

Terminal Evaluation of the UN Environment Project: "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India / Phase II"

















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ABOUT THE EVALUATION¹

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Brief Description:

This report is a terminal evaluation of a UN Environment-GEF project implemented between 2012 and 2017. The project objective was "to strengthen the biosafety management system in India with special emphasis on risk assessment and management, handling, transport, packaging and identification of LMOs, socio economic considerations and public awareness, to ensure adequate protection of human health and biodiversity from any potential harm arising from all LMO-related activities". The evaluation sought 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.

Key words:

Biosafety, Genetically Modified Organisms (GMOs), Cartagena Protocol on Biosafety (CPB), India, Competent National Authority (CNA), Genetic Engineering Appraisal Committee (GEAC), Environmental Risk Assessment (ERA), Risk Analysis, Risk Assessment and Risk Management (RARM), Evaluation, National Biosafety Authority (NBA), Biosafety Clearing-House (BCH)

¹ This data is used to aid the internet search of this report on the Evaluation Office of UN Environment Website –

Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India — Phase II: Project Identification Table

GEF Strategic	SP 6 –	Focal Area(s):	Biosafety
Objective:	Biosafety/SO3		
GEF project ID:	3751	GEF OP#	(MTS 2010-2013) Governance EA(b): States increasingly implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions. (MTS 2014-2017) Environmental Governance EA2: 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.
UN Environment approval date:	03/05/ 2012	UN Environment Sub-programme:	Environmental Governance
GEF approval date:	19/08/ 2011	Project type:	Full Size Project
Expected start	September 2011	Actual start	29/05/ 2012
date:	NA 0 2017	date:	Luly 2, 2017
Planned completion date:	May 2, 2016	Actual completion date:	July 2, 2017
Planned project budget at approval:	US\$ 8,727,273	Actual total expenditures reported as of August 2017:	US\$ 9,868,581
GEF grant allocation:	US\$ 2,727,273	GEF grant expenditures reported as of August 2017:	US\$ 2,625,2772
Expected Full-Size Project co- financing:-	US\$ 6,000,000	Secured Medium-Size Project co- financing:	US\$ 7,243,304
First disbursement:	Jun 2013	Date of financial closure:	Not yet closed
No. of revisions:	5 budget revisions, 1 project extension	Date of last revision:	January 2017
No. of Steering Committee meetings:	Four	Date of last Steering	September 15, 2016.

-

 $^{^2}$ Remaining to be disbursed on receipt of final documents and UNDP reconciliation as external consultant funds were disbursed through UNDP (source: Task Manager, 26/04/2018).

GEF Strategic	SP 6 –	Focal Area(s):	Biosafety
Objective:	Biosafety/SO3		
		Committee	
		meeting:	
Terminal Evaluation	2017	Terminal	November–December 2017
(planned date):		Evaluation	
		(actual date):	
Coverage -	India	Coverage -	Asia
Country(ies):		Region(s):	

List of Acronyms and Abbreviations

ANUBIS A New UNEP Biosafety Information System

BCH Biosafety Clearing-House

BCIL Biotech Consortium India Limited
CBD Convention on Biological Diversity
CNA Competent National Authority
CPB Cartagena Protocol on Biosafety

ERA Environmental Risk Assessment (ERA) of Genetically Engineered Plants

GE Gender Equality

GEF Global Environment Facility
GMO Genetically Modified Organism

HR & GE Human Rights and Gender Equality (HR & GE)

HR Human Rights

LMO Living Modified Organism

MoEF&CC Ministry of Environment, Forest & Climate Change

NBF National Biosafety FrameworkNPC National Project Coordinator.NPD National Project Director.PCU Project Coordination Unit

PIR Project Implementation Review
TM Task Manager (at UN Environment)

TOC Theory of Change
ToR Terms of Reference

Executive Summary

This is the final report of the Terminal Evaluation of the Project "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India — Phase II" (GFL/5060-2716-4C42). Project's operations started in May 2012 and officially ended in July 2017. The total budget was 8,727,273 USD, 31.25% of which was GEF allocation (USD 2,727,273) and the remaining 68.75% (6,000,000 USD) co-financed by the Government of India.

The project was a Full-Size Project financed through GEF-4 Funding Cycle and belonged to GEF Biodiversity Focal Area. It was relevant to GEF Strategic Programme 6 (BD-SP6): Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. The Project was part of two UN Environment Medium-Term Strategies (2010-2013 and 2014-2017) and three Biennial PoWs (Programme of Work), i.e. 2012-2013, 2014-2015 and 2016-2017, Environmental Governance Sub-Programme.

The Project followed-up the GEF-World Bank "Biosafety Demonstration Project", implemented between 2003 and 2007 by the Ministry of Environment, Forest & Climate Change, which was also the National Executing Agency of the current Project and Competent National Authority for the Cartagena Protocol on Biosafety. The Project implementation structure included a National Steering Committee, a National Project Director supported by a Project Management and Monitoring Committee, a National Project Coordinator and the Project Coordination Unit outsourced to a Public-Private company (Biotech Consortium India Limited) that carried-out all Project management and coordination functions.

Biosafety law and policies are well developed in India, including the "Environmental Protection Act" of 1986 and the "Rules 1989". India benefits from a 30-year experience in biodiversity, vigorous biotechnology competences, robust regulatory regime and consequent human and institutional capabilities. Hence, the key biosafety governance elements are in place. Additionally, biotechnology is considered as a "sunrise sector" and a key economic driver for the country.

At the start of the Project, in 2012, a constellation of legislations related to biosafety regulations was already developed. However, there was need to strengthen the regulatory procedures and enforcement mechanisms regarding the transboundary movement of Living Modified Organisms, in view of the advancements in crop biotechnology at the national and global level, since India already had several Living Modified Organisms close to commercialization and the country was expected to be soon both an exporter and an importer of Living Modified Organisms.

The Project Objective was "to strengthen the biosafety management system in India with special emphasis on risk assessment and management, handling, transport, packaging and identification of Living Modified Organisms, socio economic considerations and public awareness, to ensure that adequate protection of human health and biodiversity from potential harm arising from all Living Modified Organism-related activities". To better capitalize on Project's results, in the Theory of Change, the evaluation streamlined the Project's objectives (see Table 4 in Section 4.1)

as follows: Project's Main Outcome "Strengthened Management System and fully operational National Biosafety Framework in India" underpinned by four Direct Outcomes: a) Responsive regulatory regime, including implementing Regulations and Guidelines; b) Responsive Administrative system for handling applications, Risk Assessment and Risk Management, including Socio-Economic Considerations; c) Enforcement Monitoring and inspection system for LMOs strengthened; and d) Functional systems for public awareness, education and participation.

The evaluation's purpose was a) to provide evidence of results for accountability reasons; and b) to promote learning, feedback, and knowledge sharing among the UN Environment, the GEF, the National Executing Agency and the national partners. The evaluation analysed project related documentation and an inception report was prepared, which underwent a Peer Review at the UN Environment Evaluation Office and was shared with the Biosafety Task Manager at UN Environment. A country visit was prepared in strict collaboration with the Task Manager, the National Executing Agency and the Project Coordination Unit with which some evaluation tools were shared and the field mission agenda, as well as the list of stakeholders to be met, were fine-tuned. During the five-day country visit the Evaluation met relevant stakeholders and worked in close collaboration with the Project Coordination Unit and the National Executing Agency.

Evaluation ratings by criteria are summarized below (see also Table 7 Section 6.1, Conclusions). The Project has been rated **Satisfactory** overall.

Evaluation Criteria and Ratings Table

Criterion	Rating	Sections in the Main Report
A. Strategic Relevance	HS	Section 5.1
B. Quality of Project Design	MU	Section 5.2
C. Nature of External Context	HF	Section 5.3.
D. Effectiveness3	MS	Section 5.4
E. Financial Management	HS	Section 5.5
F. Efficiency	S	Section 5.6
G. Monitoring and Reporting	MS	Section 5.7
H. Sustainability	ML	Section 5.8
I. Factors Affecting Performance	MS	
Overall project rating	Satisfactory	

The Project gave its positive contribution to a functional and responsive regulatory regime and national monitoring system, further strengthening the institutional and technical capacity and

³ Where a project is rated, through the assessment of Project Design Quality template during the evaluation inception stage, as facing either an Unfavourable or Highly Unfavourable external operating context, the overall rating for Effectiveness may be increased at the discretion of the Evaluation Consultant and Evaluation Manager together.

promoting awareness and participation amongst the key actors, to ensure that biosafety becomes part of their permanent action.

A number of relevant Guidelines complemented the compendium of the "Administrative system" tools in place. The "Enforcement & monitoring" systems benefitted from a network of GMO laboratories and the training of key human resources. Consistent awareness-raising and information material was delivered in several national languages through the Project's support. Additionally, relying on national ownership and initiative, the Project, during its lifespan, successfully engaged the main stakeholders identified in the Project Document.

The Project focused on capacity building, achieving significant results in several areas, with particular regard to Biosafety Monitoring and Enforcement-Systems.

Based on triangulation of findings, including the perception of some national stakeholders, the Terminal Evaluation may confirm that the Project's achievements provided evidence of progress, even though the Project design and particularly the weak indicators' setting, challenged to a certain extent the evidence strength. The evaluation found that the Project's monitoring system did not provide sufficiently robust and properly weaved criteria against which a precise, unambiguous and evidence-based judgement could be formed.

Stakeholders were not classified along the key feature of "Duty-bearers" and / or "Rights'-holders". Not all of those affected by the Project or could have impact on the Project were considered, e.g. indigenous peoples and local communities were marginally encompassed, project design was blind to Human Rights and Gender Equality, and possible vulnerable groups were not identified. Generally, the Project did not consider the fact that different groups may have diverging and even conflicting interests, views and perceptions, and, on the whole, stakes; consequently, it did not perform a "root-causes analysis" of these issues.

India is a large, complex, federal country and a vigorous democracy. The political will, shaped through the political capabilities of several constituencies, is currently subject to the mainstream feeling about GMOs. However, India's robust mechanisms and competences evolve in a very dynamic context and may underpin the steady evolution of the institutional arrangements in a genuine attempt to set up the most appropriate ones for a fully responsive National Biosafety Framework.

Summary of lessons learned

<u>Lesson one:</u> If ignored, the root-causes of a problem may turn into bottlenecks that hinder change. "Root-causes analysis" is one way of identifying effective remedies to potential problems in project implementation.

<u>Lesson two:</u> Awareness-raising using a "top-down" approach is not equivalent to public dialogue and participation. The former is based on message dissemination from a "centre of knowledge" to the "periphery", while the latter is based on bi-lateral communication, implying active mutual-hearing, minimum standards of trust and engagement of all parties.

<u>Lesson three:</u> Human Rights and Gender Equality mainstreaming is compulsory to the UN programming, yet, the value of embracing Human Rights and Gender Equality (HR & GE) in biosafety will remain normative and theoretical if projects do not foster specific HR & GE aims and earmark budget for this purpose, to build up "critical mass" on the issue .

Summary of Recommendations

The Evaluation recommends that the Competent National Authority devotes efforts to build robust follow-up systems in order to measure effects and steer action in relation to: a) Human Resources capacity development; b) Information and Public awareness.

The UN Environment should also invest resources in effectively and fully integrating Monitoring and Evaluation (M&E) requirements in the whole project cycle. More specifically:

- [1]. At the design stage (ex-ante), ensure the validation of the Monitoring and Evaluation system of each project, with focus on SMART and verifiable indicators.
- [2]. At the implementation stage, promote capacity building (e.g. through workshops and coaching) on Project Cycle with focus on Monitoring and Evaluation, including soft skills for human resources involved in project management and implementation at all levels.
- [3]. Ensure that project budget is adequate for the requirements of an effective monitoring and evaluation delivery, including capacity building.
- [4] Finally, the evaluation recommends that UN Environment should work on, and invest resources in, fully mainstreaming Human Rights and Gender Equality (HR & GE) into the whole Project Cycle.

The UN Environment should work on the harmonization of the requirements at the design and evaluation stages of the project cycle. In particular, taking action to ensure consistency between the Project Document and the "Assessment of the Project Design Quality" guidelines developed by the Evaluation Office.

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1 Introduction

- 1. This report refers to the Project "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India Phase II", GEFSEC Id: 3751, (GFL/5060-2716-4C42); approved by GEF the 19/08/2011 and by UN Environment the 16/04/2012 for a duration of 48 months (9/2011- 8/2015). The operational starting date was May 2012 and the official end date was July 2017, after 5 budget revisions and 14 months of project extension; with a total budget of 8,727,273 USD, 31.25% of which is GEF allocation (USD 2,727,273) and the remaining 68.75% (6,000,000 USD) co-financed by the Government of India. The actual Indian Government allocation amounts to 7,243,304 USD.
- 2. The Project is considered as Phase II Project a follow up to the GEF-World Bank "Biosafety Demonstration Project", implemented between 2003 and 2007 by the National Executing Agency (NEA) the Ministry of Environment, Forest & Climate Change (MoEF&CC), which is also the NEA of the current Project, Phase II, and Competent National Authority (CAN) for the Cartagena Protocol on Biosafety (CPB).
- 3. The project is a Full-Size Project (FSP) financed through GEF-4 Funding Cycle and belongs to GEF Biodiversity Focal Area. It is relevant to GEF Strategic Programme 6 (BD-SP6): Building Capacity for the Implementation of the Cartagena Protocol on Biosafety.
- 4. The Project relates to two UN Environment Medium-Term Strategies (2010-2013 and 2014-2017) and three Biennial PoWs (Programme of Work), i.e. 2012-2013, 2014-2015 and 2016-2017, Environmental Governance Sub-Programme, as described in chapter 5.1.1.

2 Evaluation Methods

2.1 Overall approach of the Evaluation

5. "The terminal evaluation provides a comprehensive and systematic account of the performance of a completed project by assessing its project design, process of implementation, and achievements vis-à-vis project objectives endorsed"⁵. In line with the UN Environment Evaluation Policy and Evaluation Manual, and following the Guidelines for GEF Agencies on Conducting Terminal Evaluations, the evaluation had two primary purposes:

⁴ As noted by the Task Manager, "India was not part of the Global Umbrella Project on Development of National Biosafety Frameworks but of the 12 Country GEF Biosafety Demonstration Projects of which UNEP handled 8 Countries, World Bank 2 countries, and UNDP 2 countries".

⁵ Guidelines for GEF Agencies in Conducting Terminal Evaluations Evaluation Document No. 3, 2008

- (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 UN Environment, the GEF, the National Executing Agency and the national partners.
- 6. The report follows the format for Terminal Evaluations provided by the UN Environment Evaluation Office. In accordance with the UN Environment evaluation methodology, in order to facilitate data analysis and "common language" between stakeholders, most criteria have been rated on a six-point scale⁶. Ratings are provided at the end of the assessment of each evaluation criterion (Chapter 5: Findings) and the complete ratings table is included under the Conclusions (Section 6.1).
- 7. An Inception Report was produced at the beginning of the mission, containing a review of the project context, the quality of project design, a draft reconstructed Theory of Change of the project, evaluation framework and a tentative evaluation schedule. The Inception Report underwent a Peer Review at the UN Environment Evaluation Office and was also shared with the Biosafety Task Manager at UN Environment.
- 8. During the preparation of the field visit, the consultant, with the support of Biosafety Task Manager at UN Environment, contacted the National Executing Agency (NEA) as well as the Project Coordination Unit (PCU) outsourced to the Biotech Consortium India Limited (BCIL)⁷, shared with them some preliminary tools to systematise and discuss main achievements (see following Section 2.2) and started working on the field mission preparation, including the agenda and the list of stakeholders.
- 9. With the support of the Project Coordination Unit in preparing the agenda, the Consultant held meetings with relevant national key-players, including the National Executing Agency and PCU, three Ministerial Departments, Delhi University, private sector and one NGO / service provider, for a total of 15 people (See 2.2 and annex 3), and widely discussed with them relevant strong and weak points regarding the Project implementation, performance and sustainability.
- 10. The Project was subjected to a turn-over in two key positions National Project Coordinator (NPC) ⁸ and National Project Director ⁹ (see Section 3.4). The consultant met

⁶ 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 (HLI).

⁷ Project Coordination Unit / Biotech Consortium India Limited

⁸ National Project Coordinator. The consultant met with one former NPC and the current NPC at the time of the field visit

⁹ National Project Director. The consultant met with two former NPDs.

with one former NPC and the one in charge at the time of the field visit. However, after the country visit and during the evaluation period, another turn-over took place at NPC level.

- 11. Consultations firstly aimed at pointing out stakeholders' perceptions of Project's major issues, with focus on the four "key strategic questions" Subsequently, consulted stakeholders were requested to provide evidence underpinning their perception on the basis of which the exercise could further unfold the analysis of their views.
- 12. To increase stakeholders' engagement and meaningful consultation, the Evaluation fostered a participatory approach. During the country visit, the mission cooperated closely with the BCIL which engaged its staff related to the PCU for accompanying the consultant in all meetings with relevant stakeholders, except the meetings held with the Competent National Authority (CNA), i.e. Ministry of Environment, Forest & Climate Change (MoEF&CC) and the NPC. Several working-meetings were also organised with BCIL staff.
- 13. The Theory of Change (TOC) was instrumental for data analysis and verification. Outputs and Outcomes were assessed against their quality and effectiveness, hence their capacity to drive and sustain changes at a higher level of objectives. Quantitative and qualitative indicators were used. For a better understanding of the reasons for success or failure, the process / pathways of Project's achievements were also assessed.
- 14. The above process was enabled by triangulating the desk information (reports, etc.) with the new information gathered during the country visit, such as observation and supplementary documentation and personal interviews with stakeholders, particularly those who benefited from training and capacity building activities. Review and analysis of data supplied by key stakeholders were also carried out.
- 15. The plurality of views was only partially captured because divergent views were only marginally represented among the stakeholders met during the visit in New Delhi. This was a choice of the NEA which was respected by the mission, complying with the National Sovereignty Principle and the scope of the evaluation which focused on Project's effective implementation. The evaluation fostered an active hearing only of those stakeholders that the Project addressed as effective partners during its lifespan. As further elaborated under Section 3.3, "Stakeholders", not all potentially affected societal groups / stakeholders were encompassed by the Project¹¹; a fact that somewhat

11 "Stakeholder Analysis in the Evaluation Process", UN Environment, EO. The Evaluation Office of UN Environment identifies stakeholders broadly as "all those who are affected by, or who could affect (positively or negatively) the project's results. ... UN Environment recognizes the nine major groups as defined in Agenda 21: Business and Industries, Children & Youth, Farmers, Indigenous People and their

¹⁰ To be addressed by the evaluation (see ToR and Conclusions in Chapter 6)

reduced the possibility of data triangulation (See Section 5.7.1) and narrowed down the contribution to the evaluation (especially in the case of the component "public awareness and participation"). (See more on that also under Section 5.6).

16. The duration of the field-visit (less than five days) proved insufficient to hold all the initially planned meetings (their number had to be reduced) and to perform all the activities with the main stakeholders, i.e. National Executing Agency in particular. Another constraint was the stakeholders' limited availability as the Project had already been closed since several months at the time of the field mission.

2.2 Methods and tools for data collection and analysis

- 17. Overall, the Terms of Reference (TOR) of the Evaluation and the methodological tools and formats provided by the UN Environment Evaluation Office have proved to be a robust methodological framework for the evaluation exercise, facilitating the systematisation and presentation of the evaluation findings.
- 18. The Desk Review of all project documents and reports uploaded to the e-platform ANUBIS¹² (an online information management system for UN Environment's Biosafety portfolio) has been most helpful in gathering relevant information regarding the technical and financial performance of the Project.
- 19. The Inception phase of the Evaluation permitted a preliminary assessment of the Project and culminated in the delivery of an Inception Report, which laid the foundation for the main report with regard to some essential points by including:
 - a thorough Review of the Project Design Quality (PDQ) that highlighted strong and weak points of the Project Design (see Section 5.2);
 - the Stakeholders Analysis outlining key-players' expected roles and responsibilities (as identified in the ProDoc) against which institutional capacity could be assessed (see Section 3.3);
 - the construction of the Theory of Change (TOC) of the project (see Chapter
 4) which provided the "red thread" and the core "interpretative guide" for the evaluation exercise:

Communities, Local Authorities, NGO's, the Scientific & Technological Community, Women, Workers and Trade Unions. Stakeholders' needs and interests should be disaggregated by gender (especially focusing on differentiated intervention strategies to address the needs of women and children) and representation (e.g. marginalised groups, indigenous peoples etc.)throughout the evaluationstakeholder involvement needs to be based on a sound analysis of a project's stakeholders and the roles they play in bringing about change or the ways in which they are affected by change".

