env. Commission, 2006
- "Bhutan and the GEF" (2013, from GEF Website)
- From ANUBIS: Mid Term Review, PIR 2012 and 2013, Budget Revisions, Audit Report 2013, revised Work plans, PSC Minutes, Final Inventory
- BCH Bhutan page (<u>https://bch.cbd.int/</u>)
- BAFRA website (http://www.bafra.gov.bt)
- MoAF website (http://www.moaf.gov.bt)
- Bhutan Biodiversity Portal (http://biodiversity.bt/theportal)
- Bhutan UNDP portal (<u>http://www.bt.undp.org/content/bhutan/en/home.html</u>)
- Biosafety Law (draft)
- MoAF Eleventh Plan 2013-2018
- Biotech Consortium India Ltd, Report and draft Guidelines
- Information / Communication material produced by the Project
- "Ensuring Biosafety through legal and regulatory instruments: South Asian Perspectives" (SAARC Workshop, Thimphu, May 2014)
- "Towards Food Security: challenges and Strategies for Bhutan" (MoAF, 2012)
- "Bhutan could be world's first wholly organic nation within a decade" (The Guardian, May 2014)

#### Global:

- Cartagena Protocol on Biosafety (CPB)
- Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety
- Bali Strategic Plan for Technology Support and Capacity-building
- Status of capacity-building activities, UNEP/CBD/BS/COP-MOP/5/INF/9, September 2010
- Medium term strategy of UNEP 2010-13 "Environment for Development"
- Strategic plan of CPB 2011-20
- A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects, 2006, UNEP-GEF Biosafety Unit
- Guidance towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects, 2008, UNEP-GEF Biosafety Unit
- Learning from experience, the global UNEP-GEF BCH Capacity building project, 2008, UNEP-GEF
- Public Participation and the Cartagena Protocol on Biosafety, A review for DfID and UNEP-GEF (IDS)
- An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN, 2003
- Genetically Modified Organisms and Biosafety: A background paper for decision-makers and others to assist in consideration of GMO issues, IUCN, 2004
- Guidelines for GEF Agencies in Conducting Terminal Evaluations, GEF Evaluation Office, 2008
- "ROtI Review of Outcomes to Impact: Practitioners Handbook", 2009, GEF
- http://www.unep.org/eou/StandardsPolicyandPractices/UNEP US/Default.aspx
   EvaluationPolicy/tabid/3050/language/en-
- http://www.unep.org/eou/StandardsPolicyandPractices/UNEP US/Default.aspx
   EvaluationManual/tabid/2314/language/en-US/Default.aspx
- http://www.thegef.org/gef/sites/thegef.org/files/documents/TE\_guidelines7-31.pdf

#### Project costs and co-financing tables

## Project Costs (USD)

Component/sub-component	Estimated cost at design	Actual Cost	Expenditure ratio (actual/planned)
TOTAL	1.723.000	1.478.950 (30/09/2014)	86% (30/09/2014)

#### **Co-financing**

Co financing		IA own Government Other*		Other* Total			Total Disburse d		
(Type/Source)	Plan ned	Actu al	Planned	Actual	Plann ed	Actual	Planne d	Actual	
– Grants									
– Loans									
- Credits									
- Equity investments									
<ul> <li>In-kind support</li> </ul>			854.000	655.574 (30/09)		106.500	854.000	762.074	762.074
- Other (*)						106.500			
Totals			854.000	655.574 (30/09)		106.500	854.000	762.074	762.074(3 0/09)

\* This refers to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

Detailed information on Other Sources of Co-financing is presented in the following table:

Amount (USD)	Funding Agency	Purpose
95000	Netherland Fellowship Program	Two weeks training for 11 BAFRA enforcement officials in the area of "GMO detection, Identification and quantification" in Netherlands.
3000	Korean Biosafety Clearing House	One week training for two BAFRA officials in BCH in Cambodia
3000	ICGEB	One week training for one BAFRA enforcement official in "Strategic Approaches in Evaluation of the Science underpinning GMO Regulatory Decision-making", Trieste, Italy
1000	BICL (Biotech Consortium India Limited)	Funded the participation of one BAFRA enforcement official in the South Asia Biosafety Conference.
1500	SAARC Agriculture Centre, Bangladesh	Funded the participation of one BAFRA enforcement official in the consultative

		meeting on "Prospects, needs, benefits and risk assessment of agriculture related GM products in SAARC countries" held in Dhaka, Bangladesh
3000	USAID	Funded the participation of one BAFRA enforcement official in the Second Annual South Asia Biosafety Conference, Colombo, Sri Lanka.
106.500		

#### CV profile of the Consultant (Camillo Risoli)

Camillo Risoli (Italy, 1953) is a seasoned international expert in rural development and environmental management. He has a long experience (more than 30 years) in the implementation, coordination and management of projects and programs in Africa and Latin America, with different donors and agencies. Capacity and Institution Building for Rural Development is his main area of expertise.

Camillo has worked as an expert, a chief technical adviser and an independent consultant for UN agencies (FAO, UNEP), Bi-lateral Cooperations (SDC – Swiss Cooperation, Italian cooperation, EC Delegations) and for International NGOs. He has been Team Leader in Long-Term Missions in Nicaragua (1980-82), Cape Verde (1986-96), Mozambique (1996-99) and Zimbabwe (2003-2005).



Food Security and Poverty Reduction have been at the core of his professional commitment, through Community-based projects and participatory actions, Organization & training of rural associations, Sustainable land use and agriculture, Partnership strengthening and networking (Public, Private, Civil Society) for decentralised and participatory local development.

Mainstreaming Environmental issues in Pro-Poor Strategies has been a main component of his action, through Soil & water conservation projects, Reforestation and agro-forestry initiatives, Watershed management and land use planning, Sustainable management of natural resources (soil, water, forests and bio-diversity).

Camillo has acquired a robust experience in advising on national policies and strategic planning for rural development, a solid background in PCM (Programme Cycle Management) and strong skills in Project Monitoring & Evaluation (M&E).

Since 2005, he works as an Independent Consultant and has carried out and led relevant Evaluation missions, such as the Mozambique National Action Plan for Food Security (FAO), the LADA Project - Land Degradation Assessment in Drylands - (FAO/UNEP-GEF) in Argentina and China, the Post-Conflict Rural Development in Ivory Coast (FAO/ADB), the setting of the M&E System for FAO/CLCPRO Program (Commission for Locust Control in Western Africa and Maghreb Region), the Biosafety National Frameworks .Evaluation (UNEP-GEF) in Kenya, Namibia, Poland, Lithuania, Czech Republic and Slovakia, the terminal evaluation of the FAO Programme of Food Security through Commercialization in West Africa (Gambia, Guinea, Liberia, Senegal, Sierra Leone), the Evaluation of FAO's Decentralization in Latin America & the Caribbean (2013).

Camillo has a graduate degree in Agricultural Sciences, a Post-Graduate Diploma in Environmental Management at London University and a PhD in Adult Education. He has published with FAO training manuals and methodological guides for trainers and extensionists.

Camillo is currently engaged in the creation of a small private company in partnership with farmers associations (out-growing scheme) for the development of a profitable value-chain of Aloe Vera in Cape Verde.

# The UNEP/GEF projects of NBF implementation in Mongolia, Bhutan, Lao PDR<sup>27</sup>: elements for a comparative analysis

- <u>The concept and design of the three projects are similar</u>. They basically are Institutional and Capacity Building projects aiming at creating and consolidating in-country conditions for the implementation of the National Biosafety Framework: a combination of policy, legal, administrative and technical instruments enabling the countries to manage the safe transfer, handling and use of living modified organisms (LMOs) from modern biotechnology.
- <u>Socio-political, economic, geographical and environmental situations of the countries are</u> very different. However, they share some notable elements that are relevant for GMOs management:

a) the three countries are richly endowed in natural resources, pristine environments and biodiversity;

b) all of them are landlocked countries, with somewhat porous borders;

b) two of them (Mongolia and Bhutan) have big and powerful neighbors (Russia and China for Mongolia, China and India for Bhutan) with which they maintain strong economic and trade relations;

d) the three countries import great part of the food and feed consumed internally, which, on the one hand, entails the need for adequate measures of control, inspection and detection, and, on the other hand, is raising increased interest for the use of GMOs in agriculture.