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- a "Revised Final Output Summary", aiming at assessing Outputs' relevance and effectiveness in the pathway to Outcomes and Impact.
- 20. Exchange with the Evaluation Manager of the UN Environment Evaluation Office and with the UN Environment Task Manager was regular and most useful in clarifying methodological and technical issues regarding the evaluation process as well as the project implementation and general context.
- 21. Several tools prepared in advance by the Consultant had been shared both with the NEA and the PCU before the field mission started and discussed with them and other relevant stakeholders during the country visit. The tools include:
 - the TOC with diagrams 2 and 3 (Sections 4.2 and 4.3);
 - a Revised Final Project Outputs Summary (annexed to the Project Terminal Report) and integrated with the consultant's questions and comments, aimed at triggering a critical analysis of Outputs (see Annex VI)
 - the "Stakeholders' Matrix"¹³ that describes for each key stakeholder the
 interest and power over project implementation and results and 2)
 institutional roles and responsibilities / mandate in relation to biosafety. The
 exercise also aimed at validating the final list of relevant stakeholders. (see
 Annex IV)
 - Financial Tables (See Section 3.6 and Annex IV).
- 22. The ANUBIS¹⁴ (an online information management system for UN Environment's Biosafety portfolio) platform demonstrated to be a good tool for participatory exercises with PCU, allowing on the spot triangulation of information; e.g. through overview and sample-based reporting "validation", including financial and auditing reports.
- 23. All the proposed methodological tools were validated during the evaluation and proved useful by contributing to critical and analytical thinking as well as to the collection of evidence and triangulation of data. All of them leave room for further improvement, during any future evaluations, both in terms of content and in terms of modalities of implementation and use.

¹³ Based on the UNEP tools "Stakeholder Analysis in the Evaluation Process"

¹⁴ ANUBIS: A New UNEP Biosafety Information System

3 The Project

3.1 The Context

- 24. India has 8.1% of the world's total biodiversity, making it one of the 17 mega diverse countries of the world, and comes second worldwide in terms of farm output. A vast majority of its people depend directly on agriculture and forestry for their livelihood and food security. Yet, stagnation in the per unit productivity in food grains has been observed and the annual per capita availability is declining. The National Food Security Act or Right to Food Act, 2013, envisages the provision of subsidized food grains to almost 2/3 of the population. Consequently, to address food production, new technological interventions are required including biotechnology, a field in which India has conducted important Research and Development (R&D) activities for the two last decades. Biotechnology has been considered a "sunrise sector" and economic key driving force for the country. However, the impact on the environment and human health of the release of Living Modified Organisms (LMOs) as well as the sustainable use of biodiversity continue to be a primary concern.
- 25. Biosafety law and policies are well developed in India, including, the Environmental Protection Act (1986), the Biosafety Rules¹⁵ (1989), and the ratification of the Cartagena Protocol on Biosafety (CPB, 2003). By 2007, a constellation of legislations related to biosafety regulations was developed. However, at the start of the project, there was an urgent need to strengthen the regulatory procedures and enforcement mechanisms regarding the transboundary movement of LMOs, since India already had several LMOs close to commercialization and the country was expected to soon become both an exporter and an importer of LMOs. In this context, the Government of India aims to ensure that biotechnology Research and Development (R&D) is guided by a process of prudent decision making that safeguards environment and human health.
- 26. It is worth mentioning that GMO cotton (Bt-cotton) cultivation increased to approximately 11.6 million hectares, which is equivalent to 90% of the total area under cotton cultivation¹⁶ in India. Several GMO crops including vegetables, pigeon pea and mustard are under various stages of development and field testing as also confirmed by a survey¹⁷ conducted under Phase II. No new regulations have been developed since 2009, however, the regulatory system has been strengthened through various guidelines and notifications being put in place from time to time by the Government.

^{15 &}quot;Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells" In jargon "Rules 1989". This report will make use of the popular name; i.e. "Rules 1989".

¹⁶ www.geacindia.gov.in (ref: FAC about GE plants, 2015).

^{17 &}quot;Genetically Engineered Plants in the Product Development Pipeline in India: Results from a Survey"; around 100 crops in advanced pipeline.

27. The project builds on the previous Phase I (GEF-World Bank Biosafety Demonstration Project), completed in 2007. It aims at strengthening India's National Biosafety Framework (NBF) envisaged as a Governance System / Coordination Mechanism that encompasses policy, legal, administrative and technical instruments as well as management arrangements. This is intended to make the country fully comply with CPB requirements regarding safe transfer, handling and use of Living Modified Organisms (LMOs) from modern biotechnology, and to ensure the inclusive, equitable and sustainable character of the process.

3.2 Objectives and components

- 28. According to the ProDoc, the **overarching goal** of this project was to assist Government of India, as Party to the CPB, in building capacity to implement the Protocol through activities at the national, sub regional and regional levels.
- 29. The **project objective** was "to strengthen the biosafety management system in India with special emphasis on Risk Assessment and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure adequate protection of human health and biodiversity from any potential harm arising from all LMO-related activities".
- 30. According to the ProDoc, the Project encompassed 8 components (See table 1 below). The objectives and achievements under Components 1 to 5 were directly related to the institutional and human resources capacity building for the effective implementation of the NBF mechanism; namely:
 - Component 1, involving a stocktaking assessment to assist in priority setting
 of project activities and envisaging one (1) main outcome and five (5) related
 outputs;
 - Component 2, aiming at strengthening the legal and regulatory framework and involving three (3) outcomes and eleven (11) outputs;
 - Component 3, regarding institutional capacities' enhancement and foreseeing one (1) outcome and four (4) outputs;
 - Component 4 addressing human resources' development and envisaging two
 (2) outcomes and three (3) outputs; and
 - Component 5 dealing with raising public awareness and envisaging one (1) outcome and six (6) outputs.
 - Component 6 and 7 concern the Project management and Project Monitoring and Evaluation, and eventually,
 - Component 8 dealing with the promotion of regional cooperation, networking and sharing of experience.

Table 1 Components and Outcomes of the Project 18

	Project Components	Expected Outcomes
1	Stocktaking assessment	1.1) Updated information is consolidated to guide the planning of specific activities under this project
2	Strengthening Regulatory and Legal Framework 2A) Risk Assessment and Management 2B) Socio-economic Assessment 2C) Handling, transport, packaging and identification of LMOs	2A.1) A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk. 2B.1) Socio-economic assessment is considered. 2C.1) A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB
3	Strengthening Institutional Capacity	3.1) Institutions and staff capacity is enhanced for LMO detection
4	Human Resource Development	4.1) Human resource is developed for strategic areas such as risk evaluation4.2) Enforcement mechanism at the ports of entry is strengthened with trained staff.
5	Information and Dissemination for Enhancing Public Awareness	5.1) Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced
6	Project Management	Not considered in the Logframe
7	Project Monitoring and Evaluation	Not considered in the Logframe
8	Regional Networking and cooperation	8.1) Institutional mechanism for sharing information through networking and regional cooperation established

3.3 Stakeholders

- 31. The ProDoc deals with stakeholders under Section 2 (point 2.5, "stakeholders' mapping and analysis") and Section 5 ("Stakeholders participation" including "Table 4: Major stakeholders and their participation"), identifying five (5) major groups; namely: adecision-makers / policy makers; b- scientists / technical experts (including researchers and technicians from public and private sectors and academic institutions); c- legal experts and economists; d- enforcement officials; e- the last "amalgam" group including interest groups, teachers, students, mass media and extension workers.
- 32. The ProDoc does not include elements for analysis of the levels of influence, interest and expectations of each stakeholder group over Project's outcomes, or their diverging or conflicting interests. The ProDoc does not make due distinction between

¹⁸ As defined in the Project Document Project Logical Framework (see Appendix 4: Results Framework).

those directly affecting the Project's results (public actors, virtually almost all stakeholders identified in the ProDoc) and the ultimate potential beneficiaries (such as small and commercial farmers, consumers, the public in general). Stakeholders were not classified in terms of their rights and obligations i.e. rights-holders (such as small and commercial farmers, consumers) and the duty-bearers (holding responsibilities over biosafety and biotechnology Public Action in India). Possible vulnerable groups were not identified and included. Indigenous peoples and local communities were marginally encompassed as stakeholders (interest groups).

- 33. The ProDoc is also gender blind. The Gender approach is not taken when biosafety and biotechnology are discussed in the ProDoc. It does not question men's and women's different roles, stakes and / or power over biosafety, for example, specific roles of women / men in natural resources preservation and in household food security. The same applies to the biotechnology sector, for example the gender-uneven access to production inputs and to the market is not discussed.
- 34. As referred to in Section 5.2 (Project Design), in terms of stakeholders mapping and analysis, the assessment of the complexity of the situation was generic, which was found to be a relevant weakness, considering the multiple interests at stake and the particularly high number of institutions involved. Nevertheless, during implementation, the Project did manage to effectively engage an important number of relevant stakeholders in delivering the foreseen Outputs (see Section 5.4.1), such as for example, the involvement of both male and female participants in various workshops and trainings. The project also reports that India had previously undertaken a training needs assessment under Phase I of the World Bank project which was used to provide guidance for stakeholder mapping.
- 35. The key, legally bound, institutional stakeholders with a clear mandate in biosafety as defined by the "Rules 1989" are outlined in Box 1 below. They comprise of six Ministries / Departments and six Competent Authorities. The Ministry of Environment, Forest and Climate Change (MoEF&CC) as well as the Department of Biotechnology of Ministry of Science and Technology (DBT/MS&T) are nodal institutions, the former in terms of implementing the Rules 1989 and the Cartagena Protocol on Biosafety and the latter in terms of promoting biotechnology programmes²⁰. The Genetic Committee²¹ (GEAC) Engineering Appraisal is chaired by the Secretary/Additional Secretary of MoEF&CC and co-chaired by a representative from the

¹⁹ Notified under the Environment (Protection) Act, 1986

²⁰ It is also worth noting that, based on the National Biotechnology Development Strategy, 2007, at the time of drafting of the Project Phase II, DBT was in charge for promoting the setup of the National Biotechnology Regulatory Authority (NBRA). However, the NBRA Bill has not been approved by the Parliament (see more under Section 5.8 (Intuitional Sustainability).

²¹ Former Genetic Engineering Approval Committee see www.geacindia.gov.in

Department of Biotechnology (DBT). The committee meets once a month to review applications.

Box 1 Responsive regulatory regime in India: Key Stakeholders & Authorities / Mandate ²²

The core institutional stakeholders are defined into Environment (Protection) Act, 1986 and the Rules, 1989, attributing clear mandate to six Ministries / Departments (see annex, diagram) and six Competent Authorities; namely:

A- Ministries:

- 1. Ministry of Environment, Forest and Climate Change
 - a. Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of GMOs/LMOs
 - b. Nodal agency for implementing Rules, 1989 and the Cartagena Protocol on Biosafety
- 2. Department of Biotechnology (Ministry of Science & Technology)
 - a. Nodal department for promoting biotechnology programs
 - b. Provides scientific support in implementation of biosafety regulations
 - c. Provide services in areas of research, infrastructure, generation of human resource
- 3. Ministry of Agriculture
 - a. Policies aimed at agriculture growth.
 - b. Indian Council of Agricultural Research (ICAR) responsible for monitoring agronomic benefits of GM technology.
 - c. Monitoring post-release performance of GM crops.
- 4. Ministry of Health and Family Welfare
 - a. Policies aimed at protecting and monitoring human health.
 - Food Safety and Standards Authority of India responsible for regulating genetically engineered foods
- 5. Ministry of Commerce and Industries
 - a. Enhance trade with other countries through export/import policies.
 - b. Nodal agency for implementing DGFT²³ notification on GMOs
- 6. Central Board of Excise and Customs, Department of Revenue, Ministry of Finance
 - a. Enforcement of regulation pertaining to transboundary movement of GMOs/LMOs at point of entry

B- <u>Competent Authorities</u>, under the Rules, 1989, implemented under **a)** the Ministry of Environment Forest & Climate Change; **b)** Ministry of Science & Technology; **c)** Government of Inia and **d)** State Governments:

1.	Advisory:	The Recombinant DNA Advisory Committee	(RDAC)
2.	Approval:	Institutional Biosafety Committee	(IBSC)
3.	Approval:	Review Committee on Genetic Manipulation	(RCGM)
4.	Approval:	Genetic Engineering Appraisal Committee	(GEAC)
5.	Monitoring:	State Biotechnology Coordination Committee	(SBCC)
6.	Monitoring:	District Level Committee	(DLC)

36. The Rules for Manufacture, Use, Import, Export and Storage of hazardous microorganisms, genetically engineered organisms or cells (Rules, 1989) notified under the Environment Protection Act of 1986, provide for regulation of all activities related to GE organisms and products thereof. Six competent authorities are given the mandate of implementing these Rules by the MoEFCC, DBT, MoST and State Governments. In

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²² Source: "Regulatory Framework for Genetically Engineered (GE) Plants in India", (Phase II Capacity Building Project on Biosafety), Ministry of Environment, Forest and Climate Change in association with BCIL, 2015

²³ Directorate General of Foreign Trade

addition to these Rules, there are other Acts, Rules and Policies which are also relevant, and their mandates are clearly specified.

3.4 Project implementation structure and partners

- 37. The National Executing Agency (NEA) is the Ministry of Environment, Forest & Climate Change (MoEF&CC) which is also the Competent National Authority (CNA) for the CPB. The NEA managed the project and took overall responsibility for its implementation by providing scientific, technical, financial, and administrative support, and by working in close cooperation with relevant government agencies, the scientific community and other stakeholders.
- 38. At implementation level, five institutional actors were mandated, namely: **a-** A National Steering Committee (NSC); **b-** A National Project Director (NPD); **c-** A National Project Coordinator (NPC); **d-** A Project Management and Monitoring Committee (PMMC) and **e-** a Project Coordination Unit (PCU), the latter outsourced to a Public-Private company, Biotech Consortium India Limited (BCIL) (See diagram 1, below). The National Steering Committee (NSC) was set-up by the MoEF&CC to guide the process of implementation, including budget approval, and was composed by relevant Ministries Departments. Project Management and Monitoring Committee (PMMC) membership worked with experts and members of the regulatory committees²⁴.

diagram 1 Project implementation Structure and Partners



Institutional Coordination and Support for

²⁴ Regulatory System in India, see box 1.

39. At the level of National Project Coordinator, there were two staff changes between 2012 and 2018. The National Project Director (NPD) position was also covered by two different officials between May 2012 and May 2016 and from June 2016 to October 2017). (See Section 2.2).

40.

3.5 Changes in design during implementation

41. During its lifetime, the Project was granted 5 budget revisions, mainly for reallocation of funds between budget lines. One no-cost extension of 14 months was granted, including the administrative closure of the project. The project ended in July 2017, instead of May 2016. No changes in the Project Design were registered.

3.6 Project financing

42. Table 2 and Table 3 below present the project budget by component, including the estimated vs actual cost, as well as the sources of funds.

Table 2 GEF Budget at design and expenditures by components (August 2017)25

Component/sub-component	Estimated cost at design	Actual Cost	Expenditure ratio (actual/planned)
A. Stocktaking Assessment	55,000	41,396	75.26%
B. Strengthening Regulatory & Legal Framework - Risk Assessment & Management	450,000	458,632	101.91%
- Socio Economic Assessment	150,000	151,574	101.04%
- Handling, Transport, Packaging & Identification of LMO	165,000	155,041	96.96%
C. Strengthening Institutional Capacity	850,000	761,021	89.53%
D. Human Resource Development	360,000	364,908	101.36%
E. Information dissemination for Enhancing Public Awareness	325,000	348,548	107.24%
F. Project coordination & Monitoring Unit	260,000	268,707	103.35%
G. Project Monitoring and Evaluation	45,000	75,450	167.67%
TOTAL	2,660,000 ²⁶	2,625,277	98.7%

Table 3 Co-financing Table

²⁵ Last instalment still due by UN Environment. At the time of the Evaluation 2,542,861.81 USD was disbursed 26 This grand total does not include the sub-budget for "Regional Network" (USD 67,273). Actually, the total GEF budget is USD 2,727,273

	UNEP	own	Gover	nment	Oth	er*	Tot	al	Total
Co financing	Finan	cing							Disbursed
(Type/Source)	(US\$1	,000)	(US\$1	I,000)	(US\$1	,000)	(US\$1	,000)	(US\$1,000)
	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	
- Grants			900	900			900	900	900
- Loans									
- Credits									
Equity									
investments									
– In-kind			5,100	6,343			5,100	6,343	6,343
support									
Other (*)									
Totals			6,000	7,243			6,000	7,243	7,243

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

4 Theory of Change

4.1 Overview

- 43. This sub-chapter includes an analysis of the intervention logic. The proposed conceptual approach of the Theory of Change (TOC) complies with the constitutive components / building blocks of a fully operational National Biosafety Framework²⁷, as outlined below (see Box 2), corresponding to what will herein be referred as the "standard conceptual framework"²⁸.
- 44. It is also to be noticed that the Evaluation fully fosters the view that the standard conceptual framework as well as the TOC are conventions, i.e. constructs or attempts of interpretative models which stakeholders agree upon through a knowledge-building consultative process, in order to facilitate common action, based on common language

²⁷ The term Fully Operational Nacional Biosafety Framework (NBF) implies not only an already existing NBF but also a sufficiently strengthened one in order to be operational along all its inter-dependent and mutually reinforced components / pillars. The term "Fully Operational" is used for highlighting the idea of gradual and progressive development of the systems, which is an approach largely fostered by main stakeholders worldwide. (e.g. K. Vijay Raghavan, Secretary of Government of India, Ministry of Science & Technology, Department of Biotechnology, states in the Preface of "Risk Analysis Framework", 2016, "Due to evolving nature of science of safety assessment and GM technology developments, the regulatory system has also been dynamic and flexible to adopt global best practices from time to time"). Based on Decision of MOP BS-III/3, the term "Fully Operational" implies a flexible, gradual, progressive and adaptive (case-by-case), country-fitted and country-driven approach, where "...key elements are meant to be considered in a flexible manner, taking into account the different situations, capabilities and stages of development in each country" (https://www.cbd.int/kb/record/decision/11059?RecordType=decision&Subject=CPB). The term "operational" is widely used in the Strategic Plan 2011 – 2020 (BS-V/16, Annex I).

http://staging.unep.org/biosafety/Documents/Drafting_the_NBF_Formulation_of_the_regulatory_regime.pdf

and minimally shared understanding²⁹. (See also Section 5.4.2, Achievement of Outcomes, relevant to the issue § 92).

Box 2 Implementation of National Biosafety Frameworks ³⁰

Implementation (Phase II) projects aim that, by the end of a project, a country should have:

- i. A <u>workable and transparent regulatory regime</u> consisting of: **a** enabling legislation; **b** implementing regulations and **c** complementing guidelines; and
- ii. <u>Implementing systems</u> for: a- handling notifications or requests for approvals (including systems for administrative processing, risk assessment and decision making), b- follow-up (enforcement and monitoring); c- public information and public participation.
- 45. The reconstruction of the TOC of the Project took into account the following aspects:
 - formulation of the Project Impact and of the Main Project Outcome;
 - the main Components of the Project and correspondent Outcomes, in the ProDoc (as concisely exposed under Section 3.2. Table 1: Components and Outcomes).
 - the standard conceptual framework of the National Biosafety Framework (NBF), which usually comprises five main components: a- A Government policy on biosafety; b- A regulatory regime for biosafety; c- A system to handle notifications or requests for authorisations; d- Systems for 'follow up' such as enforcement and monitoring for environmental effects; e-Mechanisms for public awareness, education and participation.
- 46. As elaborated in Section 5.2, the Project Design did not fully succeed in drawing the hierarchy and causal pathways of the envisaged achievements, therefore, at the evaluation stage some restructuring of the intervention logic was undertaken. Fully respecting the spirit of the Project's envisaged results, the reconstructed TOC

^{29 &}quot;.....the development of a regulatory regime for biosafety is, in many ways, a work in continuous progress. Biotechnology is a rapidly evolving field in which new issues and activities are constantly emerging, and governments have to be able to deal with changes in their national priorities and in public concerns. Therefore, a regulatory regime is a living document constantly reviewed and revised in the light of these changes" (source: same as footnote 28).
30 Based on "UNEP-GEF on Implementation of National Biosafety Frameworks, Guidance towards Implementation of NBFs: Lessons Learned from the UNEP Demonstration Projects", by UNEP-GEF Biosafety Unit, April 2008. Note: globally, Phase I refers to "NBF development" and Phase II to "NBF implementation".

streamlines the Project logframe as shown in Table 4. The TOC is complemented by Diagrams 2 and 3 that re-organise the logframe elements and shape the intervention logic in order to understand the causal pathways from Outputs to Outcomes, and from Outcomes to Impact, as well as the main driving forces and assumptions..

 Table 4 Comparison of Results Framework

Results as stated in the ProDoc Logframe	Results as stated in the reconstructed TOC at Evaluation
	Impact
	Enhanced Conservation and Sustainable Use of Biological Diversity in India
Overall Goal (in the ProDoc)	Intermediate States to Impact
To assist the GoI, as Party to the CPB, to build capacity to implement the CPB through activities at the national, sub regional and regional levels.	(IS 3) Protection of biological diversity against possible adverse effects of LMOs by means of ensuring safe transfer, handling, use and transboundary movement of LMOs, in compliance with Art. 1 of Cartagena Protocol (CPB)
	(IS 2) Improved governance of national / regional biosafety systems based on: Accountability and Liability, Transparency, Rule of law, Equity, Citizens' Participation, in full compliance with CPB and other relevant international obligations.
	(IS 1) LMOs safe intentional release into the environment with emphasis on India's numerous LMOs from its national laboratories"
Objective of the project ³¹ (in the ProDoc)	Main Project Outcome
To strengthen the biosafety management system in India with special emphasis on Risk Assessment and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure that adequate protection of human health and biodiversity from potential harm arising from all LMO-related activities.	Strengthened Management System and fully operational National Biosafety Framework in India
Outcomes (in the Logframe)	Direct Outcomes
Updated information is consolidated to guide the planning of scientific activities under this project	

³¹ Appendix 4, Project Results Framework and ProDoc, § 45

Results as stated in the ProDoc Logframe	Results as stated in the reconstructed TOC at Evaluation
2A.1) A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk.	Outcome 1: Responsive regulatory regime, including implementing Regulations and Guidelines
2B.1) Socio-economic assessment is considered. 2C.1) A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB.	Outcome 2: Responsive Administrative system for handling applications, Risk Assessment and Risk Management, including Socio-Economic Considerations
3.1) Institutions and staff capacity is enhanced for LMO detection.	Outcome 3: Enforcement Monitoring and inspection system for LMOs strengthened
4.1) Human resource is developed for strategic areas such as risk evaluation.	
4.2) Enforcement mechanism at the ports of entry is strengthened with trained staff.	
5.1) Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced	Outcome 4: Functional systems for public awareness, education and participation
Outputs ³²	Outputs
1.1.1 Baseline information to evaluate potential changes due to introduction of LMOs is compiled and updated.	Output 1: A baseline established (Stocktaking Report) on current status of modern biotechnology and biosafety system
1.1.2 Existing documentation is reviewed for compliance between the information needed under the prevailing regulatory system and the CPB.	
1.1.3 A survey is conducted to identify the public institutions, facilities and laboratories to be upgrated to be national referral laboratory.	
1.1.4 An assessment is carried out on the long term funding needed for Gol.	
1.1.5 National consultation with all stakeholders and parties is carried to discuss results from this needs assessment study.	
2A 1.2 Crop-specific biology and ecology document is developed to assist dossier preparation.	Output 2: Guidelines for RA in 4 selected crops prepared (for specific traits) (2A.1.4 4 crops mentioned in 2A.1.2., 2A.1.3.)

³² In the ProDoc, a number of Outputs are but Activities (e.g. 2A 1.3 "Baseline data on presence of wild relatives is gathered for better risk management of LMOs"). However, in this comparative table, the first column lists the Outputs as identified in the ProDoc, hence, Outputs and Activities are indiscriminately listed.

Results as stated in the ProDoc Logframe	Results as stated in the reconstructed TOC at Evaluation
2A 1.3 Baseline data on presence of wild relatives is gathered for better risk management of LMOs.	Output 3: Review of existing RA and RM guidelines (2A.1.1)
2A 1.1 Existing RA and RM procedures and guidelines are reviewed to confirm whether India is compliant with CPB obligations.	Output 4: Indicators defined for gene flow and impact on non-target organisms in selected areas (2A.1.6)
2A 1.6 Indicators to measure gene flow and impact on non-targets are developed to assist RA and RM.	
2B 1.1 Questionnaire is developed for conducting a socio-economic survey.	Output 5: Guidelines and methodologies in place for socio-economic assessment of 3 specific
2B 1.2 Methodologies and guidelines are developed for socio-economic assessment of GM crops apart from Bt cotton.	traits (2B.1.1 + 2B 1.2) Output 6: Guidelines in place for risk-benefit analysis (2B.1.3)
2B 1.3 Guidelines are developed for risk benefit analysis.	Output 7: A national certification and testing system in place (2C. 1.2.)
2C 1.2 To identify best practices suitable for India, a review is undertaken for strategies.	
2A 1.5 LMOs are monitored by regulatory agencies after environment release.	Output 8: Post-release monitoring mechanism in place (2A.1.5)
2C 1.1 A feasibility study is carried out on measures to be taken for putting in place an "identity preservation system" for handling of	Output 9: feasibility study on Identity Preservation (IP) of 3 crops (2C.1.1)
LMOs in agriculture. 4.2 Enforcement mechanism at the port of entry is strengthened with trained staff.	Output 10: enforcement mechanisms strengthened at the ports of entry (4.2 + 4.2.1) through training
4.2.1 Training modules / manuals are prepared for training of custom and plant quarantine officials for enhanced enforcement at the port entry.	
3.1 Institutions and staff capacity is enhanced for LMO detection.	Output 11: A network of 2-3 laboratories in place and operational for LMO detection (3.1 + 3.1.2) (encompassing Human Resources development)
3.1.1 A feasibility study is carried out on public private partnership (PPP) for LMO detection.	
3.1.2 Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMO in agriculture.	
3.1.4 Staff, irrespective of gender, is trained for LMO detection and maintenance of laboratory.	Output 12: Methodology and procedure for GMO detection, developed and adopted (3.1.3)
3.1.3 Methodology and procedures are developed for LMO detection.	

Results as stated in the ProDoc Logframe	Results as stated in the reconstructed TOC at Evaluation
5.1.1 Innovative outreach programs are developed for risk communication both through print and electronic media.	Output 13: Outreach material in 8 languages (5.1.1)
5.1.2 Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national agencies.	Output 14: Educational programmes (5.1.2)
5.1.3 Primers / brochures / booklets / FAQs and glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society, etc.	Output 15: Brochures, booklets, etc. (5.1.3)
5.1.4 A mechanism is established to communicate regulatory decisions on LMOs to the public.	Output 16: Regular/timely upload of decision to
5.1.5 Biosafety newsletters are published regularly and distributed.	BCH and other national websites (5.1.4) Output 17: quarterly newsletter (5.1.5)
5.1.6 National, regional and international workshops are organized for targeted audiences.	
	Output 18: workshops (5.1.6)

4.2 The causal logic from Outputs to Outcome

- 47. Based on the causal logic of the project from the project documents (to include, the Logical Framework (Results Framework), the "Key deliverables and milestones" and the Project Workplan), the following Diagram 2 maps out the lower part of the reconstructed Theory of Change (TOC), from Outputs to the Main Outcome, i.e. "Strengthened Management System and fully operational National Biosafety Framework in India".
- 48. Project's Outputs have been grouped under five components / groups, the first being a preliminary Output "baseline assessment" (stocktaking) to be delivered in the first eight months of the Project. The other four groups evolve around the building-blocks underpinning an effective NBF. Each group of Outputs supports a Direct Outcome that represents a change expected to be achieved within a specific component of the NBF.
- 49. Institutional Capacity Building³³ and Human Resources Development³⁴ evolve around and refer to the key structural requirements for an effective NBF. The TOC considers Human Resources Development at the Output level, as it is necessary to underpin the achievement of Direct Outcomes. On the other hand, Institutional Capacity Building is closely related to the Main Outcome as stated in the reconstructed TOC. 4).

³³ Referring to Component III of the ProDoc (Strengthening Institutional Capacity)

³⁴ Referring to the component IV of the ProDoc.

- All the foreseen outputs were taken on board in the TOC, with few exceptions in the case of those outputs that were found to be identical to activities (e.g. Output 2A. 1.3 "Baseline data on presence of wild relatives is gathered for better risk management of LMOs" or 2B 1.1 "Questionnaire is developed for conducting a socio-economic survey").
- 51. In the TOC, a number of <u>Drivers</u>³⁵ are considered, specific to each level of results. For the delivery of all Project's Outputs, "Building on experience gained in Phase I by the National Executing Agency" has been considered as a <u>key Driver</u>. This is related to the "institutional memory" and the existence of appropriate mechanisms for the retention of experience and related achievements.
- 52. Moving from the Outputs level to the Direct Outcomes, four other relevant <u>Drivers</u> have been identified. It should be noted that all of them are explicit elements of the Project even if they are not identified as Drivers within the ProDoc.
- 53. In relation to Direct Outcome 3, "Enforcement Monitoring and inspection system for LMOs established", two main <u>Drivers</u> were considered; namely:
 - Staff attrition mitigated through training a core mass of qualified human resources;
 - ii. Existing enforcement mechanisms are built upon.
- 54. In relation to the Direct Outcome 4, "Functional systems for public awareness, education and participation", the following two <u>Drivers</u> were considered relevant, namely:
 - iii. Appropriate participatory methods are identified for Risk Communication throughout the decision-making process;
 - iv. The Biosafety Clearing House is regularly updated.
- 55. Two main <u>Assumptions³⁶</u> are identified along the pathway from Outputs to Direct Outcomes; namely: **a-** affirmation of a "a strong political will towards having in place an effective regulatory system" (this was identified in the ProDoc as a risk); and **b-** "strong coordination and clear definition of tasks and responsibilities, particularly between the Competent National Authority (CNA) and the Department of Biotechnology of Ministry of

³⁵ Drivers: external conditions necessary for project results to lead to next-level results, over which the project has a certain level of control. Source, UN Environment Evaluation Office https://www.unenvironment.org/about-un-environment/evaluation-approach/theory-change

³⁶ Assumptions: external conditions necessary for project results to lead to next-level results, over which the project has no control https://www.unenvironment.org/about-un-environment/evaluation/our-evaluation-approach/theory-change

Science and Technology (DBT/MS&T) 37 - considering that these are two nodal institutions in the Indian Regulatory System, the former in terms of implementation of the Biosafety Rules 1989 and the CPB, and the latter in terms of promoting biotechnology programmes.

4.3 The pathway from Outcome to Impact

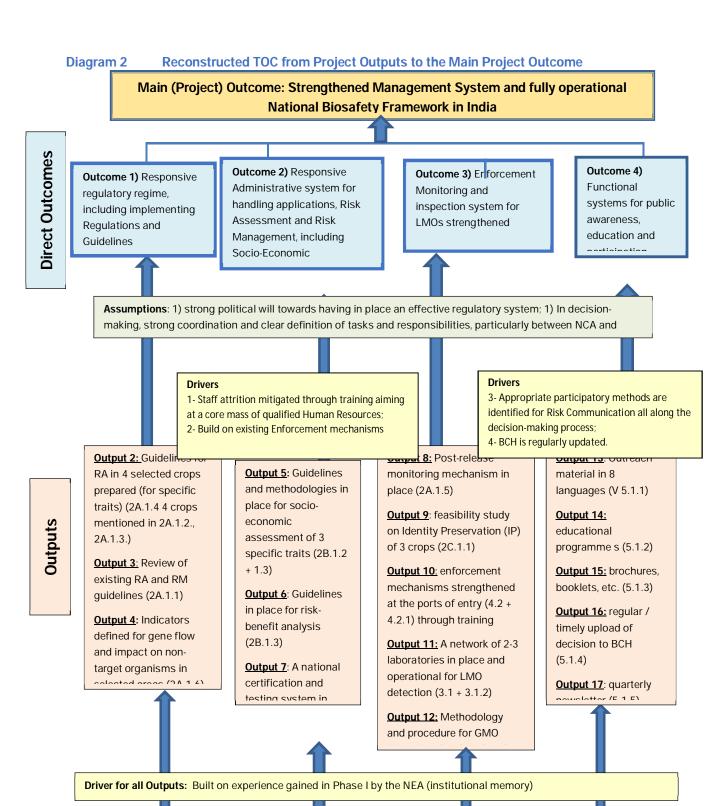
- 56. The intended Impact of the project is the Global Environmental Benefit (GEB) to which it contributes, i.e. "enhanced conservation and sustainable use of biological diversity in India". The pathway from the Main Project Outcome to the intended Impact is not a straightforward process. Transitional conditions (referred to in the TOC as 'Intermediate States') should be fulfilled, as shown in Diagram 3. Three main Intermediate States (I.S.) were identified.
- 57. <u>Intermediate State 1</u>, regarding "LMOs' safe intentional release into the environment with emphasis on India's numerous LMOs from its national laboratories", implies an improved regulatory regime and effective implementing systems, including enhanced quality information and transparency. The underlying <u>assumption</u> is that NBF still has the financial resources (National Budget allocation) and CNA ensures NBF coordination in full harmonisation with the Department of Biotechnology (DBT). Key <u>drivers</u> at that stage are: a critical mass of human resources is in place; quality information is available and flowing into BCH; and last but not least, there is affirmed participation of stakeholders and general public.
- 58. <u>Intermediate State 2</u> is "Improved Governance of National / Regional Biosafety systems based upon: Rule of Law Compliance, Accountability and Liability, Equity, Transparency and Citizens' Participation". The underlying <u>assumption is</u> that there is sustained political goodwill towards having in place a stronger and more effective regulatory system. This should be reflected in the development of a National Action Plan to streamline national policy on Biosafety into government plans and resource mobilisation strategies. The main <u>drivers</u> at that stage will be effective forms of stakeholders' participation (in planning, decision making and funding) which are conducive for open and transparent information flows; BCH is regularly and meaningfully updated; and negotiation processes at different levels are open and transparent.
- 59. Intermediate State 3 (I.S. 3) refers to the objective of the Protocol itself, as stated in its art. 1. Political will and negotiations, also at regional and international levels, will still represent a strong <u>assumption</u>, while the <u>driver</u> to be sustained is the capacity of the

21

³⁷ This is a cross-cutting Assumption that is particularly relevant to the decision-making process / Direct Outcome two, "Responsive systems of handling notifications or requests for approval, including Administrative processing, Risk Assessment and Decision-making systems".

CNA to continuously update its decision-making mechanisms based on rigorous Risk Assessment and Risk Management best practices.

60. Under the assumption that the NBF is in place and fully functional, and that approvals for large scale deployment of GMOs are based on internationally followed Risk Assessment (RA) and Risk Management (RM) principles and methods, the Project Impact (Enhanced Conservation and Sustainable Use of Biological Diversity in India) could be achieved.



IMPACT

Enhanced conservation and sustainable use of biological diversity



ASSUMPTIONS: The NBF is in place and fully functional. Approvals for large scale deployment of GMOs are based on internationally followed Risk Assessment (RA) and Risk Management (RM) principles and methods

Intermediate State 3: Protection of biological diversity against possible adverse effects of LMOs by means of ensuring safe transfer, handling, use and transboundary movement of LMOs.. in compliance with **art. 1 of Cartagena Protocol (CPB)**

DRIVERS: The capacity of the CNA to continuously update its decision-making mechanisms based on rigorous Risk Assessment and Risk Management best practices

ASSUMPTIONS: Political will, enforcement of legislation and regulations, regional cooperation, international commitment. Financial Resources flow is consolidated

Intermediate State 2: Improved **governance** of national / regional biosafety systems based upon: Rule of law and compliance, Accountability and Liability, Equity, Transparency, Citizens' Participation

DRIVERS: Effective forms of stakeholders' participation (in planning, decision making and funding). BCH is regularly and meaningfully updated. Negotiation processes at different levels are open and transparent.

ASSUMPTIONS: Political will of the Government. A National Action Plan is developed to streamline national policy on Biosafety into government plans. An effective resource mobilisation strategy in place.

Intermediate State 1: "LMOs' **safe intentional release** into the environment with emphasis on India's numerous LMOs from its national laboratories"

DRIVERS:

Human Resources critical mass in place. Quality information available and flowing into BCH.

Stakeholders and public participation



ASSUMPTION: NBF still has the financial resources. National Budget Allocation CNA ensures NBF coordination in full harmonisation with DBT / Dep. Of Biotechnology.

Main (Project) Outcome: Strengthened Management System and fully operational National Biosafety Framework in India

5 Evaluation Findings

61. Complying with the UN Environment Evaluation Office requirements and guidelines, in this chapter, the Evaluation findings are exposed, discussed and consequently rated against a set of criteria. Rating uses a six-point scale, i.e. Highly Satisfactory (6), Satisfactory (5), Moderately Satisfactory (4), Moderately Unsatisfactory (3), Unsatisfactory (2), Highly Unsatisfactory (1).

5.1 Strategic Relevance

5.1.1 Alignment to the UN Environment Medium Term Strategy (MTS) and Programme of Work (POW)

62. The Project crosses over two UN Environment Medium-Term Strategy periods (2010-2013 and 2014-2017) and three Biennial Programmes of Work, i.e. 2012-2013, 2014-2015 and 2016-2017, of the Sub-Programme Environmental Governance. Table 5 here below provides a summarised outline of the contribution of the Project to the Expected Accomplishment (EA) of the Environmental Governance Sub-programme in the two Medium-term Strategies.

Table 5 Contribution of the Project to the Medium-Term Strategy (MTS)

Expected Accomplishment (EA)	Contribution of the Project
MTS 2010-2013, Sub-programme Environmental Governance, EA(b): States increasingly implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions	 Overall support to the implementation of the NBF Biosafety Guidelines
MTS 2014-2017, Sub-programme Environmental Governance, EA2: 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;	 Overall support to the implementation of the NBF Biosafety Guidelines Capacity Building in Risk Assessment and Management Public Awareness and Information Biosafety Clearing-House Mechanism of India linked to BCH and updated Establishment of four (4) national referral laboratories for detection of GMOs

5.1.2 Alignment to UN Environment /GEF Strategic Priorities

63. The project is a Full-Size Project (FSP) financed through GEF-4 mechanism and belongs to GEF Biodiversity Focal Area. Under GEF-4, Strategic Objective 3, it is relevant

to GEF Strategic Programme 6 (BD-SP6): Building Capacity for the Implementation of the Cartagena Protocol on Biosafety³⁸. Given its focus on Capacity Building, the Project is aligned with Bali Strategic Plan (BSP). The project was 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 guidelines, and compliance with obligations under Multilateral Environmental Agreements. The Project was gender neutral in its formulation as discussed in Chapter 3.3 (stakeholders) and 5.2 (project design).

5.1.3 Relevance to Regional, Sub-regional and National Environmental Priorities

64. The Project fostered a regional and sub-regional approach to Biosafety starting with its design (project component on regional networking and cooperation). The participation of Indian experts in several activities within the Asia Region was supported and regional workshops were promoted. The annual meeting of the teams of the Biosafety UN Environment / GEF Projects at regional level was also been instrumental in enhancing the regional dimension.

5.1.4 Complementarity with Existing Interventions

- 65. As described in Chapter 3.1 (Context), the Project was designed to complement the previous GEF/World Bank Project "Development of the NBF" completed in 2007 and was considered as the Phase II of that project. It builds upon and consolidates the achievements and the institutional network developed in the context of the previous project.
- 66. The National Biosafety Framework has progressively been built through the contribution of several government ministries, universities, research institutions, regulatory agencies and, to a minor extent, the involvement of the private sector and some NGOs. It is also consistent with and relevant to a number of national priorities and plans, as discussed under Chapter 3.1 'Context'. The Project supported the national effort in protecting the country's biodiversity and genetic resources, and was well aligned with national priorities in those areas.
- 67. As a whole, the strategic Relevance of the Project can be rated as **Highly Satisfactory.**

5.2 Quality of Project Design

68. The assessment of the quality of the of Project Design was done in the Inception Report of the Terminal Evaluation, using the Project Document (ProDoc) and its

³⁸ GEF, "Focal area strategies and strategic programming for gef-4", 2007,

https://www.thegef.org/sites/default/files/documents/GEF4-Focal-Area_strategy.pdf See also MOP / BS-III/3

Decision: Capacity-building, Action Plan,

Appendices³⁹ as a basis. The review applied the "Template for the assessment of the Project Design Quality (PDQ)⁴⁰" which is a tool provided by the Evaluation Office of UN Environment. The Project design reveals strengths and weaknesses. While, in fact, most of the criteria deserve a positive score between Moderately Satisfactory (4) and Satisfactory (5), the most relevant parts of the Project document (with a higher weighting) are weakly developed and in some instances score Moderately Unsatisfactory (3). This is the case with the following assessment criteria: "Project Preparation", "Intended Results and Causality" and "Sustainability". Consequently, the average score for the Project Design is 2.9 and falls under the classification "Moderately Unsatisfactory".

- 69. Strengths in the project design that one may consider include *inter alia*: Project's relevance; institutional and financial arrangements; partnerships; governance; and supervision. The Project was relevant to UN Environment and /GEF strategic priorities, and to Regional, sub-regional and national environmental priorities. There was complementarity with other interventions, building upon a consistent network with relevant international partners (e.g. FAO, SABP, USAID, GTZ). The Project was also explicitly instrumental to the Government of India strategy on biotechnology, which is generally considered a major factor of sustainability for biosafety.
- 70. The ProDoc provided clear and comprehensive elements regarding the institutional arrangements for its implementation and identifies appropriate methods for communication with key stakeholders, including the use of the national BCH. Also, the National Steering Committee was identified as a core institutional channel of communication between the partners. Learning, Communication and Outreach aspects were well developed in the appropriate chapters. Efficiency and cost-effectiveness presented valuable elements of analysis. The Costed M&E Plan in the ProDoc was of relatively good quality, encompassing a clear baseline, mid-term and final targets. The institutional, sectoral and policy context were well described; though any critical approach comes short.
- 71. However, assessing against the standard criteria⁴¹, a number of weaknesses emerge in the criteria: "Preparation", "Intended Results and Causality" and "Sustainability", related to aspects which this report extensively elaborates on also under Chapter 4 (TOC) and Sections 3.3 (Stakeholders), 5.4 (Effectiveness), and 5.8

³⁹ Particularly Appendix 1 (Budget), Appendix 4 (Results Framework), Appendix 5 (Workplan and timetable), Appendix 6 (Key deliverables and benchmarks), Appendix 7 (Costed M&E plan), Appendix 15 (Tracking tools).
40 Tool prepared by UN Evaluation Office, based on a rating system of a six-point scale: Highly Satisfactory (6), Satisfactory (5), Moderately Satisfactory (4), Moderately Unsatisfactory (3), Unsatisfactory (2), Highly Unsatisfactory (1).

⁴¹ Criteria encompassed by the compulsory to the final assessment "Template for the assessment of the Project Design Quality (PDQ)

(Sustainability), as well as Lessons one, two and three. Herein, we succinctly report some key issues.