- Due to the above listed elements, the <u>relevance of the projects is equally high for the three</u> <u>countries.</u>
- <u>The baseline situation of the three countries at the starting of the projects was quite</u> <u>different</u>. Mongolia had already a national Biosafety Law (since 2007), while the other two countries had not. Bhutan was in a particular situation, due to a ministerial decree issued by the Ministry of Agriculture in 2000 that banned all imports of LMOs into the country (moratorium).
- As a consequence of the previous point, <u>Mongolia</u> project focused on the elaboration and implementation of a "National Biosafety Programme" (NBP), considered the pivotal instrument for the implementation of all programs and activities concerning Biosafety in the country. The NBP is a comprehensive instrument of public planning including Work plans (2014-2017, 2018-2021), Monitoring & Evaluation framework and a Budget. Moreover, building upon the National Biosafety Law of 2007, the Project has largely contributed to the elaboration of five Regulations (General Regulations and specific Regulation on Inspection,

<sup>&</sup>lt;sup>27</sup> "Capacity Building for Biosafety Implementation for Mongolia"; "Implementation of the National Biosafety Framework of Bhutan"; "Support the implementation of National Biosafety for Lao PDR"

Customs, Registration & Risk Assessment, Transportation), two of which already approved (Inspection and Customs) and three other at the final stage of their process of approval.

- <u>Bhutan and Lao PDR</u> have obviously focused on the elaboration and approval of the National Biosafety Laws, which occurred in both countries during 2014, with a strong impulse by the respective projects. The process leading to the adoption of the new Laws was, however, quite different between the two countries.
- In one case, <u>Bhutan</u>, the Project, while technically and methodologically supporting the discussions and the gradual revisions of the text, eventually leading to the Biosafety Act approved in November 2014, has, in a parallel way, acted "as if the law existed already". As a matter of fact, the two main bodies established by the new Biosafety Law (the National Biosafety Commission / NBC with responsibility for strategic guidance and coordination, and the Technical Working Groups with advisory function) are the natural evolution of the implementing mechanisms set by the Project. They have already given evidence of meaningful participation and of strategic and technical capacities during the phase of the elaboration and discussion of the Law.
- Lao PDR had started the process of discussion and elaboration of the National Law well before (2004) and, after a complex and challenging process (also including a governmental reshuffling, the creation of new Ministries, a new NCA, a reshaped project team), eventually the National Biosafety Law was approved in February 2014. Due to the complex structure of the public administration and to the convoluted mechanisms of decision-making, the formal absence of a law hampered many related activities and represented a major obstacle to the smooth progress of Biosafety agenda in the country. After the adoption of the Law, the biosafety regulatory framework has been completed with the preparation of three draft Regulations (Secondary Law) and the elaboration and discussion of a draft National Biotechnology Strategy and Action Plan (NBSAP), which will permit to insert Biosafety into national plans and policies.
- The experience of the three projects shows how relevant <u>socio-political conditions and</u> <u>governance mechanisms</u> are for the implementation of National Biosafety Frameworks. On this regards, the three projects' teams have responded with different assets and capabilities: capacity of coordination and partnership have been strong driving forces of the <u>Mongolia</u> team, flexibility and management adaptation have been strong assets of <u>Bhutan</u> project, while resilience and strong motivation have been major assets of the <u>Lao</u> project team.
- Some interesting elements of analysis can also come from the observation of the <u>different</u> institutional frameworks of the three projects. Few lessons can be drawn by the <u>Lao PDR</u> experience on this aspect, due to the renewed institutional frame, while both <u>Mongolia and</u> <u>Bhutan</u> present two different institutional frames, each of them with strong and weak points.
- In <u>Mongolia</u>, the setting of a permanent Secretariat (three full-time MEGD staff) of the National Biosafety Committee (NBC), within the MEGD structure (Ministry of Environment and Green Development) is an interesting institutional approach that combines a higher degree of autonomy and decision-making (when compared with a ministerial department)

and the advantages of being inserted within a Ministry (institutional anchorage), which is also the NCA<sup>28</sup>. <u>This is a strong point</u>. Nevertheless, most of the national stakeholders stress the need to link Biosafety and Food Safety, particularly on issues such as imported food's quality control and labelling, which are under different institutional umbrellas. This perspective entails a <u>strong need of coordination and partnership</u> of the NBC Secretariat particularly with Inspection and Customs Agencies (which is actually what the Secretariat is doing), and with the Ministry of Agriculture.