- 72. Although the ProDoc successfully elaborated on the general problems related to the biosafety / biotechnology sectors, pointing out and explaining the need for a project supporting India's efforts to comply with its obligations under CPB, it did not provide a problem analysis which would discuss "why" India, with such a relevant and pioneering background in the area of Biotechnology and Biosafety, had not implemented and satisfactorily strengthened its NBF at the time of the Project design. Although Risks were outlined⁴², the ProDoc did not critically discuss the underlying dynamics.
- 73. At the time of the Project formulation, use of the Theory of Change approach was not a requirement. Nevertheless, the ProDoc encompassed a logframe which was assessed to determine how well it depicted the hierarchy and causal pathways of the envisaged project results. Some Outcomes were, in a stricter sense, project Outputs (e.g. Outcome 1.1 'Updated information is consolidated to guide the planning of specific activities under this Project'). The majority of the 29 Outputs were documents (products), such as baseline studies, reviews, surveys, assessments, guidelines and manuals, but the causal linkage between these Outputs and the achievement of expected Outcomes was unclear. Indicators were not SMART or were insufficiently defined to support performance monitoring.

74.

75. The ProDoc⁴³ remained generic and vague in terms of stakeholders mapping and analysis, particularly considering the multiple vital interests and the high number of institutions involved⁴⁴. There was no differentiation of stakeholders in terms of their specific interests and influence on the project. The stakeholders analysis was blind to gender as well to the fact that the effects of biotechnology/biosafety will not have the same impact on all societal groups. The Human Rights based sustainable development approach was not taken on board and stakeholders were not differentiated into "rights-holders" and/or "duty- bearers". Vulnerable groups, local communities and indigenous peoples are groups that did not clearly emerge.

⁴² e.g. "Lack of consensus", "changes in priorities", "overlapping mandates"

⁴³ Under Section 2, point 2.5, "stakeholders' mapping and analysis" and Section 5, "Stakeholders participation" 44 e.g. there are "about 400 IBSC, Institutional Biosafety Committees, in various public and private sector organisations in the country".

5.3 Nature of the External Context

76. In the case of the current Project there were no external factors that hampered Project's implementation. Hence, the evaluation deems the external context as **Highly Favourable**.

5.4 Effectiveness

5.4.1 Delivery of Outputs

Preliminary Output: A baseline established (Stock-taking Report) on current status of modern biotechnology and biosafety system

77. An array of meetings was held with prospective project partners and experts for the finalization of the project design, including a two-day inception workshop in June 2012 (51 participants) and a consultative meeting held in May 2012 to discuss, with 50 participants, the stocktaking assessment report. Among the specific products related to this Output include inter alia: **a-** a "Project Brief"; **b-** a "Base Paper" documenting the gaps between the Existing System and the Country Obligations under Articles 8, 10 and 18(2) of CPB; **c-** the results from a survey on "Genetically Engineered Plants in the Product Development Pipeline in India".

Output 2: Guidelines for Risk Analysis in 4 selected crops prepared (for specific traits);

Output 3: Review of existing Risk Assessment and Risk Management guidelines;

Output 4: Indicators defined for gene flow and impact on non-target organisms in selected areas

Related to <u>Immediate Outcome 1: Responsive regulatory regime, including implementing Regulations and Guidelines</u>

- 78. All above Outputs were delivered, and in some cases, results exceeded the targets. For instance, eight instead of four crop specific biology documents were prepared (on Tomato, Potato, Pigeon pea, Chickpea, Papaya, Mustard, Sorghum and Rubber) and published, and baseline data on the presence of wild relatives were included in eight crop specific biology documents, instead of two crops target. Worth noting are: **a-** a report on "Review of Conformity of India's Regulatory System for GE Plants with the CPB"; **b-** a resource document on "Multi-country comparison of information and data requirements for the Environmental Risk Assessment (ERA) of GE Plants"; and **c-** the resource document on "Safety Assessment of Genetically Engineered Plants containing Stacked Traits".
- 79. A milestone achievement of the Project was the delivery of the "Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered Plants", 2016, composed of three documents; namely: **a-** the Guidelines for Environmental Risk

Assessment of GE plants; **b-** the Risk Analysis Framework; and **c-** the Stakeholders Guide prepared through a consultative approach and accepted and currently used by the Genetic Engineering Appraisal Committee / GEAC⁴⁵, the apex regulatory authority in India in decision making.

Output 5: Guidelines and methodologies in place for socio-economic assessment of 3 specific traits;

Output 6: Guidelines in place for risk-benefit analysis;

Output 7: A national certification and testing system in place

Related to <u>Outcome 2: Responsive Administrative system for handling applications.</u>
<u>Risk Assessment and Risk Management</u>

- 80. The Outputs related to Outcome 2 were partially delivered. A "Resource document on Socio-Economic Considerations of LMOs" was prepared under the lead institution "Research and Information System for Developing Countries" (RIS) and published, including a literature review of Socio-Economic Assessment Studies in India, a guidelines framework, methodologies for Socio-Economic Assessment and Cost Benefits Analysis. However, guidelines and methodologies for specific traits, as envisaged by the ProDoc, were not delivered. Actually, as referred to in the conclusions of the resource document, "the challenge lies in developing comprehensive methodologies for SEA⁴⁶ and in this the report of AHTEG⁴⁷ can be very relevant".
- 81. One may also notice that the preparation of the "Resource Document" triggered a dynamic process involving relevant institutions and resource people both for the preparation and the socialization of the output. Additional relevant products were also delivered, inter alia, an e-application platform instrumental to both decision-making and monitoring (enforcement) process and public confidence building (information, participation and transparency requirements).

Output 8: Post-release monitoring mechanism in place;

Output 9: feasibility study on Identity Preservation (IP) of 3 crops;

Output 10: enforcement mechanisms strengthened at the ports of entry through training;

Output 11: A network of 2-3 laboratories in place and operational for LMO detection;

Output 12: Methodology and procedure for GMO detection, developed and adopted,

⁴⁵ Former Genetic Engineering Approval Committee / GEAC

⁴⁶ Socio Economic Analysis

⁴⁷ Ad Hoc Technical Expert Group

Related to <u>Outcome 3</u>: <u>Enforcement Monitoring and inspection system for LMOs established</u>

- 82. The Outputs related to Outcome 3 were partially delivered. Among the Outputs delivered worth noting are: **a-** a feasibility study for "Implementing an Identity Preservation System for Handling Living Modified Organisms (LMOs) in India"; **b-** a network of four, LMO detection laboratories, two of which were accredited by August 2017, including one referral lab, one in Punjab and one in Hyderabad; **c-** a relevant number of lab qualified staff as well monitoring teams for field trials⁴⁸ and enforcement officials, including customs, 49 which benefited from several training activities.
- 83. Output 8⁵⁰ was not fully delivered. A Manual on "Monitoring of Confined Field Trials (CFTs) of Regulated GE⁵¹ Plants" as well as on "Post release Monitoring of GE Crop plants" were produced, which can be considered a step forward⁵². An online training module on monitoring of CFTs was also developed. In the ProDoc, monitoring reports to GEAC⁵³ are foreseen as "means of verification". Nevertheless, during the lifespan of the Project, decisions on environmental release were not registered⁵⁴. It should be noted that "Post-release monitoring mechanism in place" is not just about the delivery of an output but about the achievement of a more complex change in the system; which is supposed to be underpinned by relevant outputs. It can thus be argued that it is misplaced as just an Output.

Output 13: Outreach material in 8 languages;

Output 14: educational programmes;

Output 15: brochures, booklets, etc.;

Output 16: regular/timely upload of decision to BCH and other national websites;

Output 17: quarterly newsletter;

Output 18: workshops

Related to <u>Outcome 4</u>) <u>Functional system for public awareness education and participation</u>

84. All Outputs related to Outcome 4 were delivered, inter alia: **a**- a "Risk Communication Strategy for LMOs in Agriculture"; **b**- a document on "Capacity Building"

⁴⁸ Two training workshops on monitoring of confined field trials of regulated GE Plants for members of monitoring teams, scientists and extension functionaries

⁴⁹ Twelve training workshops on trans-boundary movement of LMOs for enforcement officials including customs and plant quarantine officials

⁵⁰ Appendix 4: Results Framework (ProDoc); 2A 1.5 LMOs are monitored by regulatory agencies after environment release; Indicator: "Within 30 months effective post release mechanism in place for monitoring of compliance".

⁵¹ Genetically Engineered

⁵² These manuals are tools used on a case by case basis for addressing post release monitoring requirements.

⁵³ Genetic Engineering Approval Committee (currently Genetic Engineering Appraisal Committee)

⁵⁴ in the international BCH only five decisions have been uploaded, being the last one in 2009.

in Communicating Science and Biosafety"; **c-** programs on biosafety broadcast on community radio station 'Apna Radio' and also on regional community radios of five states; **d-** a short animated film explaining the concepts of biosafety; **e-** a Biosafety Resource Kit consisting of five brochures, translated into eight regional languages; **f-** two booklets "Understanding CPB: A Guide" and "Handbook on BCH: An information Platform"; **g-** 20 issues of the quarterly biosafety newsletter published and circulated to over 18,000 stakeholders; **h-** "Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016", approved by GEAC⁵⁵, encompassing "risk communication" as a core strategic component⁵⁶.

- 85. The overall delivery of outputs was high. Based on data triangulation (project reports, documents, consultation, interviews and field observations), targets were met to a satisfactory degree. This may largely be attributed to the executing arrangements, project implementation structures, and choice of project partners.
- 86. The Project Coordination Unit / PCU, ensuring the day-by-day Project management, was outsourced to a Public/Private company, BCIL⁵⁷, with the necessary competences for efficient overall management in the sector of biosafety and biotechnology. BCIL, which had accumulated experience with several projects in this sector, including the previous Phase I, ensured smooth implementation of the activities as well as efficient delivery of services and products, according to the perception of several stakeholders met during the final evaluation.
- 87. The <u>Key Driver</u> for the delivery of all Project's Outputs, was the building upon experience gained in Phase I by the National Executing Agency, as the oversight and day-by-day management was ensured by an actor with experience. However, questions may be raised in relation to the strengthening of the "institutional memory" of NEA, including appropriate mechanisms for the retention of experience and achievements..
- 88. Concluding, the Outputs delivery is rated **Satisfactory**.

5.4.2 Achievement of Outcomes

89. The Evaluation assesses to what extent the actual delivery of the Outputs outlined in previous Section 5.4.1 has produced, or has the potential to produce, in the short - medium term, the institutional changes and systemic effects (Direct Outcomes) conducive to a fully operational National Biosafety Framework in India. On this basis,

⁵⁵ GEAC, Genetic Engineering Appraisal Committee

^{56 &}quot;Risk communication is integral to the processes of risk analysis and involves an interactive dialogue between the Regulatory Agencies and stakeholders to exchange information of mutual interest and to build trust in the Regulatory system by discussing issues and addressing concerns"

⁵⁷ BCIL Biotech Consortium India Limited

this section presents a qualitative analysis and interpretation of the Outcomes achieved, in the light of the reconstructed Theory of Change (TOC), outlined in Diagram 2.

- 90. Triangulation of data underpins the current evaluation judgement, and is based on Project reports and outputs, stakeholders' perception on Outcomes achievement, and the GEF Tracking Tool⁵⁸; the latter encompasses key information structured along the NBF components.
- 91. Interviewed stakeholders' perceptions on the level of the outcome achievements was positive. They acknowledged that significant progress was registered, yet there is still room for improvement in several aspects, particularly concerning the awareness raising, education and participation aspects of the NBF. This component was pointed out by virtually all stakeholders as the major bottleneck of the NBF.
- 92. As explained under Chapter 4, a reshaping of the Project components was necessary to harmonize the Project with the standard construct of a NBF, which corresponds, among others, to the GEF Tracking Tool against which a country reports progress..
- 93. From a methodological standpoint, based on the TOC, the evaluation assumes that the identified Outputs are meant to make a significant contribution to the achievement of the Project's Direct Outcomes. The fact that Outputs delivery is satisfactory implies good probability of progress in the pathways to Outcomes. Indeed, the evaluation confirmed that the four Outputs clusters have significantly contributed to the achievement of the four Direct Outcomes that represent the desirable changes required for the NBF.
- Moving from the Outputs level to the Direct Outcomes, four relevant Drivers were identified. In relation to **Direct Outcome 3** "Enforcement Monitoring and inspection system for LMOs established", two main Drivers were considered and confirmed; namely: **a-** staff attrition mitigated through training aimed at a core mass of qualified human resources; **b-** building on existing enforcement mechanisms. In relation to **Direct Outcome 4** "Functional systems for public awareness, education and participation", the following two Drivers were considered, namely: **c-** appropriate participatory methods are identified for Risk Communication all along the decision-making process; and **d-** BCH is regularly updated. These drivers were partially "activated" during the Project lifespan. BCH is regularly updated with relevant information, but the actual date of the last decision is 2009. Participatory methods as such were not consistently explored. However, significant progress is registered through two major strategic documents

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⁵⁸ Appendix 15, of the ProDoc

related to Risk Communication, envisaging trust building on the NBF, among all stakeholders, including the general public (see Section 5.4.1).

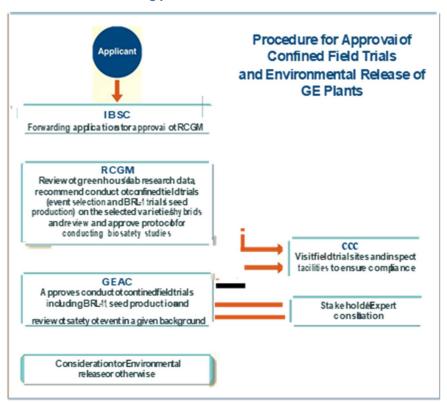
- 95. Two main <u>Assumptions</u>⁵⁹; were identified on the pathway from Outputs to Direct Outcomes; namely: **a-** Affirmation of a "Strong Political Will" which, to the stakeholders' perception, coupled with the averse public opinion, is still the core bottleneck; **b-** "strong coordination and clear definition of tasks and responsibilities, particularly between the Competent National Authority and Department of Biotechnology of Ministry of Science and Technology "; which was not confirmed among the priorities of the main stakeholders during the field visit or sensed by them as a current challenge.
- 96. Direct Outcome 1 was achieved to a satisfactory level, in the perception of the relevant stakeholders who actively participated in the final evaluation exercise. Moreover, in the GEF Tracking Tool, the National team states that "the Regulatory Regime has full legal force, is operational, and linked to the administrative system, i.e. used for decisions". India may claim a well consolidated system that is anchored in the Environment Protection Act, 1986 and the "Rules 1989". Several Guidelines have complemented the Regulatory Regime. The supplementing three Environmental Risk Assessment (ERA documents)⁶⁰ delivered during Phase II provide a comprehensive framework for regulators, is highly appreciated by Indian Authorities, and the preparation and socialization of which triggered a dynamic involvement of relevant institutions and resource people. Some argue that the three Environmental Risk Assessment (ERA) documents provide a compendium of the Risk Assessment and Risk Management (RARM) international standards and best practices, yet, they are not a country-tailored tool, specifically adhering to the Indian context. However, the Evaluation noticed that the relevant achievements under Output 2 (See Section 5.4.1, § 77) regard country-tailored tools (specific to the Indian context, complying with Annex III of the CPB on case-by-case requirements), which are exhaustive and relevant⁶¹.
- 97. **Direct Outcome 2** was achieved to a satisfactory level. As pointed-out in the GEF Tracking Tool, requests have been received, processed, and decisions communicated to BCH.. With regard to the National Budget Allocation, not much was reported during the Project's lifespan, and no reference is made of this in the Project's final report. According to the Project however, a separate budget for biodiversity and biosafety has been allocated in MoEFCC. Box 3 below visualises the procedures for decision-making in India for both import and environmental release.

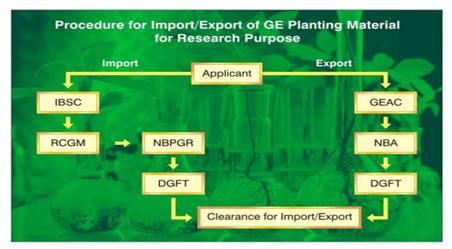
⁵⁹ Both assumptions are already identified in the ProDoc as risks

^{60 &}quot;Environmental Risk Assessment / ERA Guidelines for GE Plants"; "Risk Analysis Framework 2016"; and the Users' Guide

⁶¹ According to TM information, "India is the only country aside of the OECD that processes to develop its own crop specific biology documents tailored to its country specific crops mostly not covered by the OECD Biosafety Programme which is a global reference source".

Box 3 Decision-making process in India⁶²





98. **Direct Outcome 3** "Enforcement Monitoring and inspection system for LMOs established" was achieved to a Moderately Satisfactory level. Nevertheless, a lot of effort was made in this thrust area and several quality knowledge products, training manuals, and guidelines *inter alia* were developed and are expected to underpin a robust follow-up and monitoring system. In the GEF Tracking Tool, on "follow-up and monitoring", the

⁶² Source: "Regulatory Framework for Genetically Engineered (GE) Plants in India", published by Project Phase II, 2015

project met only one out of the four requirements⁶³. As a matter of fact, the last out of five "decisions" taken by the "decision-making system" is dated 2009.

- 99. The network of four laboratories, two of which were accredited by August 2017, including a referral laboratory and two decentralised at State level, is a relevant achievement. However, considering the dimension of the country, its multi-decade experience, as well as India's robust capabilities in biotechnology, this can appear a modest result, as also referred to by some stakeholders.
- 100. As far as Human Resources capacity in relation to the "Enforcement" component of the NBF is concerned, the final evaluation judgement is challenged by the gaps in the capacity building approach. Evidence supplied by the Project's reporting system refers to inputs provided/activities completed (e.g. the number of training sessions and numbers of engaged participants) rather than outputs (e.g. comparing entry to exit profile of participants) and other outcome indicators, the latter requiring a follow-up system to check the capacity improvement in human resources <u>after</u> the training was received, and/or identifying possible gaps and remedies (e.g. follow-up training). Nevertheless, the participants gave a positive assessment of the training, affirming that the training workshops "should be regularly organized from time to time to update the officials". This shortcoming is addressed in Recommendation of the Terminal Evaluation report (section 6.3).
- 101. **Direct Outcome 4,** "Functional systems for public awareness, education and participation", was achieved to a moderately satisfactory level, although, as exposed in the previous Section 5.4.1, significant Activities and Outputs were delivered in order to address this Project thrust area. Also, to the perception of virtually all stakeholders consulted by the evaluator, this constitutes a major bottleneck. According to the GEF tool, information on LMOs was used for awareness-raising campaigns; however, survey results on the levels of public awareness were not available at the time of the evaluation. Participation is underpinned by a "mechanism for public involvement in LMO decision-making" but the evaluation found no evidence of the level of public involvement in LMO decision-making, nor of regular open consultation meetings held on biosafety.
- 102. Although the extent of feedback from targeted groups on biosafety issues⁶⁴ is identified in the ProDoc as an indicator, no further reference is made to this indicator in the Project reporting. A relevant number of training sessions related to Outcome 4 focused on awareness-raising, but the presumed multiplying / snow-ball effect was not measured. The Evaluation did not find any assessment of the effectiveness of the

⁶³ i.e. 1- "Institutional and human capacity in place to follow-up and monitoring, including Risk Management for field-trials and post-release" and 2- "Compliance mechanisms for Risk Management established" in place. Instead, "Liability mechanisms" are not yet in place and "Decisions, risk management plans, and reports on compliance and liability" have not been "posted to the BCH".

⁶⁴ Appendix 4: Results Framework

brochures or other public-awareness material and activities. Hence, any informed judgement on the direct results, deriving from such activities and outputs, is limited. . Such operations obviously require time, staff and budget and these are resources that were not fully encompassed in the service-provision contracts or taken on board during the Project implementation.

- 103. Awareness-raising was intended to promote attitude change of the general public as well as of a number of selected groups (e.g. politicians, judiciary, scientists). Social sciences have demonstrated that one-way, top-down information and social-marketing strategies do not lead to lasting behaviour change. Instead, dialogue a bilateral process, may constitute a more sustainable platform for building consensus, in this case, towards the NBF as a functioning system that guarantees biodiversity and people's health.
- 104. Generally, a more strategic approach to public awareness and participation is still to be consolidated. Awareness-raising and public-opinion concerns are a top priority for all stakeholders, including high-level public administration officials, academics and private sector. The "Risk Communication Strategy for LMOs in Agriculture⁶⁵" (See Section 5.4.1) as part of the "Guidelines for the Environmental Risk Assessment of Genetically Engineered Plants, 2016", approved by Genetic Engineering Appraisal Committee (GEAC), encompasses key elements for a future strategic platform on the subject.
- 105. Despite the high level of performance in Outputs delivery and the progress registered, as discussed in this Section, the Outcomes delivery can be considered partial. As the interviewed stakeholders also indicated, there is still room for further improvement, although good results were achieved during the Project's lifespan. The GEF Tracking Tool also registers a relatively modest progress. Drivers and Assumptions were also partially confirmed. To conclude, the Outcomes delivery is rated **Moderately Satisfactory (MS)**.

5.4.3 Likelihood of impact

106. The Outputs and Outcomes analysed above have to be understood along the whole causal pathway as shown in the TOC, where a "Strengthened Management System and fully operational National Biosafety Framework in India" (Main Outcome) is not the end but a precondition for progressively achieving high international standards in Risk Assessment and Risk Management, consequently ensuring "Enhanced Conservation and Sustainable Use of Biological Diversity in India" (See diagram 3).