- Quite different the situation in <u>Bhutan</u>, where the NCA is the BAFRA (Bhutan Agriculture and Food Regulatory Authority) of the Ministry of Agriculture, a solid and dynamic institution playing a strategic role at national level, being <u>responsible for the application of relevant</u> <u>national policies and legal instruments</u> such as the Plant Quarantine Act, Seed Act, Pesticide Act, Livestock Act, Food Act, Forest and Nature Conservation Act, Biodiversity Act and, eventually, the Biosafety Act. It functions as the National Food Quality and Safety Control agency and is the <u>National Competent Authority not only for the CPB</u>, but also the IPPC (International Plant Protection Convention), CAC (Codex Alimentarius Commission), the WTO-SPS Agreement (World Trade Organization-Sanitary and Phytosanitary Agreement). Biosafety can therefore take profit from a robust and polyvalent institutional anchorage, which offers large guarantees of institutional and socio-political sustainability. <u>This is a major strong point</u>.
- <u>Bhutan and Lao PDR</u> (especially Bhutan) look more dynamic in searching and fostering regional cooperation (within SAARC and ASEAN umbrella, respectively) probably due to the dimension of those countries entailing a greater need of cooperation / integration and the existence of more dynamic regional associations in those regions.
- The partnership with Academic Institutions in <u>Mongolia</u> (the University and the national Academy of Sciences, where the GMO lab is placed) is a strong asset that is not yet fully explored in the other two countries (in Bhutan, National University is at a very early stage).
- This brief comparative analysis cannot omit mentioning the peculiarity of the <u>Bhutan</u> <u>Biosafety Act</u> of November 2014 that, in its art.20, <u>prohibits the import, transit, intentional</u> <u>introduction, any use including contained use, research and development of modified</u> <u>organisms capable of reproducing and the socio-politically different set ups of the countries.</u>

<sup>&</sup>lt;sup>28</sup> This approach could probably also be adopted in Lao PDR, where the BEI Biosafety team could perhaps play the role of NBC Secretariat within the NCA, the Biotechnology and Ecology Institute (BEI) of the Ministry of Science and Technology.

## **Annex 8: UNEP Evaluation Quality Assessment**

Evaluation Title:

Evaluation of the Project: National Biosafety Framework for Bhutan, Laos, Mongolia

All UNEP evaluations are subject to a quality assessment by the Evaluation Office. The quality assessment is used as a tool for providing structured feedback to the evaluation consultants.

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

		UNEP Evaluation Office Comments	Draft	Final
			Report	Report
			Rating	Rating
Sub	stantive report quality criteria			
Α.	Quality of the Executive Summary: Does the executive summary present the main findings of the report for each evaluation criterion and a good summary of recommendations and lessons learned? (Executive Summary not required for zero draft)	Final report: Good summary and to the point		6
В.	Project context and project description: Does the report present an up-to-date description of the socio-economic, political, institutional and environmental context of the project, including the issues that the project is trying to address, their root causes and consequences on the environment and human well-being? Are any changes since the time of project design highlighted? Is all essential information about the project clearly presented in the report (objectives, target groups, institutional arrangements, budget, changes in design since approval etc.)?	Draft report: Good overview, changes described and precise presentation of key points. Final report: Same as above	5	5
C.	Strategic relevance: Does the report present a well-reasoned, complete and evidence-based assessment of strategic relevance of the intervention in terms of relevance of the project to global, regional and national environmental issues and needs, and UNEP strategies and programmes?	Draft report: Very good analysis based on info provided by EOU and TM Final report: Same as above	5	5
D.	Achievement of outputs: Does the report present a well-reasoned, complete and evidence-based assessment of outputs delivered by the intervention (including their quality)?	Draft report: Detailed assessment Final report: Same as above	5	5
E.	<b>Presentation of Theory of Change</b> : Is the Theory of Change of the intervention clearly presented? Are causal pathways logical and complete (including drivers, assumptions and key	Draft report: ToC was of good quality and discussed during the field visits Final report: Same as above	5	5

	actors)?			
F.	Effectiveness - Attainment of project	Draft report:		
	objectives and results: Does the report	Yes, good assessment		
	present a well-reasoned, complete and	Final report:	-	5
	evidence-based assessment of the	Same as above	5	5
	achievement of the relevant outcomes			
	and project objectives?			
G.	Sustainability and replication: Does the	Draft report:		
	report present a well-reasoned and	Yes all dimensions considered		
	evidence-based assessment of	Final report:	5	5
	sustainability of outcomes and	Same as above		
	replication / catalytic effects?			
Н.	Efficiency: Does the report present a	Draft report:		
	well-reasoned, complete and evidence-	Yes, but no comparisons		
	based assessment of efficiency? Does	Final report:	5	5
	the report present any comparison with	Same as above	5	5
	similar interventions?			
١.	Factors affecting project performance:	Draft report:		
1.	Does the report present a well-	Good analysis		
	reasoned, complete and evidence-based	Final report:		
	-	Same as above		
	assessment of all factors affecting	Same as above		
	project performance? In particular, does		5	5
	the report include the actual project			
	costs (total and per activity) and actual			
	co-financing used; and an assessment of			
	the quality of the project M&E system			
	and its use for project management?			
J.	Quality of the conclusions: Do the	Draft report:		
	conclusions highlight the main strengths	Conclusions highlight key points	5	6
	and weaknesses of the project, and	Final report:	5	Ũ
	connect those in a compelling story line?	Very good and relevant conclusions		
К.	Quality and utility of the	Draft report:		
	recommendations: Are	R are targeted		
	recommendations based on explicit	Final report:		
	evaluation findings? Do	R targeted and well presented		
	recommendations specify the actions		5	6
	necessary to correct existing conditions			
	or improve operations ('who?' 'what?'			
	'where?' 'when?)'. Can they be			
	implemented?			
L.	Quality and utility of the lessons: Are	Draft report:		
	lessons based on explicit evaluation	Lessons are short but useful		
	findings? Do they suggest prescriptive	Final report:	5	5
	action? Do they specify in which	Same as above		-
	contexts they are applicable?			
Ren	port structure quality criteria			
M.	Structure and clarity of the report: Does	Draft report:		
	the report structure follow EO	Very good structure		
	guidelines? Are all requested Annexes	Final report:	6	6
	included?	Same as above	Ū	0
N.	Evaluation methods and information	Draft report:		
	sources: Are evaluation methods and	Yes good description		
	information sources clearly described?	Final report:	_	_
	Are data collection methods, the	Same as above	5	5
	triangulation / verification approach,			

	OVERALL REPORT QUALITY RATING		5.1	5.375
Ρ.	<b>Report formatting</b> : Does the report follow EO guidelines using headings, numbered paragraphs etc.	Draft report: Yes well layouted and formatted report Final report: Same as above	6	6
0.	Quality of writing: Was the report well written? (clear English language and grammar)	Draft report: Good writing style Final report: Same as above, final report very well presented	5	6
	details of stakeholder consultations provided? Are the limitations of evaluation methods and information sources described?			

The quality of the <u>evaluation process</u> is assessed at the end of the evaluation and rated against the following criteria:

		UNEP Evaluation Office Comments	Rating
Eva	luation process quality criteria		
Q.	Preparation: Was the evaluation budget	Yes	
	agreed and approved by the EO? Was		6
	inception report delivered and approved		U
	prior to commencing any travel?		
R.	Timeliness: Was a TE initiated within the	Yes, except for the long period necessary to	
	period of six months before or after	obtain comments from the task manager	
	project completion? Was an MTE		4
	initiated within a six month period prior		
	to the project's mid-point? Were all		
	deadlines set in the ToR respected?		
S.	Project's support: Did the project make	Yes	
	available all required documents? Was		
	adequate support provided to the		6
	evaluator(s) in planning and conducting		
-	evaluation missions?		
Т.	Recommendations: Was an	Implementation plan prepared and shared	
	implementation plan for the evaluation	with the project	6
	recommendations prepared? Was the		6
	implementation plan adequately		
U.	communicated to the project?		
0.	<b>Quality assurance:</b> Was the evaluation peer-reviewed? Was the quality of the	Yes, all reports have been peer reviewed, assessment completed	
	draft report checked by the evaluation	assessment completed	
	manager and peer reviewer prior to		
	dissemination to stakeholders for		6
	comments? Did EO complete an		
	assessment of the quality of the final		
	report?		
V.	Transparency: Were the draft ToR and	Yes, response to comments prepared by	
	evaluation report circulated to all key	EOU and evaluator	
	stakeholders for comments? Was the		6
	draft evaluation report sent directly to		
	EO? Were all comments to the draft		

		OVERALL PROCESS RATING	5.75
X.	Independence: Was the final selection of the evaluator(s) made by EO? Were possible conflicts of interest of the selected evaluator(s) appraised?	Yes	6
W.	commentators? Did the evaluator(s) prepare a response to all comments? <b>Participatory approach:</b> Was close communication to the EO and project maintained throughout the evaluation? Were evaluation findings, lessons and recommendations adequately communicated?	Yes	6
	evaluation report sent directly to the EO and did EO share all comments with the		

Rating system for quality of evaluation reports

A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1

The overall quality of the evaluation report is calculated by taking the mean score of all rated quality criteria.