^{65 &}quot;Risk communication is integral to the processes of risk analysis and involves an interactive dialogue between the Regulatory Agencies and stakeholders to exchange information of mutual interest and to build trust in the Regulatory system by discussing issues and addressing concerns relating to protecting the health and safety of people and the environment"; "Risks Analysis Framework, 2016", Executive Summary.

- 107. As explained in Section 3.1 (Context), India has a robust, multi-year, experience in biosafety, a strategic vision, vigorous technical / scientific, economic and institutional capabilities. The NBF is in place and it may be expected to move to the next intermediate states, up to the final impact / global environmental benefit.
- 108. With regard to Intermediate State 1, i.e. "LMOs' safe intentional release into the environment with emphasis on India's numerous indigenous LMOs from its national laboratories", only five decisions have been made and uploaded in the BCH since 2009 although the legal framework is ensured through the Regulations 1989, and implementing guidelines are in place.
- 109. The assumptions related to I.S. 1 and I.S. 2 are not yet fully satisfied, i.e. the political will⁶⁶ does not seem sufficient and a National Action Plan that includes budgetary allocations, and a resources-mobilisation strategy is not yet put in place..
- 110. Not much is reported on the Public-Private Partnership although its relevance is acknowledged by virtually all stakeholders consulted. Participation was pointed out as the "weakest link in the chain". Effective forms of stakeholders participation (in planning, decision making and funding), conducive to open and transparent information flows and negotiation processes at different levels, are still to be strengthened and confirmed. However, a contrasting view is held by the project in this regard; they report that the Indian biosafety project has been appreciated in various national and international fora, in terms of the achieved Outcomes and knowledge products that have been produced under each thrust area. The project was actually showcased at the COP-MOP meeting at Cancun, Mexico (2016), and other Parties such as Sri Lanka, Bangladesh, South Africa have requested India to assist them to replicate similar project activities in their countries.
- 111. All in all, the project's intended outcomes were partially achieved at the time of the evaluation, the Assumptions for progress to the Intermediate States identified in the Theory of Change held partially, and the Drivers to support transition to towards Impact were also partially in place. Notwithstanding the robust technical and institutional background of the country, the Impact i.e. "Enhanced Conservation and Sustainable Use of Biological Diversity in India" is rated **Moderately Likely** to be achieved, at least in the medium term.

5.5 Financial Management

112. All the dimensions of the financial management have been very satisfactorily addressed by the Project (see table 7 below). Information about actual project costs and co-financing used have been supplied by the Project (see financial tables in chapter 3.6).

⁶⁶ The Political will, shaped through the political "bargaining" capabilities of the several constituencies, is currently instrumental to the mainstream feeling about GMOs; which is unfavourable, at least concerning food crops.

Actual Project expenditure by operational component was effectively used. Audit reports were timely of quality. Consequently, based on the summary of findings presented in Table 7 below, the overall rating for Financial Management is **Highly Satisfactory**.

Table 6 Financial Management Table

Financial management components:	Rating	Evidence/ Comments	
Questions relating to financial management across the life of the project:			
Compliance with financial requirement and procedures of UN Environment a all funding partners (including procurement rules, financial reporting	nd	Financial reports have been regularly provided (quarterly) and are filed in ANUBIS platform. Inventory reports have been prepared	
and audit reports etc)		and uploaded in ANUBIS platform, including the terminal inventory.	
		Audit Reports have regularly been implemented and yearly uploaded in ANUBIS.	
		Procurement rules have been correctly followed.	
Timeliness of project financial report and audits	s HS	Financial reports and audits have been presented timely	
Quality of project financial reports an audits	nd HS	Up to the standard	
Contact/communication between the PM/TM & FMO	e HS	Through Periodic Progress Reports, Financial Reports, field visits of the Task Manager and constant communication (email). Participation to the annual meetings of the NPCs, problem-solving through exchange with other Projects' Admin. Assistants	
PM/TM & FMO responsiveness to addressing and resolving financial issues	S		
Questions relating to financial information provided during the evaluation:			
Provision of key documents to the evaluator (based on the provision of a below)	A-F HS		
A. An up-to-date 'Co-financing and Project Cost's table	Υ	Delivered	
B. A summary report on the project annual financial expenditures during the life of the project.	t's Y	In ANUBIS and during the country visit (see Chapter 2.2)	

Fina	ncial management components:	Rating	Evidence/ Comments
C.	Financial documents from Mid- Term Evaluation/Review (where appropriate)	n/a	
D.	All relevant project legal agreements (e.g. SSFA, PCA, ICA) — where appropriate	Υ	In ANUBIS and at the Project Office, during the Evaluation
E.	Associated financial reports for legal agreements (where applicable)	n/a	
F.	Copies of any completed audits	Υ	All available in ANUBIS and "validated" by sample during the country visit
Demonstrated knowledge by the PM/TM & FMO of partner financial expenditure		HS	
PM/TM & FMO responsiveness to financial requests during the evaluation process		HS	
Overall rating		HS	

5.6 Efficiency

- 113. The Project implementation did not experience major delays and happened smoothly and efficiently. A no-cost extension of 14 months (including 6-month extension for administrative closure) was granted to allow completion of certain activities.
- 114. The Project built on the pre-existing institutional capacity and institutional memory acquired through the previous Phase I, particularly at the level of the NEA (Ministry of Environment, Forest & Climate Change (MoEF&CC). Actually, the Project built on pre-existing agreements and partnerships among relevant national stakeholders promoting synergies and complementarities.
- 115. Everything considered, Project's Efficiency is rated **Satisfactory (S)**.

5.7 Monitoring and Reporting

5.7.1 Monitoring design and budgeting

116. The Project Document included (as in most GEF-UN Environment Projects) a costed Monitoring and Evaluation (M&E) Plan (Appendix 7 to the ProDoc), with a forecast of 5,000 -10,000 USD for a Mid-term review and 30,000 — 40,000 USD for a Terminal Evaluation; these amounts were however not explicitly reflected in the specific budget

lines (UNEP format) but, according to the project, they were included in the budget line termed "Others".

117. A relevant number of M&E tools were incorporated in the ProDoc appendixes, namely:

- Appendix 3 (Incremental Cost Analysis);
- Appendix 4 (Results Framework);
- Appendix 5 (Work Plan);
- Appendix 6 (Key Deliverables and Benchmarks);
- Appendix 7 (Costed M&E work plan);
- Appendix 8 (Reporting Requirements);
- Appendix 9 (Standard Terminal Evaluation TOR).

Some of the Appendices to the Project Document are of good quality, e.g. the 118. Costed M&E Plan, encompassing a clear baseline, mid-term and final targets. However, the general picture is not satisfactory. The evaluation finds that several Indicators in the M&E plan were not SMART⁶⁷, and qualitative indicators were in some cases not concise. For instance, the indicator "Within 30 months effective post-release mechanism in place for monitoring of compliance ⁶⁸ does not provide the criteria against which one may attempt an evidence-based judgement, because it does not explain what the constitutive qualities (features / criteria) of an effective mechanism are. Another instance is related to Outcome 2C.1 which does not translate the requirements into measurable features of progress, by defining in precise and unambiguous terms what is being measured. Yet another example is the indicator related to Outcome 5.169 of the logframe which does not specify the data required, the population from which the indicator should measure, or even the baseline reference, although it aims at measuring a 50% increase in targeted groups' feedback. As evidenced above, the monitoring system does not provide sufficiently robust and properly weaved criteria against which an objective, evidencebased, judgement can be provided. (See also Section 5.4.2.).

119. Plans for collection of disaggregated data are partially addressed by ProDoc Appendix 7 (Costed M&E Work Plan) and by Appendix 4 (Project Results Framework), however leaving room for improvement. Data collection methods and tools were not adapted to integrate Human Rights & Gender Equality (HRs&GE) dimensions as well as the intervention's diversified impact on different stakeholders. The project's monitoring system remained blind to the fact that different interests may exist between and within groups of stakeholders, and that the intervention may influence in diverse ways the

⁶⁷ Specific, Measurable, Achievable, Relevant and Time-bound.

⁶⁸ Referring to "LMOs are monitored by regulatory agencies after environmental release" (Output 2A.1.5)

^{69 &}quot;Within 48 months extent of feedback from target groups on biosafety issues, regulations and procedures is increased up to 50%".

different stakeholders involved in or possibly affected by the interventions. Consequently, the steering of the Project was deprived of data triangulation, based on the diversity of perceptions and interests. ⁷⁰.

5.7.2 Monitoring implementation

- 120. The execution of a National Steering Committee (NSC) and of a Project Management and Monitoring Committee (PMMC) were instrumental to the overall strategic steering of the Project. The National Steering Committee (NSC) meetings took place three times, i.e. in June 2012, June 2014 and, the last meeting was held in March 2015. The Project Management and Monitoring Committee (PMMC) held nine meetings between March 2013 and January 2017. Annual meetings organised by the UN Environment Task Manager (TM) for the National Project Coordinators and teams related to the NBF Phase II Implementation, were also very useful, promoting exchange, mutual learning and to a certain extent, shared self-evaluation of project progress and problems. As exposed in the Project Final Report, the project team participated in all four meetings of the National Project Coordinators during the course of the project.
- 121. The implementation endeavoured to comply with the ProDoc⁷¹ requirements concerning project supervision and adaptive management. Through the periodic production of Project Implementation Reviews (PIRs), an effort was made to report progress on project progress, activities, outputs, including outcomes. Weaknesses observed by the evaluation are related to the structural gaps, including in the Project design (see Section 5.2) and weak monitoring indicators (also explained in section 5.2 above),. During the inception workshop, these structural gaps were partially addressed, deciding to focus on four "thrust areas". However, the indicators and means of verification were not fine-tuned during that workshop, as foreseen in the ProDoc § 66⁷².

5.7.3 Project Reporting

- 122. Progress reporting was regular and timely delivered twice a year and corresponded with the Project Implementation Review (PIR). Reporting is detailed and clearly reflects efforts to maintain accuracy in supplying information in relation to the ProDoc objectives.
- 123. Disaggregated data by gender and by beneficiaries are missing in all Project reports, reflecting the fact that the project design was blind to the diversity of interests / stakes of the different stakeholders over the Project's results, and generally over GMOs and biosafety.

⁷⁰ See more on UNEG / UN Evaluation Group guidance document on "Integrating Human Rights and Gender Equality in Evaluations", 2014.

⁷¹ Section 6: Monitoring and Evaluation plan

⁷² Indicators and their means of verification may also be fine-tuned at the inception workshop"

- 124. Data systematization (aggregation / disaggregation) along operational criteria for effective steering of the project is weak. For instance, in relation to the Result 2A.1.5, "To have in place effective post-release mechanism for monitoring of compliance", the means of verification foresee "Monitoring reports submitted to the apex body GEAC". Instead, project reporting only refers to "Two publications prepared viz., Monitoring Confined Field Trials (CFTs) of Regulated GE Plants: Monitoring Manual and Post release monitoring of GE crop plants", considering these as evidence of Highly Satisfactory performance. As regards the same point, no statistics for instance on labs performance, has been provided, although requested by the evaluation as underpinning evidence. Similarly, no data are presented in relation to the indicator underpinning Outcome 5.1, i.e. "Public awareness".
- 125. Despite the efforts to offer a more structured approach, reporting focuses more on performance on the completion of activities and outputs delivered. In fact, the final PCU report is activity-focused, providing a detailed table listing 56 "Activities / Outputs" and reporting on their status of completeness. In the third column, a measurement against the ProDoc indicators is attempted, yet, without succeeding in providing and discussing evidence on the achievement of outcomes and progress towards Project's intended results. The "lessons learned" chapter of the final report is mostly about results and conclusions / considerations on these results.
- 126. As visualised in the Ratings Table 8, section 6.1, the rating of the sub-components of the Monitoring and Reporting System is uneven, and the overall rating is considered as **Moderately Satisfactory (MS)**.

5.8 Sustainability

127. The evaluation has analysed to what extent follow-up work was initiated and how project results could be sustained and enhanced over time. Three aspects of sustainability were addressed: a) Socio-political sustainability, b) Financial sustainability, c) Institutional sustainability.

5.8.1 Socio-political sustainability

128. The sustainability of project outcomes is characterized by a *high* degree of dependency on social/political factors and there is strong ownership, interest and commitment among government and other stakeholders, as extensively elaborated on previously. A generally conducive environment is ensured by India's commitment to biodiversity and to biosafety, as proved by the CBD ratification in 1994 and the CPB ratification in 2003. Environmental protection is enshrined in the Constitution of India, Article 48-A and Article 51-A (g) of the Directive Principles of State Policy. Since 1986, the Environment Protection Act (EPA) has provided an umbrella legislation at Central Government level. In 1989, under EPA, the Government of India ratified the "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically

Engineered organisms or cells" (In jargon "Rules 1989"). Eventually, the project is explicitly instrumental to Government of India strategy on biotechnology which is considered a "sunrise" sector in economic terms. Functional linkages between biosafety and biotechnology would be a major factor in ensuring sustainability.

- 129. However, a number of factors may challenge the NBF effectiveness, as elaborated under Section 5.4.2 (Achievement of Outcomes). Actually, the last decision was in 2009 as the political will, shaped through political "bargaining" capabilities of the several constituencies, is currently responsive to a public opinion generally averse to LMO / GMO for agriculture. As exposed under Sections 3.3. (Stakeholders), 5.2. (Project design), and 5.7 (Monitoring and Reporting), the Project was blind both to Gender Equality and to Human Rights, hence lacking elements for an evidence-based judgment on parameter so relevant to socio-political sustainability.
- 130. On the whole, and with particular respect to the dynamic and evolving context, Socio-political sustainability is judged as **Likely (L)**.

5.8.2 Financial sustainability

131. The stakeholders consulted did not express a clear view on the future financial sustainability of the National Biosafety Framework. The Project final report and other reporting documents (e.g. PIR⁷³ June 2017) remain silent on the issue, although in the ProDoc specific action was foreseen for a technical paper on the "long term funding" by the Government of India to be prepared. However, as also pointed out in the GEF tracking tool, national budget allocation is still not in place. Additionally, the Evaluation found that the presence of a robust Public-Private Partnership possibly underpinning financial requirements of the NBF, did not emerge. Financial Sustainability is rated **Moderately Likely (ML)**

5.8.3 Institutional sustainability

- 132. The institutional framework of Biosafety in India is enshrined in the Environmental Protection Act 1986, including a constellation of relevant Regulations and Guidelines. A robust and complex net of institutions underpin the Regulatory Framework at Central Government and State levels, as shown in box 1, Section, 3.3. Due to the federal nature of India, the number of relevant Committees amount to more than 400 (e.g. in the case of the institutional biosafety committees).
- 133. The coordination between the two nodal institutional players, namely, the Ministry of Environment, Forest & Climate Change (MoEF&CC) and the Department of Biotechnology of the Ministry of Science and Technology, presents a promising field for

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the development of apt institutional arrangements, as discussed in previous Sections.⁷⁴ It is worth noting that Department of Biotechnology has been devoting efforts towards promoting a streamlined "single window" mechanism - National Biotechnology Regulatory Authority" (NBRA)⁷⁵, without so far bringing about conclusive institutional arrangements. However, the need to streamline and simplify the institutional network is clearly expressed by key stakeholders.

- 134. Institutional arrangements, further promoting the Public-Private Partnership as well as effective forms of stakeholders broader and meaningful participation (in planning, decision making and funding) are also to be further strengthened.
- 135. The Evaluation may just observe that the current institutional complexity is associated with robust mechanisms in place, a three-decade experience and a very dynamic context, a fact that may underpin evolving institutional arrangements in a genuine attempt at setting up the most appropriate ones.
- 136. For all the above, Institutional Sustainability is rated **Likely (L)**.

6 Conclusions and Recommendations

6.1 Conclusions

- 137. Biosafety law and policies are well developed in India, including the Environmental Protection Act (1986), the Rules (1989)"⁷⁶, and the ratification of the Cartagena Protocol on Biosafety (2003). India benefits from a 30-year experience in biodiversity, vigorous biotechnology competences, robust regulatory regime and consequent human and institutional capabilities. Hence, the key biosafety governance elements are in place. Additionally, biotechnology is considered as a "sunrise sector" and economic key driver for the country.
- 138. The project builds on the previous Phase I GEF-World Bank project on NBFs development, completed in 2007. At the start of the Phase II Project in 2012, a constellation of legislations related to biosafety regulations were already developed.

⁷⁴ See box 1, Section 3.3 (Stakeholders) and Chapter 4 (TOC)

⁷⁵ According to the "National Biotechnology Development Strategy, 2007", a "National Biotechnology Regulatory Authority" (NBRA) was foreseen as "independent, autonomous and professionally led body envisaged to provide a single window mechanism for biosafety clearance of genetically modified products and processes". However, NBRA Law Framework (NBRA Bill, 2009) has not been approved by the Indian Parliament and new institutional arrangements are in phase of preparation.

^{76 &}quot;Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms Genetically engineered organisms or cells" (In jargon "Rules 1989")

However, there was an urgent need to strengthen the regulatory procedures and enforcement mechanisms regarding the transboundary movement of LMOs, in view of advancements in crop biotechnology at the national and global level. India already has several LMOs which are close to commercialization and the country is expected to be soon both an exporter and an importer of LMOs.

- 139. There is a risk of illegal GMO cultivation that would require robust response capacity from the NBF enforcement system and would generally challenge the NBF governance capabilities. However, India's robust mechanisms and competences, which are now in place, and evolve in a very dynamic context, may underpin steady evolution of the institutional arrangements in a genuine attempt to set up the most appropriate ones for a fully responsive NBF.
- 140. It is in this context that the Project gave its positive contribution to a functional and responsive regulatory regime and national monitoring system, further strengthening the institutional and technical capacity, and promoting awareness and participation amongst the key actors to ensure that biosafety becomes part of their permanent action.
- 141. In this respect, it is worth noting a number of relevant Guidelines that complemented the compendium of the Administrative system tools in place. The enforcement & monitoring systems benefitted by a network of GMO laboratories and the training of key human resources. Consistent awareness-raising and information material, produced in several languages, was delivered through the Project support. Additionally, relying on National ownership and initiative, the Project during its lifespan successfully engaged the main stakeholders identified in the ProDoc.
- 142. The Project focused on capacity building and indeed achieved significant results in several areas, particularly with regard to Biosafety Monitoring and Enforcement Systems, yet as discussed in this report, adequate follow-up systems to evaluate the effectiveness in developing human resources capacity over time, are not in place.
- 143. Based on a triangulation of findings' the Evaluation may confirm that the Project's achievements provide evidence of progress, even though the monitoring system did not provide sufficiently robust and properly weaved criteria against which a precise, unambiguous and evidence-based judgement could be formed.
- 144. There still exists a number of bottlenecks that challenge the process, as indicated in the evaluation findings presented. In this context, in the overall assessment the Project is rated **Satisfactory**.
- 145. Table 7 below summarises the rating for each of the evaluation criteria.

Table 7 Evaluation Criteria and Ratings Table

Criterion (section ratings A-I are formed by aggregating the ratings of their respective sub-categories, unless otherwise marked)	Summary Assessment	Rating
A. Strategic Relevance	Very satisfactory in all aspects.	HS
1. Alignment to MTS and POW	Well aligned with MTS (2010-2013 and 2014-2017), Sub- Programme Environmental Governance, Expected Accomplishment (EA) b and (EA) 2.	HS
2. Alignment to UNEP/GEF/Donor strategic priorities	Project belongs to GEF Biodiversity Focal Area, Strategic Programme 6 (BD-SP6): "Building Capacity for the Implementation of the Cartagena Protocol on Biosafety".	HS
3. Relevance to regional, sub- regional and national environmental priorities	Relevant for the management and safe use of GMOs in the context of Sustainable Development at national level and conducive to harmonized Regional priorities	HS
4. Complementarity with existing interventions	Builds upon GEF-WB Project "Project on the Development of Biosafety Frameworks", implemented between 2003 and 2007.	HS
B. Quality of Project Design	Project Design Quality assessed in Inception Report and found weak against a number of relevant aspects such as Intended Results and Causality and in Sustainability.	MU
C. Nature of External Context	The external context did not affect Project implementation	Highly Favourabl e
D. Effectiveness		MS
1. Achievement of outputs	Not all Expected Outputs were fully delivered.	S
2. Achievement of direct outcomes	2. Achievement of direct outcomes No all Direct Outcomes were fully achieved, some of them are in need of consolidation. Assumptions and Drivers hold partially.	
3. Likelihood of impact Assumptions and Drivers for progress to Intermediate States (i.e. transitory conditions needed to progress from direct outcomes to impact) hold only partially		ML
E. Financial Management		HS
1.Completeness of project financial information	Financial information available and administrative requirements fulfilled	HS
2.Communication between finance and project management staff	In place throughout project life and effective	HS
3.Compliance with UNEP standards and procedures	Inventory reports regularly prepared and yearly audits submitted	HS
F. Efficiency	No major delays registered but one 14-month no-cost extension was granted. The Project built on pre-existing institutional capacity, agreements and relevant partnerships.	S

Criterion (section ratings A-I are formed by aggregating the ratings of their respective sub-categories, unless otherwise marked)	Summary Assessment	Rating
G. Monitoring and Reporting		MS
1. Monitoring design and budgeting	Monitoring Plan not clearly reflected in the budget. SMART indicators and plans for collection of disaggregated data leave room for improvement.	
2. Monitoring of project implementation	Systems in place, yet, poorly formulated monitoring indicators were not much helpful to adaptive management	MS
3.Project reporting	Reporting, based on GEF and UNEP M&E tools, timely delivered and ANUBIS document repository uploaded. Report focus mainly on Activities and Outputs. Some judgement elements are present as well as efforts for more structural approach / Outcomes reference	
H. Sustainability	(the overall rating for Sustainability will be the lowest rating among the three sub-categories)	
1. Socio-political sustainability	Conducive socio-political environment and international commitments endorsed by India. Challenges from adverse public opinion and "blocked" decision-making system. High dependency on social/political factors and high ownership.	
2. Financial sustainability	National Biosafety budget allocation not in place.	
3. Institutional sustainability	Robust Regulatory Regime and Authorities in place. Dynamic context underpinning evolving institutional arrangements.	
I. Factors Affecting Performance		MS
A number of weaknesses emerge in the project design, particularly with regard to the following dimensions assessed by the evaluation: "preparation", "intended results and causality" and "sustainability". Development of partnership agreements and financing arrangements are satisfactory. The inception meeting and the response to Project Review Committee minutes are satisfactory.		MS
2. Quality of project management and supervision	Procedures of management met good standards. The working relationship between the TM and project partners was constructive and effective. The speed of responses to execution challenges provided evidence of "adaptive management" capabilities.	
3. Stakeholders participation and cooperation	All stakeholders envisaged by the ProDoc, actively engaged in the Project implementation. Yet, not "all of those who are affected by or could affect this project ⁷⁷ " were considered, e.g. the ultimate potential beneficiaries (such as small and commercial farmers, consumers, the public in general) were marginally included and possible vulnerable groups were not	MS

⁷⁷ Stakeholder Analysis in the Evaluation Process (UNEP, 2017) "stakeholder' should be considered in a broad sense"

Criterion (section ratings A-I are formed by aggregating the ratings of their respective sub-categories, unless otherwise marked)	Summary Assessment	Rating
	identified. Indigenous peoples and local communities were marginally encompassed as stakeholders (interest groups).	
4. Responsiveness to human rights and gender equity	The Project was blind to questions related to gender as well as to diverging and even conflicting interests between different groups. Not referred to in any Project document from design to reporting.	U
5. Country ownership and driven-ness	Fully enacted through robust Regulatory Regime and the involvement of several Ministries and Competent Authorities.	
6. Communication and public awareness	To be consolidated	MS
Overall project rating	Satisfactory	S

6.2 Lessons Learned

Lesson one: "Root-causes analysis" is one way of identifying effective remedies to potential problems in project implementation. If ignored, the root-causes of a problem may turn into bottlenecks that hinder change.

146. Projects are tempted to neglect "root-causes analysis" because the underlying causes of a problem may often concern controversial issues that require much effort including mobilising emotional resources, and time to be understood and to negotiate with stakeholders holding contrasting views. However, "Root-causes analysis" helps with effective identification of remedies, in the sense that identification of a "key problem" should be followed by the definition of a "hierarchy of root-causes", right from those most immediate ones, on the basis of which a "hierarchy of remedies" i.e. an action-plan for producing the envisaged change from the causes to the effects, is to be defined.

147.

148. Similarly, the Project did not include elements for analysis of the levels of influence, interest and expectations of each stakeholder group needed for the achievement of the project's expected outcomes. This is important in order to, for example, understand **why** the effective participation of some stakeholders was not optimal or was even limited ("root-causes analysis") and consequently to address the issue ("hierarchy of remedies").

Lesson two: Awareness-raising using a top-down approach is not equivalent to public dialogue and participation. The former is based on message dissemination from a centre of

knowledge to the periphery, while the latter is based on bi-lateral communication, implying active mutual-hearing, minimum standards of trust and engagement of all parties.

149. Despite the good performance of the Project in terms of activities and products for awareness-raising, adverse public opinion was pointed out by a significant number of the stakeholders consulted as a persisting bottleneck. The case confirms the theory that awareness-raising is less effective in influencing attitude change if it focuses on "top-down" dissemination of scientific information. Public participation and interactive dialogue between the Regulatory Agencies and a wide range of stakeholders can promote the exchange of information of mutual interest and help to build trust in the regulatory system by discussing concerns related to protecting human health and safety and the environment. Indeed, dialogue may constitute a sustainable platform for fostering a bilateral process that may result in a shift in the attitude and/or positions of all parties.

Lesson three: Human Rights and Gender Equality mainstreaming is compulsory to the UN programming⁷⁸, yet, the value of embracing it in biosafety remains normative and theoretical as long as biosafety Projects do not foster specific HR & GE aims, and do not earmark budget for this purpose.

- 150. As mentioned in the report, the project was blind to Human Rights and Gender Equality (HR & GE) dimensions e.g. on men's and women's different roles, stakes and power over biosafety issues such as natural resources preservation and food security (See Section 3.3). Concerning Human Rights, the project did not distinguish stakeholders along "rights-holders", a characterisation that would underpin a more inclusive approach and a better understanding of the root-causes of key problems and risks. Data collection methods and tools were not adapted to integrate Human Rights and Gender Equality (HRs&GE) as well as the Project's diversified impact on different stakeholders.
- 151. The Evaluation attempts to show "why" this was a weakness in the efforts to strengthen biosafety capabilities, yet this is an arduous task since empirical work on mainstreaming Human Rights and Gender Equality in biosafety is extremely modest (only few references from IUCN79).
- 152. As a matter of fact, as long as projects do not start devoting efforts and earmark budget to effectively comply with the compulsory requirement to mainstream Human

⁷⁸ Human Rights and Gender Equality mainstreaming, in compliance with: the UN Programme for Reform, A/51/950, 14 July 1997; the UN Development Group Human Rights Mainstreaming Mechanism (UNDG-HRM); the UN Beijing Platform for Action from the Fourth United Nations World Conference on Women in Beijing in 1995; the UN system-wide policy on gender equality and the empowerment of women; the UN strategy on gender mainstreaming as well as the UNEG / UN Evaluation Group guidance document on "Integrating Human Rights and Gender Equality in Evaluations", 2014.

⁷⁹ IUCN: International Union for Conservation of Nature

Rights and Gender Equality, any attempt to analyse the issue at the terminal evaluation stage will remain theoretical and normative, and will evoke little, if any, interest among the implementing agents.

6.3 Recommendations

153. Based on the main Findings and Conclusions, the evaluation recommendations are as follows:

Recommendation 1.

To the Ministry of Environment, Forest & Climate Change (MoEF&CC) - the Competent National Authority, regarding follow-up systems for human resources capacity development and public awareness strengthening.

The Evaluation recommends that the Competent National Authority devotes efforts to build robust follow-up systems in order to measure the effects of and steer action in relation to:

- Human Resources capacity development;
- Information and Public awareness

Summary of Findings and Conclusions supporting the Recommendation

Public awareness shortcomings have been pointed out as a priority by virtually all stakeholders consulted during the evaluation. To address the challenge and to objectively measure change in people's knowledge and attitudes, follow-up capacity is a key requirement.

Continuous capacity development of Human resources, as a core element for an effective NBF, requires a more systematic approach particularly in terms of assessing the effectiveness in developing capacity over time. Follow-up requirements have to be established at the design stage of training, (e.g. to allow for a comparison of entry-to-exit profile of participants), ensuring disaggregated baseline data collection and readjustment capacity. Such measures would positively impact both effectiveness and efficiency (improving cost-effectiveness) in capacity development initiatives.

(Ref: Conclusions § 141; section 5.4.2, Achievement of Outcomes, § 99 and 101).

Recommendation 2.

To UN Environment, concerning the Programming / Project Cycle discrepancies with focus on Project Design and Results-based Management (RBM) approaches.

The Evaluation recommends working on the harmonization of the requirements at the design and evaluation stages of the project cycle. In particular, taking action to ensure consistency between the Project Document and the "Assessment of the Project Design Quality" guidelines developed by the Evaluation Office of UN Environment.

Summary of Findings and Conclusions supporting the Recommendation

As revealed in the evaluation report, the elements for assessment set in the "Assessment of the Project Design Quality" guidelines (provided by the Evaluation Office of UN Environment) were largely missing; the shortcomings identified in the project design appear to have led to modest results in its overall quality assessment, which could have impacted negatively on the implementation stages of the project cycle.

(Ref: Conclusions § 142; Chapter 4, Theory of Change; Sections 5.2, Quality of Project Design; 5.4.2 Achievement of Outcomes; 5.7, Monitoring and Reporting).

Recommendation 3.

To UN Environment regarding Project Cycle discrepancies between Monitoring & Evaluation (M&E) and Results-based Management (RBM) approaches.

The Evaluation recommends working on, and investing resources in, effectively and fully integrating Monitoring and Evaluation (M&E) requirements in the whole project cycle. More specifically:

- At the design stage (ex-ante), ensure the validation of the M&E system of each project with focus on SMART and verifiable indicators.
- At the implementation stage promote capacity building (through workshops and coaching) on Project Cycle with focus on Results-based Management, including soft skills for human resources involved in project management and implementation.
- Ensure that project budget is adequate for the requirements of an effective monitoring and evaluation delivery, including capacity building.

Summary of Findings and Conclusions supporting the Recommendation

Relevant gaps in the monitoring and evaluation system limit, to a certain extent, an evidence-based judgement on the Project's progress towards the achievement of its objectives.

(Ref: Conclusions § 143; Chapter 4, Theory of Change; Sections 5.2, Quality of Project Design; 5.4.2 Achievement of Outcomes; 5.7, Monitoring and Reporting).

Recommendation 4.

To UN Environment, regarding mainstreaming of Human Rights and Gender Equality⁸⁰ in project design and implementation.

The Evaluation recommends working on, and investing resources in, fully mainstreaming Human Rights and Gender Equality (HR & GE) into project design and in the Project Cycle.

Summary of Findings and Conclusions supporting the Recommendation

Human Rights and Gender mainstreaming is compulsory to the UN programming.

Male and Female roles, stakes and / or power over biosafety were not discussed (e.g. their roles in natural resources preservation and in household food security and food safety). Stakeholders are not classified along the key feature of "Duty-bearers" and / or "Rights'-holders". Possible vulnerable groups and local communities remained at the margins of the Project. Data collection methods and tools were not adapted to integrate HR & GE dimensions as well as the diversified impact of the intervention on different stakeholders' groups.

The value of embracing Human Rights and Gender Equality (HR & GE) in biosafety remains normative and theoretical as long as the biosafety Projects do not foster specific aims and do not earmark budget for the purpose, in order to build up "critical mass" on the issue.

(Ref: Chapter 3.3 Stakeholders, 5.2 Project Design, 5.7 Monitoring and reporting, and Chapter 5.8.1, Socio-political sustainability).

⁸⁰ Human Rights and Gender Equality mainstreaming, in compliance with the UN Programme for Reform, A/51/950, 14 July 1997, the UN Development Group Human Rights Mainstreaming Mechanism (UNDG-HRM), the UN Beijing Platform for Action from the Fourth United Nations World Conference on Women in Beijing in 1995, the UN system-wide policy on gender equality and the empowerment of women, the UN strategy on gender mainstreaming as well as the UNEG / UN Evaluation Group guidance document on "Integrating Human Rights and Gender Equality in Evaluations", 2014.

Annexes

- 1. Response to stakeholder comments received but not (fully) accepted by the evaluators
- 2. Evaluation TORs (without annexes)
- 3. Evaluation itinerary, containing the names of locations visited and the names (or functions) and of people met/interviewed. (A list of names and contact details of all respondents should be given to the Evaluation Manager for dissemination of the report to stakeholders, but contact details should not appear in the report, which is publicly disclosed on the EOU website).
- 4. Summary of co-finance information and a statement of project expenditure by activity
- 5. Evaluation Bulletin: A short (2-page) and simple presentation of evaluation findings and lessons to support the dissemination of learning to a wide range of audiences. (Samples and a template can be provided by the EOU)
- 6. List of documents consulted
- 7. Brief CVs of the consultants

ANNEX I. RESPONSE TO STAKEHOLDER COMMENTS RECEIVED ON THE DRAFT REPORTS

The evaluator acknowledges the feedback provided by the UN Environment Task Manager responsible for the Project as well as the Project Team and other stakeholders who provided their feedback in previous draft versions of the evaluation report.

The Evaluator wants to express her thankfulness for the feedback provided that helped better the Final Report and she wants to ensure that even the comments that were not accepted, or were accepted only partially, and consequently addressed here below, are highly valuable to the knowledge building process.

Actually, these comments led to further critical thinking, further research, analysis and structuring on challenging sectors of action. In this process, the oversight of the Evaluation Office of UN Environment was outstanding.

The evaluation shares the stakeholders' concerns and wants to ensure that a lot of effort was put into finding the right balance and reaching a common understanding on the objective criteria against which a constructive judgement could be reached. The evaluation is also aware of the sensitivities that any assessment involves, also reason for which a participatory approach was adopted.

Comments by the National Executing Agency - Ministry of Environment, Forest & Climate Change (MoEFCC)

Sections	Inputs/Comments	Remarks (Evaluation Office)
Acknowledgements	The last line of the second para of acknowledgments needs to be revised as "Office in charge of the Project Coordination Unit, Dr Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited".	Text has been amended
About the Evaluation	 Information under "Brief Description", is missing. Editorial correction required in the line 3 of 'Key Words' 	Text has been amended
Project Identification Table	 Reports of all four Steering Committee meetings have been uploaded in ANUBIS and are available for download. The fourth Steering Committee was held jointly with the eighth Project Management and Monitoring Committee meeting and is available in ANUBIS as "Final-Approved Minutes of the 4th NSC and PMMC". Mid Term evaluation report on best practices and lessons learnt was planned as part of the project and has been undertaken by a UNEP consultant. (This information was shared during the country visit but not included in the report). 	No further change required
Introduction	 It has been incorrectly mentioned that five revisions or extension in the project have taken place. There has been only one extension for the project, and five budget revisions (which is a routine exercise at the end of each year). In the first two budget revisions, no changes were made in the budget lines, and only the unspent amount was carried forward to the next year. The next three budget revisions involved few changes between the budget lines. 	Text has been amended in ¶1
Evaluation Methods • Overall approach of the evaluation	Point 9: The meeting agenda for the evaluator was prepared by BCIL as per the advice from the implementation agency which is the MoEFCC and the Task Manager.	No further change required

Point 10: Meetings of the evaluator were organised with two NPDs and two NPCs who have been associated with the project for the period 2012 -2017.

A clarification has been provided in the footnotes

Point 15: It appeared during the meetings with the stakeholders that the consultant was not quite comfortable when the stakeholders appreciated the project and no negative views were presented by the project partners. Instead of acknowledging the successful completion of all outputs/outcomes, attempts were made to find gaps with the agenda prepared for the meetings, which was shared with her in advance. Further, due to limited time and some meetings extending beyond scheduled time by her, all planned meetings could not be held, and some had to be cancelled by the evaluator during the country visit.

Evaluator's description of the limitations experienced has been retained

It was also noted that the stakeholders were asked questions on issues not relevant to the project. Inadequate response to these were then shown as gaps. For example, in spite of providing all evidence about active participation of women which at times outnumbered males, the issue of gender equality and human rights was repeatedly raised with stakeholders, irrespective of their relevance to specific project components.

In 2014 the United Nations Evaluation Group published a guidance document "Integrating Human Rights and Gender Equality in Evaluations". (follow link). The Evaluation Office of UN Environment consequently revised its evaluation Terms of Reference accordingly in order to ensure that gender equality and human rights would be adequately addressed in all evaluation reports produced by the Office.

This resulted in deviating from the actual purpose of evaluation and resultant dissatisfaction of the consultant. Most project partners who were interviewed were also not satisfied with the meetings, and raised concerns about the lack of relevant expertise of the consultant.

No edits have been made to the text regarding dissatisfaction with interviews conducted; no communication from said partners has been received by the Evaluation Office.

	Point 16: The distance between BCIL and MoEFCC was not a constraint as both are conveniently located with about 15 minutes travel time only.	Evaluator's description of the limitations experienced has been retained
Methods and tools for data collection and analysis	Point 24: Various documents shared by the evaluator prior to the visit to India were received and acknowledged by MoEFCC and PCU. It was understood that these are for information only towards preparedness for the visits. During the visits, these documents were discussed in one to one meetings with the consultant. However, as mentioned earlier, there was a clear disconnect between the topics of interest to the evaluator and the relevant thrust areas and focus of the project.	Issue on disconnect is duly noted and acknowledged. An Inception Report containing the detailed evaluation framework, proposed approach and methods inter alia, was however shared with the Task Manager and the project. Several evaluation tools were submitted to relevant persons prior to the mission. No objections were communicated in this regard.
The Project • The Context	Point 26: No new regulations have been developed. However the regulatory system has been strengthened through various guidelines and notifications being put in place from time to time by the Government.	Text has been amended in ¶26
Stakeholders	Point 33: Since biosafety is a cross-cutting issue and relates to several sectors, various categories of stakeholders were identified who have been involved throughout the project towards fulfilling the project objective to help comply with the CPB.	¶33 refers more specifically to the omission of gender disaggregation in the project's stakeholder analysis. Although gender equality had not been considered in the project design, the project has been running between 2011 – 2017 during which time there was an opportunity to adopt to the UN systemwide action plan on gender equality.

	Point 34: The project objective and the overarching goal of the project is not based solely on gender requirements, and hence the information on gender equality was not explicitly mentioned. However, during the country visit, information about involvement of both male and female participants in various workshops and trainings has been provided to the evaluator as desired.	¶34 has been amended to include information on workshop/training participation.
	Point 35: It is incorrect to mention that stakeholder mapping is inadequate. Table 4 of the project document clearly indicates the same. In fact, India had undertaken a training needs assessment under Phase I of the World Bank project which was used to provide guidance for stakeholder mapping. Various categories of stakeholders have been involved for each of the project activities and the same is clearly evident from the project reporting documents such as the NSC meeting minutes etc.	Text has been amended in ¶34 to include information on the Training Needs Assessment
	Point 36: Information provided in the text as well as in the box 1 on responsive regulatory regime in India, has been not been interpreted correctly. The Rules for Manufacture, Use, Import, Export and Storage of hazardous microorganisms, Genetically engineered organisms or cells (Rules, 1989) notified under the Environment Protection) Act, 1986 provide for regulation of all activities related to GE organisms and products thereof. Under these Rules, 1989, six competent authorities are notified that function towards implementing these Rules by the MoEFCC, DBT, MoST and State Governments. In addition, to these there are other Acts, Rules and Policies which are also relevant, and their mandates are clearly specified.	¶36 amended to include the clarification on the regulatory regime in India
Project implementation structure and partners	Point 39: It may be noted that the NPD and the NPC have been changed only twice in the five-year period between 2012 to July 2017 (official project commencement period)	Noted. Correction made in ¶39

Theory of Change • Overview	Point 45: During evaluation stage, assumptions taken while reshaping are not appropriate. For example, the Intermediate State 1 "LMOs safe intentional release into the environment with emphasis on India's numerous indigenous LMOs from its national laboratories", is not the objective of the Phase II Capacity Building Project on Biosafety. The objective of the project is to have regulatory preparedness in the country for ensuring safe use and trans boundary movement of LMOs/GMOs. The project has been highly successful in achieving the same. Further, the meaning of the phrase used 'indigenous LMOs from its national boundaries' is not clear.	The text in section 4.1 has been retained as is, save for the removal of the term "indigenous". In the theory of change approach, 'Intermediate States' are added where the 'leap' from one result to another requires the existence of a transitionary step/condition, usually between direct outcomes and the desired [long-term] Impact.
The causal logic from outputs to outcome	Point 54: Regarding the two assumptions referred to by the evaluator viz., strong political will and strong coordination and clear definition of tasks, it is relevant to mention that it is not lack of political will, but the need to listen to all voices/opinions as an inherent component of a genuine democratic system. Further, both MoEFCC and DBT work in a coordinated manner as per the national regulatory framework through the two committees RCGM and GEAC.	Clarification noted and accepted. Please note too that in the theory of change approach, the term 'Assumption' refers to contributing conditions that can influence the change process but are considered to be beyond the direct control of the project.
The pathway from outcome to impact	The reconstructed Theory of Change from the project outputs to outcomes needs to be revised keeping in mind the various actions that were taken during the project implementation stage. The fact that the project has been fine-tuned after the project inception workshop, following which the activities were categorised into four thrust areas, need to be considered while reconstructing the theory of change. Accordingly, the drivers and the assumptions would also need to be modified.	Section 4.3 has been retained. The comment does not offer a specific prescription to remedy the analysis as presented.
	The assumption DO 1, "Strong Political Will" is not correct as many activities for strengthening the biosafety regulatory system in the country are ongoing	The Assumption has been edited to further define 'political will' as that which is specific to the establishment

	and implemented from time to time. There is a strong political will towards having in place a strong and effective regulatory system.	of a stronger and more effective regulatory [biosafety] system (¶ 55, ¶ 58, Diagram 2)
	As mentioned earlier, the concerns and opinions of different stakeholders which may sometimes be contradictory have to be heard and addressed in a vibrant democracy like ours. It is not clear what the Intermediate State (IS .1) "LMOs safe intentional release into the environment with emphasis on India's numerous indigenous LMOs from its national laboratories", actually means. The Indian regulatory system is applicable to all LMOs whether they are indigenously produced or imported.	Text has been edited to omit the term 'indigenous' from the 'Intermediate State 1' statement
Evaluation Findings: • Strategic Relevance	The table on contribution of the project to the medium-term strategy doesn't take into account two important achievements viz. detection capacities for GMOs, and the enforcement capacities of the custom and plant quarantine officials. The four national referral laboratories that have been notified for detection of GMOs is one of the significant achievements of the project.	Table 5 amended to include information on the establishment of national referral laboratories
Quality of project design	Point 69: Budget revisions were made five times, of which three revisions included changes between the budget lines which were only marginal changes. These cannot be presented as financial weakness in planning at the design stage. The changes were made based on the progress in actual implementation of activities which is not always possible to determine in advance. All projects have an element of such flexibility built in, and such revisions are the norm, rather than exception.	Noted and accepted. ¶70 has been amended accordingly.
	Point 71: While India has made significant investments in biotechnology, it may also be noted that it is a vast country with large number of stakeholders. It is absolutely incorrect to say that India doesn't have a NBF in place. India has in fact been one of the early countries that had a system in place for biosafety regulations in the form of Rules for Manufacture, Use, Import, Export and	The report does refer to India having in place a National Biosafety Framework (e.g. sections 3.1, 5.4.3, 6.1, etc.). We however also accept the report stating that the rationale for the Project, as

Storage of hazardous microorganisms, Genetically engineered organisms or cells notified way back in 1989 itself, followed by a series of other guidelines issued thereafter. Release Bt Cotton and more than 40 therapeutic derived LMOs following these Rules are examples. At the project designing stage, areas were identified to strengthen the regulatory system in line with the COP-MOP decisions and national priorities. Also risks have been analysed and mitigation methods also suggested. The project has been implemented as per the plan and plugging the gaps for strengthening the regulatory system.

indicated in the ProDoc, was the recognition that some crucial elements of the India NBF were in need of strengthening and improvement.

Point 73: It is once again reiterated that the project design is in line with the Strategic Plan for the CPB for period 2010-2020, and also with the national priorities. The views of the reviewer cannot be agreed to.

Noted and accepted. The statement referred to in this comment has been omitted.

Point 74: The issues raised such as human rights are not directly related in the context of implementation of this project on biosafety.

The project design is very much in line with the national needs and prepared in a consultative manner with inputs from all categories of stakeholders. The four thrust areas of the project that were fine-tuned at the project inception workshop with concurrence from the task master are in line with the prioritized areas of the Strategic Plan for CPB for period 2010-2020. This has enabled achievement of the overarching project goal.

An explanation on the integration of Human Rights and Gender Equality (HR&GE) in evaluation criteria has already been offered. Assessing how/whether Human Rights issues were mainstreamed into the project was a requirement in the evaluation Terms of Reference. While the report acknowledges that HR&GE language was not used in CPB and GEF-4, it also points out that no adaptation was made over time to mainstream it as a UN system-wide policy. Worth noting that one of the purposes of evaluation is to promote organisational improvement in the implementation of future initiatives.

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Point 83: Information about the Resource catalogue prepared by CABI is missing. The hard copy of the same was shared with the evaluator during the country visit.

The Resource Catalogue is listed in Annex V

Point 94; The assumptions that have been made by the evaluator to identify a pathway from project outputs to direct outcomes need to be rechecked and changed.

Comment does not prescribe a specific recommendation

Point 96: The information uploaded in BCH has been updated with all information under various sections. The decision for release has been updated only for Bt cotton as no other approval has yet been taken.

Noted. Reference to the date of the latest upload is needed to make an amendment to the text.

Regarding the national budget allocation, a separate budget for biodiversity and biosafety is allocated in MoEFCC. This information was provided to the reviewer during her country visit.

Text in ¶97 has been amended to include this information.

Point 103: It may be noted that the preparation of the risk communication strategy is not a part of the Guidelines for the Environmental Risk Assessment of GE plants, and it has not been approved by GEAC. The three guidance documents on Environmental Risk Assessment of GE plants that have been approved and adopted by GEAC are the Guidelines for ERA of GE Plants, a stakeholder user guide and the Risk Analysis Framework.

The evaluation observes that a risk communication strategy was delivered by the project (section 5.4.1 discussion on Outputs 13-18). The document "Environmental Risk Assessment of Genetically Engineered Plants: A Guide for Stakeholders" (Government of India2016) states that risk analysis shall comprise of three main elements namely: risk assessment, risk management and risk communication.

Point 110: It is relevant to mention that India's project has been highly appreciated in various national and international fora, in terms of the achieved outcomes and knowledge products that have been produced under each thrust

Text in ¶110 has been amended to accommodate this view

	area, which contradicts the views of the consultant. The Indian biosafety project was showcased at the side event of the COP-MOP meeting at Cancun, Mexico. The CBD Secretariat and participants highly appreciated all the project outcomes. Countries such as Sri Lanka, Bangladesh, South Africa have requested for India to assist them to replicate similar project activities in their countries.	
Conclusions and recommendations • Conclusions	Point 144: There are several GM crops in the product developmental pipeline. A robust biosafety regulatory system is in place for overseeing the activities related to GMOs and their products thereof. The system is not blocked.	Noted. Statement relating to a "blocked" system has been omitted.

Comments from the project's Task Manager

Comments	Response by Independent Consultant
Comment 1	
these projects are under the GEF Strategy on Implementation of the Cartagena Protocol on Biosafety so the primary guidance in the design and execution of such projects is per guidance through the GEF Strategy and Guidance from COP-MOPs or Convention Processes through Strategies and Action plans and may not always fit directly into UN programming. The project is not a Human Rights based approach project but speaks directly to Convention and GEF strategic guidance.	 The evaluation shares the TM concerns. The general considerations spelt out above as well as the evaluation's ToRs constitute an overall, positive response to such concerns. Considering the relevance of the subject addressed by the TM, the response is two-fold, i.e. (a) explain why the evaluation did express judgement in relation to the subject of Human Rights and Gender Equality (HRs&GE) and (b) put the subject into perspective (knowledge-building). The evaluation recognises the fact that HR&GE language is not used in CPB or in relevant COP-MOPs and GEF-4. Human Rights and Gender Equality mainstreaming (HRs&GE) is however compulsory to the UN programming. The UN Evaluation Group (UNEG) provides a guidance document on "Integrating Human Rights and Gender Equality in Evaluations" (2014), explaining why and how HR&GE is addressed in evaluation. The Evaluation Office tools on "Stakeholder Analysis" in introduces Human Rights language (distinguishing between "rights holders" and "duty bearers") in the evaluation process. The Evaluation was requested to assess the Project Design against Human Rights criteria in relation to sustainable development (Question 6 of the Completed assessment of the Project Design Quality).

Comments	Response by Independent Consultant
	 UN Environment, under the Environmental Governance Sub-programme, promotes the UN Environmental Rights Initiative that is directly related to eight (8) Sustainable Development Goals (SDGs), including SDC 15 to which Biodiversity is directly related. UN Environmental Rights Initiative represents the next phase of UN Environment's work on human rights and the environment https://www.unenvironment.org/news-and-stories/video/uns-environmental-rights-initiative GEF fully aligns with Sustainable Development Goals (see annex VI of this report, "The GEF and the Sustainable Development Goals"). Under Biodiversity, GEF identifies its contribution to SDG 15 (life on land) and with additional impact to other five SDGs (1- No Poverty, 2- Zero Hunger, 5- Gender Equality, 8- Decent Work and Economic Growth, 16- Peace, Justice, and strong institutions), all corresponding to fundamental rights as spelled out in the Bill of Human Rights

Comments	Response by Independent Consultant
Issues of gender mainstreaming came up way after these projects and also we have to note that building capacity on biosafety is skills-based and in some cases gender neutral	 The TM affirmation on gender neutral domain of action is not, to the evaluation's knowledge, evidence based. Additionally, in this affirmation the scope of the NBF is narrowed. The evaluation recognises that Gender Equality (GE) mainstreaming in biosafety remains normative and theoretical as long as the biosafety Projects do not earmark budget for this purpose in order to build up experience. Empirical work on mainstreaming Gender Equality in biosafety is extremely modest (only few references from IUCN). However, case-studies on the specific roles of women / men in natural resources preservation or in the key role of women in food safety and food security as well as the gender differentiation in the case of "hybrid seeds" provide empirical evidence of the need to thoroughly look at gender differentiation and its possible impact on biosafety and biotechnology promotion. The same applies to the biotechnology sector, for example, access to production inputs and to the market may be gender uneven. (See Section 3.3, Stakeholders, § 34) See Lesson 3 See Recommendation 4
Comment 2 Chapter 1, Introduction	
Factually the project is not the traditional Implementation of the National Biosafety Framework Project. India had that opportunity through the 12 Country UNEP/World Bank/UNPD Demonstration Project for 12 countries. UNEP handled 8 of those countries, 2 by the World Bank (India and Colombia and 2 by UNDP (Mexico and Malaysia). That pilot was the basis for the roll out of the implementation projects.	 Partially accepted and integrated. The report makes reference to the GEF Phase I project executed through The World Bank (Chapter 1, Introduction, § 2; Section 3.1, Context § 28; Section 5.1.4, Complementarity with existing interventions, § 64).

Comments	Response by Independent Consultant	
Comment 3 Section 3.3, Stakeholders		
Regulatory approaches focus on ensuring the rights for all in terms of safety and confidence on utilisation based on science-based risk analysis in decision making. There is a confusion here of access to biotechnology products and its benefits, which is not the focus of a regulatory or safety process.	Generally, Regulations are legal instruments that protect the rights of all and define responsibilities (duties) of others (e.g. public authorities, public sector, private sector, among others). States are the most prominent duty-bearers (ensuring the rights of all).	
Comment 4 Section 3.3, Stakeholders		
When the proposal was developed concerns on gender approach were not applicable, and if utilised were based on national imperatives. The Evaluation should be put in its proper context	 Noted. Please refer to answer in <i>Comment 1</i> above Lesson Three (Section 6.2) and Recommendation Four (Section 6.3). 	
Comment 5 Section 4.1, Overview		
(On the Comparison of Results Framework)it must be emphasised that this project is not a traditional implementation framework project of the 5 components but a thematic or issue specific project building on the Demonstration Project (the GEF support thematic based projects)	 Noted. The institutional / strategic and funding framework of this Project is briefly introduced in "Project Identification Table" and consequently explained under Chapter 1, Introduction, Section 5.1.1 "Alignment to the UN Environment Medium Term Strategy (MTS) and Programme of Work (POW)", Section 5.1.2 "Alignment to UN Environment /GEF Strategic Priorities", and Table 5, "Contribution of the Project to the Medium-Term Strategy (MTS)". Each project is assessed in its specificity, yet, against the framework defined in relevant strategic and technical documents and in the ProDoc. The evaluation did not find evidence underpinning the exceptionality of the Project. To the evaluator's understanding, development, demonstration and implementation projects constitute a continuum in which each new step is built on the previous ones, so that project phases and stages are not mutually excluding but reinforcing each other. 	

Comments	Response by Independent Consultant		
	Although largely consulting documents related to Phase I of the Project, the evaluation did not find any reference to "GEF support thematic based projects". Also, in the ProDoc such reference was not identified.		
Comment 6 Chapter 4, diagram 2, Reconstructed TOC from Project Outputs to Outcome			
The TOC is not fully correct. India already has an operational National Biosafety Framework which has already been tested e.g. Bt Cotton 9 (approvals), Bt Brinjal and Bt Mustard. Current project is basically to build institutional capacity with technical tools and human resource to manage applications, enforcement, assess risk etc. basically to further strengthen the decision-making system. Based on my comments, the main outcome is not fully correct and needs to be updated	 Noted. With reference to the Main Outcome, readjustment as proposed by the TM has been made. Readjusted the wording on the Main Outcome in an attempt to reach a more suitable and concise expression which all parties may feel comfortable The report largely makes reference to India's multi-year, prominent capabilities in both biosafety and biotechnology (e.g. Section 5.4.3) and reference to specific crops is also discussed (e.g. Section 3.1). 		
Comment 7 Chapter 4, diagram 3, Reconstructed TOC from Project Outcomes to Impact			
NBF is fully in place and is already in use for large scale deployment e.g. Bt Cotton	 The report in several sections (e.g. Section 3.1, Section 6.1) refers to the fact that India has in place a National Biosafety Framework. Reference to the Bt Cotton is also made in a number of paragraphs. The report highlights the capabilities of India in addressing biosafety requirements in a quickly evolving context (e.g. Section 5.8.3, Section 6.1). However, having a fully operational National Biosafety Framework, firstly implies having a NBF in place (NBF was firstly developed and then implemented). "Fully operational" is a more advanced stage. A fully operational NBF is not a definitely-achieved status, as also clearly explained in the "UNEP-GEF Toolkits" 		

Comments	Response by Independent Consultant
	for the Development of National Biosafety Frameworks" that states: "the actual implementation of the NBF gives a country an opportunity to ensure that the NBF is able to respond to changing needs, priorities and circumstances. In developing and implementing their NBF, countries need to make sure that they have some means for gathering information on how the NBF systems work in practice, what problems are arising, and how the NBF responds to changing circumstances". • At the core of the rationale for the Project (in the ProDoc) is the recognition that some crucial elements of the India NBF were in need of strengthening and improvement (e.g. risk assessment, management and communication, public participation, detection capacity, among others).
Comment 8 Chapter 4, diagram 3, Reconstructed TOC from Project Outcomes to Impact	
CNA does not have to coordinate NBF in full harmonisation with DBT, the legal mandates are different. The former is regulatory and DBT is developmental	Partially accepted. The evaluation agrees on the observation that legal mandates are different but, this, per se, is not a reason for denying the relevance of the assumption that CNA can ensure NBF coordination in full harmonisation with the Department of Biotechnology. As an 'Assumption' it is however considered as a factor/condition outside the direct influence of the Project.
Comment 9 Section 5.2, Quality of Project Design	
The intended results and causality or sustainability are clearly defined, and in the case of sustainability it is further strengthened by the legal approved functional mechanism the "Genetic Appraisal Review Committee" with a dedicated budgetary support. The initial assertions does not support the rating. How was this rating achieved?	 Under Section 5.2, Quality of Project Design, sustainability is discussed against the criteria in the "Completed assessment of the Project Design Quality", an assessment tool developed by the Evaluation Office of UN Environment. The completed assessment was annexed to the Inception Report (Annex C) at the inception phase of the evaluation. Sustainability with reference to the quality of the project design document (i.e. Prodoc) considers the following criteria: (a) Was there a credible sustainability strategy at design stage? (b) Does the project design include an appropriate exit strategy? (c) Does the project design present strategies to promote/support scaling up, replication and/or catalytic action? (d) Did the design address any/all of the following: socio-political, financial, institutional and environmental sustainability issues? On this issue see also Recommendation 2 of this Evaluation.

Comments	Response by Independent Consultant
Comment 10 Section 5.2, Quality of Project Design	
There is no GTZ biosafety program?	Please refer to ProDoc § 38
Comment 11 Section 5.2, Quality of Project Design	
India already had an NBF in place supported by the Biosafety Rules of 1989. The Evaluator is fundamentally confusing the generic NBF implementation projects with this project	Noted and accepted. For better clarity the wording has been amended to read " had not implemented and satisfactorily strengthened its NBF at the time of the Project design".
Comment 12 Section 5.2, Quality of Project Design	
These documents are regulatory tools especially the manuals that the regulator and the applicant need to be able to go through the pathway of the biosafety process	 This section focuses on the Project Design and its shortcomings. Consequently, the response is contextualised to this specific report section. Of course, the relevance of the manuals to the decision making is undisputed. From a methodological standpoint, the evaluation assumes that the identified Outputs are meant to make a significant contribution to the achievement of the project's direct Outcomes. The fact that Outputs delivery is satisfactory implies good probability of progress in the pathways to Outcomes. However, the evaluation did not identify in the ProDoc, a clear cause-effect description of "why" and "how" the different result levels would lead to the envisaged Impact. For instance, India had already a relevant compendium of guidelines. "Why" would those produced by this Project make the difference at Outcome level? These questions are of interest to an evaluation process. As extensively elaborated in the report, the project's logframe does not fully succeed in elaborating the hierarchy and causal pathways of the envisaged achievements.

Comments	Response by Independent Consultant
Comment 13 Section 5.2, Quality of Project Design	
Component 2 was "Strengthening the Legal and Regulatory Framework" implying the framework already exists. Please look at the objective of the project "is to strengthen the biosafety management system in India to ensure adequate protection of human health and biodiversity from potential harms arising from all living modified organisms (LMOs) related activities in agriculture." The focus was also specific in this particular project on Agriculture, though LMOs are crosscutting and there is a reason for that	• The Evaluator partially agrees with this comment and consequently readjusted the wording on the Main Outcome in an attempt to reach a more suitable and concise expression with which all parties may feel comfortable. The final report also integrated further clarifying elements, including in § 43 and in footnotes 27, 28, and 29, inter alia.
Comment 14 Section 5.2, Quality of Project Design	
India's project is not to do an NBF nor are they obligated to that as they already had an operational biosafety system in place. The comments here are rather confusing and being used to judge a process which is totally different from the implementation of National Biosafety Projects	 Such relevant remarks should have been raised at least at the stage of the Inception Report which was produced at the beginning of the mission, containing a review of the project context, the quality of project design, a draft reconstructed Theory of Change of the project, evaluation framework and a tentative evaluation schedule. The Inception Report underwent a Peer Review at the UN Environment Evaluation Office and was shared with the Biosafety Task Manager at UN Environment.

Comments	Response by Independent Consultant		
Comment 15 Section 5.2, Quality of Project Design			
The project is not a Human Rights based sustainable development approach project but a regulatory project speaking to a specific international instrument on biosafety to which the project design was guided by the Framework Action Plan on capacity building and the GEF Strategy on Biosafety	See above response to Comment 1		
Comment 16 Section 5.4.1, Achievement of Outputs			
The tool required for post-release monitoring was developed and released. An online training module on monitoring of CFTs were developed. These tools are used on a case by case basis on release of LMOs	 Noted and addressed. Footnote number 58 added and § 82 amended to add that an online training module on monitoring of CFTs was also developed. As mentioned in § 82, "post-release monitoring mechanism in place" is not just about the delivery of an Output but about the achievement of a more complex change in the system which corresponds to the "post release monitoring and enforcement" component of a NBF. The comment emphasises the above argument. Outputs (e.g. tools and training packages) actually are the means underpinning the envisaged results in terms of enforcement and monitoring capacities of the system. 		
Comment 17 Section 5.4.1, Achievement of Outputs			
A decision was released on bt Mustard in the life of the project	In the national BCH of India only five records (all cotton related) are found under decisions http://in.biosafetyclearinghouse.net/decisions.shtml and five records under Risk Assessment http://in.biosafetyclearinghouse.net/riskassessments.shtml In BCH international last decision uploaded is dated 2009 (Bt cotton).		

Comments	Response by Independent Consultant		
	The evaluation is evidence based, observing reference to related sources. Please provide reference to the source of information on the bt Mustard for this to be included in the final report.		
Comment 18 Section 5.4.1, Achievement of Outputs			
(On post-release monitoring mechanism) If there is no output, how does the evaluator expect the "complex change" to be initiated or achieved.	See Response to Comment 12 and 16		
Comment 19 Section 5.4.1, Achievement of Outputs			
And also the level of understanding of the various stakeholders and ongoing developments in biotechnology which requires a matching biosafety regulatory system.	"implementing management arrangements" encompasses stakeholders and the opportunity given to them to participate in the process		
Comment 20 Section 5.4.2, Achievement of Direct Outcomes			
(§ 95) There are globally acceptable Risk	Noted and incorporated into the report.		
Assessment. You do not prepare your	The issue was raised by interviewed stakeholders and the evaluation deemed it important to refer to		
tools to suit only your country as this	their perceptions, which may present interesting elements for further analysis.		
must respond to transboundary obligations and best practices. The	• Consequently, § 95 was reworded as follows: "The Direct Outcome 1 was achieved to a satisfactory level, in the perception of the relevant stakeholders who actively participated in the final evaluation exercise.		
country tailored needs aspect was and is	Moreover, in the GEF Tracking Tool, the National team states that the Regulatory Regime has full legal force, is		
usually catered through the biology	operational, and is linked to the administrative system, i.e. used for decisions".		
documents for which India developed 8	The Evaluation notes that achievements under Output 2 (Section 5.4.1) refer to country-tailored tools		
Crop Specific Documents. It must be noted India is the only country aside of	(specific to the Indian context, complying with Annex III of the CPB on case-by-case requirements), which are exhaustive and relevant.		

Comments	Response by Independent Consultant
the OECD processes to develop its own crop-specific biology documents tailored to its country specific crops mostly not covered by the OECD Biosafety Programme which is a global reference source	Based on the comment, a footnote is also added that states: "India is the only country outside of the OECD that processes to develop its own crop specific biology documents tailored to its country specific crops mostly not covered by the OECD Biosafety Programme which is a global reference source".
Comment 21 Section 5.4.2, Achievement of Direct Outcomes	
The obligation for uploading Biosafety decisions relates only to Environmental/Commercial/Deliberate releases. After Bt Cotton, due to the court case and its follow up, even though Bt Brinjal and Bt Mustard were technically cleared the final decision was not made; so it will not be available on the BCH. Whilst there are several laboratory and field trial approvals it is not obligatory for parties to upload those decisions. Please see http://www.geacindia.gov.in/approved-products.aspx It was only in COP-MOP 8 in Cancun in December 2016 that parties are being encouraged to upload such information, but it is voluntary and not obligation in line with article 6 of the Cartagena Protocol on Biosafety	This issue has noted and the wording has been rephrased as follows: "The Direct Outcome 2 was achieved to a satisfactory level. In fact, requests have been received, processed, and decisions communicated to BCH, as pointed-out in the GEF Tracking Tool".

Comments	Response by Independent Consultant		
Comment 22 Section 5.4.2, Achievement of Direct Outcomes			
(Ref: § 101 with regard to 'state of the art communication') Such as ??	State-of-the-art in social communication requires a pre-test to be conducted before the final production of communication material, in order to adjust and fine-tune the product to the targeted public before a significant amount of money is spent on mass production. Once a communication product is widely distributed, a follow-up assessment is an important component in the social communication process.		
Comment 23 Section 5.4.2, Achievement of Direct Outcomes			
The evaluator is pinning on issues which come as a follow up by the government, as what is expected here cannot be fully achieved within a project life span and also by the size of India as a subcontinent	 Noted and accepted. Several issues, to be sustainable, need follow-up by the Government. As for the communication and awareness raising material produced by the project, the Evaluation deems that on the spot follow-up surveys are needed and are feasible. For that, earmarked budget ought to be part of the related activities and service provision contracts. 		
Comment 24 Section 5.7.1, Monitoring design and budgeting			
The evaluation budget initially of \$40,000 was reflected under "others" in the Project budget. The same is captured under the Initial Anubis Budget for evaluations under others. Also under the budget version 1 (initial). All the documents I have referred to are in Anubis under "initial documents" and is aside of auditing. The Terminal evaluation allocation on revisions was increased to \$50,000	The phrase has been reformulated as follows: "amount which was not explicitly reflected in the Project specific budget line (UNEP format) but according to TM information was included in the budget line 'Others'". Others'".		

Comments	Response by Independent Consultant		
Comment 25 Section 5.7.1, Monitoring design and budgeting			
M&E Plan of a good quality but general picture not satisfactory. What is the basis for this assessments	 Section 5.7.1 provides concrete examples on the weaknesses identified in the monitoring design. The assessment criteria used, are specified in the Evaluation Terms of Reference. In assessing the quality of the M&E system, several parameters have to be taken into account. The fact that key M&E tools are in place does not ensure their satisfactory implementation or that each tool is set-up in a satisfactory level. See Recommendation 3 		
Comment 26 Section 5.7.3, Project Reporting			
This follows the structure of UNEP Reporting formats for project closure	The assessment does not refer to the format but to the content.		
Comment 27 Section 5.8.1, Socio- political sustainability			
§ 128 Implies the system is robust to take in concerns of varied stakeholders meanwhile the Evaluation suggests the system is a top-down approach that does not allow public participation. Both the bt Mustard and Bt Brinjal went through a thorough public input and hearing both at the national and international level through the GEAC and that shaped the final decision	 On the issue of public opinion, which constitutes a bottleneck in the progress towards the envisaged aims (see Section 6.1), we would like to add the following elements: The bt Mustard and Bt Brinjal, in terms of public influence in decision-making, have been more complex cases. In the "Risk Communication Strategy for LMOs in Agriculture" (2017) published with the Project's support and referring to Article 23 (see page 5 and 14 on Brinjal case) we learn: "There is a high premium on trust in MOEFCC if it is to facilitate meaningful participation and under Clause 2, consult the public in the decision-making process regarding living modified organisms under Article 23. Whilst the entire process of risk communication is part of a process to build trust through providing direct evidence of its capacity, motivations and alignment of interests for example, this is not to be taken as given. In the specific case in India, it is more likely that public and stakeholders will adopt a low trust position at the beginning of the process. They may regard the Bt Brinjal episode as a breach of trust, certainly an infringement of due process and fairness". 		

Comments	Response by Independent Consultant		
	Both the environmental release of GMO Mustard and Brinjal initially approved by GEAC were halted, due to public inputs, as the TM says. No GEAC decision (either positive or negative) on these two requests of authorisations has been uploaded in the BCH.		
Comment 28 Section 6.2, Lessons Learned			
(Lesson two) Awareness raising and Public Participation are two different issues and the Evaluator seems to be missing the two. The approach in implementation is guided by article 23 of the Cartagena Protocol on Biosafety	 Lesson two affirms the distinction between "awareness-raising" and "public-dialogue and participation". A Lesson should be general, i.e. have the potential for wider applicability. However, when referring to the CPB, "awareness raising and participation" is taken within the scope of Article 23. 		
Comment 29 Section 6.2, Lessons Learned			
(Lesson three) The Project is a GEF project and not a UN Programme, the primary directions and guidance are shaped by the GEF strategy at the time and the Parties guidance on Implementation of the Cartagena Protocol on Biosafety. Even though the issues of Human Rights are integral to the Rio principle, the Evaluation seems to push on the angle of the project as if it is a Human Rights and Gender Equality Mainstreaming Project	See response to comment 1		

Comments	Response by Independent Consultant
Comment 30 Section 6.3,	
Recommendation 4	
The evaluation seems to confuse roles in	See also response to comment 1 and 3
utilisation of resources to a	
regulatory/safety responsibility	
(biosafety) which are totally different.	
Stakeholders were classified in the	
Prodoc and the Terminal Report according	
to these roles,	

ANNEX II. TERMS OF REFERENCE FOR THE EVALUATION

Terminal Evaluation of the UN Environment/Global Environment Facility projects: "Implementation of National Biosafety Framework for Turkey" <u>And</u>

"Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India — Phase II"

a. SECTION 1: PROJECT BACKGROUND AND OVERVIEW

o Project General Information

Table 1. Project summary

GEF Strategic Objective:	SP 6 –	Focal Area(s):	Biosafety
OLI Strategio Objective.	Biosafety/SO3	1 ocui /ii cu(3).	Biosurety
GEF project ID:	4067 (Turkey)	GEF OP#	BS
OLI project ib.	3751 (India)	OLI OI W	D5
UN Environment	January, 2011	UN Environment	Environmental
approval date:	(Turkey)	Sub-programme:	Governance
арриотан аатол	May 2012 (India)	Can programmor	001011100
GEF approval date:	January 2011	Project type:	Medium Size Project
	(Turkey)	3, 31, .	(Turkey)
	August 2011 (India)		Full Size Project (India)
Expected start date:	September 2011	Actual start date:	September 2013
,	(Turkey)		(Turkey)
	September 2011		May 2012 (India)
	(India)		
Planned completion	August 2014 (Turkey)	Actual completion	August 2017 (Turkey)
date:	August 2015 (India)	date:	July 2017 (India)
Planned project budget	US\$ 1,292,650	Actual total	US\$ 532,385.90
at approval:	(Turkey)	expenditures	(Turkey)
	US\$ 8,727,273 (India)	reported as of April	
		2016:	
GEF grant allocation:	US\$ 542,650 (Turkey)	GEF grant	US\$ 175,813.20 (Turkey
	US\$ 2,727,273 (India)	expenditures	as of 30 June 2015)
		reported as of [date]:	US\$ 1,487,953.51.00
			(India as of 30 June
			2016)
Expected Medium-Size	US\$ 750,000 (Turkey)	Secured Medium-	US\$ 291.867,00
Project co-financing:-	US\$ 6,000,000.00	Size Project co-	(Turkey)
	(India)	financing:	US\$ 5,761,994.00
			(India)
First disbursement:	October 2011	Date of financial	-
	(Turkey)	closure:	
No. of revisions:	5 (Turkey)	Date of last revision:	January 2017 (Turkey)
	4 (India)		January 2016 (India)
No. of Steering		Date of last Steering	December, 2014
Committee meetings:		Committee meeting:	(Turkey)
			January 2017 (India)
Mid-term Review/	June, 2012 (Turkey)	Mid-term Review/	N/A
Evaluation (planned	September 2015	Evaluation (actual	
date):	(India)	date):	
Terminal Evaluation	2017	Terminal Evaluation	2017
(planned date):		(actual date):	
Coverage - Country(ies):	Turkey, India	Coverage -	Europe and Asia
		Region(s):	

Project rationale

Turkey

Turkey is one of the richest countries in endemic plants in its geographical zone, with 34 % (3,150) of the species in Turkey being endemic. This high rate of endemism makes Turkey interesting in terms of seed plants and maintains its character as a centre of attraction in this regard. The number of seed plant species identified in Turkey is currently about 9,200 and the number of species and sub-species taxa has reached 11,000. This number increases every day with the identification of new species. As a country having genetic centres of origin and diversity of crops, adverse effects of Living Modified Organisms constitutes substantial threat on conservation and sustainable use of biological diversity in Turkey. Root causes of the threat arise from the insufficient legislative, administrative, institutional and technical capacity to regulate introduction of Living Modified Organisms and to prevent unintentional and/or illegal transboundary movements of them as well as low level of public awareness and participation in biosafety issues. Unregulated introduction of products of modern biotechnology could lead to loss of wild and agricultural biodiversity in Turkey and thus an operational biosafety framework with adequate capacity is required to ensure that the potential benefits of modern biotechnology can be captured in a fully legal and transparent manner.

Turkey has been a Party to the Convention on Biological Diversity since 14 May 1998 and participant of the process of preparations of the Cartagena Protocol on Biosafety since 1998. Turkey also participated to the UN Environment/GEF project on Development of National Biosafety Frameworks between 2002 andn2005. The main components of the framework (comprising of biosafety policy, regulatory regime, monitoring and enforcement, public awareness, education and participation) were reflected on the draft Biosafety Law, which was adopted by the Turkish General National Assembly in March 2010 and entered into force in September 2010.

The National Biosafety Framework (NBF) of Turkey and its Law on Biosafety provide a political and legislative baseline for biosafety. However there were gaps in terms of technical capacity and human resources to achieve a functional system. Institutional gaps also existed for the identification and detection of Living Modified Organisms, implementation of standard methods, and verification of results. The national biosafety Clearing-House Mechanism was also not operational due to technical and financial constraints. Capacities of two food control laboratories had been built up to be able to detect Living Modified Organisms, but still there wasn't sufficient capacity to manage both intentional and unintentional/illegal introduction of Living Modified Organisms. The awareness of the public about Living Modified Organisms had been substantially raised, but disinformation became an important problem due to some inappropriate interventions by programmes of some Non-Governmental Organisations, private sector and the media.

In order to safeguard biodiversity, countries require management systems and frameworks that have the capacity to detect, exclude, eradicate, control and effectively manage introduced organisms that pose a risk to biodiversity. In addition, to be able to implement their obligations, Parties to the Cartagena Protocol on Biosafety need appropriate institutional mechanisms and infrastructure, well-trained human resources, adequate funding as well as easy access to relevant information. Capacity building is therefore a key prerequisite for the effective implementation of the Cartagena Protocol on Biosafety (CPB).

This project builds on UN Environment's portfolio of enabling activities in over 123 countries on capacity building for the implementation of the CPB through the development and implementation of National Biosafety Frameworks. This portfolio has already produced relevant results, generated lessons learned and best practices being used. In this respect, the project will benefit from UN Environment's experience and expertise to develop a fully operational NBF in Turkey, where best practices and lessons learned will add to those being acquired through the eight demonstration projects already being implemented in Turkey.

India

India second worldwide in farm output and a vast majority of its people depend directly on agriculture and forestry for food security and livelihood. In the last decade, per unit productivity in food grains has

plateaued and annual per capita availability is on the decline thereby requiring an urgent need for new technological interventions. India has made rapid progress in biotechnology research and development. The impact of the release of living modified organisms (LMOs) on the sustainable use of biodiversity and human health however continue to be a primary concern among many.

In terms of biosafety law and policies, India was one of the first in the developing world to enact a biosafety regulation in as early as 1989, 3 years before the Convention on Biological Diversity (CBD) was adopted in 1992. The Government of India ratified the Cartagena Protocol on Biosafety (CPB) in 2003 and by 2007, a constellation of legislations cognate to biosafety regulations were developed. Nevertheless, there is an urgent need to strengthen the regulatory procedures and enforcement mechanisms with regard to transboundary movement of LMOs, in view of advancements in crop biotechnology at the national and global level.

The Phase-II Capacity Building Project on Biosafety will build on the foundations of a previous project in India by The GEF and World Bank. It aims to strengthen the biosafety management system in India with special emphasis on Risk Assessment and Management, Handling, Transport, Packaging and Identification of LMOs, Socio Economic Considerations and Public awareness, to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO related activities.

Since India already has several LMOs which are close to commercialization, India will soon be both an exporter and an importer of LMOs. The GOI needs to ensure that biotechnology R&D is guided by a process of prudent decision making that safeguards both biodiversity and human health with adherence to the highest ethical standards.

The project will assist India, to build capacity to strengthen the biosafety management in the country. Strengthening the biosafety management system will be very important to ensure adequate protection of human health and biodiversity from potential harm arising from all LMO related activities, and at the same time, allow the country to derive maximum benefits from biotechnology through increasing crop yields with more "green" practices such as the reduction of pesticide use, less irrigation, less desertification and fewer chemicals to the soil.

Project objectives and components

Turkey

Turkey has globally important components of biological diversity and genetic centres of origin and diversity of genetic resources important for food and agriculture. The overall **goal** (global environmental benefit) of the project is the protection of biological diversity against possible adverse effects of Living Modified Organisms (LMOs) by means of ensuring safe transfer, handling and use, and transboundary movement of LMOs.

To achieve **overall objective** (development objective), the project aims on building capacity in Turkey for effective and full implementation of National Biosafety Framework (NBF) that is in line with national development priorities, Cartagena Protocol and other international obligations.

The **specific objectives** of the project in Turkey are as follows:

- (i) Identification of gaps and need for regional harmonization and consistency where there is potential for reciprocal (transboundary) movement as well as analysis of stakeholders who will take part on implementation of NBF.
- (ii) Putting in effects the administrative and legislative system of biosafety to ensure protection of biological diversity and human health during the development, handling, transport, use, transfer and release of any LMOs.
- (iii) Building institutional and human resource capacity for handling of requests for authorization, decision-making, risk assessment and risk management of LMOs.
- (iv) Building institutional and human resource capacity for effective monitoring, surveillance and inspection of LMOs to ensure compliance with consents and to prevent illegal and/or accidental releases and transboundary movements of LMOs.

(v) Raising awareness of public on issues with regard to safe use of LMOs and building institutional and human resource capacity to ensure their participation into implementation of NBF including decision-making process on authorization of LMOs.

These project objectives were expected to be achieved through five output clusters (project components) with corresponding activities and outcomes, as summarized in Table 2 below. (A detailed Results Framework is available in Annex 14).

Table 2: Summary of Project's Results Framework - Turkey

Project Component	Expected Outcome
1 Stocktaking on biosafety	Outcome 1: Stakeholder and gap analysis with regard to implementation of NBF of Turkey prepared
2 Regulatory biosafety regime	Outcome 2: Regulatory biosafety regime in place and legally mandated
3 System for handling of requests, risk assessment, decision-making and risk management of LMOs	Outcome 3: Functional system for handling of requests, risk assessment, decision-making and risk management of LMOs established
4 Monitoring and inspection system for LMOs	Outcome 4: Monitoring and inspection system for LMOs established
5 Public awareness and participation for biosafety	Outcome 5: Functional system for public awareness and participation established for biosafety

India

The overarching **goal** of this project is to assist the Government of India, as Party to the Cartagena Protocal on Biosafety (CPB), to build capacity to implement the CPB through activities at the national, sub regional and regional levels.

The **overall objective** is to strengthen the biosafety management system in India with special emphasis on four key: Risk Assessment and Management; Socio Economic Considerations; Handling, Transport, Packaging and Identification of LMOs in agriculture; and Public Awareness.

The project's activities were grouped under 8 components: Component 1 involves a stocktaking assessment to assist in priority setting of project activities and ensure that all project outcomes are achieved; Component 2 aims to strengthen the legal and regulatory framework; Component 3 covers the enhancement of institutional capacities; Component 4 is designed to develop human resources; and Component 5 deals with raising public awareness.

Project management and Project monitoring and evaluation form Component 6 and 7; Promotion of regional cooperation, networking and sharing of experience is covered under Component 8.

Components 1-5, with corresponding objectives and expected outcomes, are summarized in Table 2 below. (A detailed Results Framework is available in Annex 14).

Table 3: Summary of Project's Results Framework - India

Project Component	Specific Objectives	Expected Outcomes	
Component 1:	To assist India to update its	Outcome 1: Updated information is	
Stocktaking Assessment		consolidated to guide the planning of specific activities under this project	

Project Component	Specific Objectives	Expected Outcomes	
	documentation and identification for compliance.		
Component 2: Strengthening Regulatory and Legal Framework	To assist India to strengthen biosafety regulatory framework that is consistent with CPB.	Outcome 2.1: A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk	
		Outcome 2.2 : Socio-economic assessment are considered	
		Outcome 2.3: A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB.	
Component 3: Strengthening Institutional Capacity	To assist India to establish a network of laboratories for detection of LMOs.	Outcome 3: Institutions and staff capacity is enhanced for LMO detection	
Component 4: Human Resource Development	To assist India in enhancing human resource for RA, RM, LMO detection and enforcement.	Outcome 4. 1: Human resource is developed for strategic areas such risk evaluation.	
		Outcome 4.2: Enforcement mechanism at the ports of entry is strengthened with trained staff.	
Component 5: Information Dissemination for Enhancing Public Awareness	To assist India to establish and consolidate systems for public education, awareness, participation and access to biosafety information.	Outcome 5: Public awareness on biosafety issues, biosafety regulation and regional cooperation is enhanced	

Executing Arrangements

Turkey

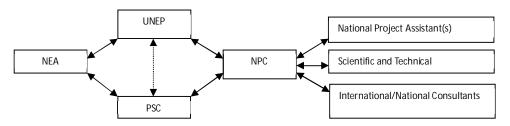
The project was implemented by UN Environment (Implementing Agency). The UN Environment unit responsible for project implementation was the Division of Environmental Policy Implementation (Law Division). The project was executed at the country level by the Ministry of Agriculture and Rural Affairs (MARA) which was also executing agency of National Biosafety Framework development project - the National Executing Agency (NEA). Those duties and responsibilities of the MARA which concern biological diversity are performed by its central and provincial organizations through the General Directorate of Agricultural Research (GDAR), the General Directorate of Protection and Control (GDPC) and the General Directorate of Agricultural Production and Development (GDAPD), which are among its main service units.

A **National Coordinating Committee** (NCC) was established by the National Executing Agency to advise and guide the implementation of the National Biosafety Framework. This committee included representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety as well as the private and public sectors. A **National Project Coordinator** was appointed by the National Executing Agency to be responsible for the overall co-ordination, management and supervision

of all aspects of the National Project. The Project Coordinator reported to the **National Coordinating Committee** and UN Environment, and was expected to 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. The Project Coordinator was also responsible for all substantive, managerial and financial reports from the National Project, overall supervision for project staff, as well as guiding and supervising all other staff appointed for the execution of the various National Project components.

The departments, research institutes and laboratories of the MARA are main the beneficiaries of the project. Governmental institutions who also participated in project activities include: Ministry of Health, Ministry of Justice, Ministry of Industry and Trade, Undersecretary of State Planning Organization, Undersecretary of Foreign Trade, Undersecretary of Customs, Turkish Patent Institute, The Scientific and Technical Research Council of Turkey and Universities. Other key stakeholders of the project include NGOs acting on conservation and sustainable use of biodiversity and on consumer rights as well as the private sector. Figure 1 below shows the project's execution arrangements.

Figure 1: Decision making flowchart and organigram - Turkey



UNEP: UN Environment

NEA: National Executing Agency (Ministry of Agriculture and Rural Affairs, Turkey)

PSC: Project Steering Committee **NPC**: National Project Coordinator

India

The project was implemented by UN Environment (**Implementing Agency**). The UN Environment unit responsible for project implementation was the Division of Environmental Policy Implementation (Law Division).

The project was executed at the country level by the Ministry of Environment and Forests (MoEF) - the **National Executing Agency** (NEA). It is also the the national competent authority for the CPB. The Executing Agency worked on behalf of GOI to manage the project and took overall responsibility for the implementation of the project and achievements of its objectives. It would also provide the necessary scientific, technical, financial and administrative support to the project, working in close cooperation with relevant government agencies, the scientific community and other stakeholders.

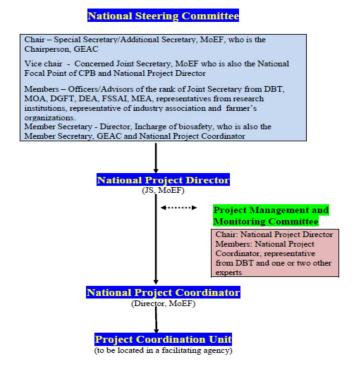
A **National Steering Committee** (NSC) was established by the National Executing Agency to advise and guide the implementation of the project. This committee included representation from government agencies with mandates relevant to the Cartagena Protocol on Biosafety, as well as scientific experts, NGOs and a UNEP representative. The NSC would oversee the project progress through receipt of half-yearly progress reports and make recommendations to UNEP on the need to revise any aspects of the Results Framework or the M&E plan.

A **National Project Director** (NPD) appointed by the Executing Agency provided overall supervision of the project. The NPD was required to oversee the preparation of the annual Project Implementation Reports (PIRs), participate in the mid-term review and terminal evaluation, and at the conclusion of the project oversee the completion of the project closure procedures, including timely submission of all technical, financial and audit reports to UN Environment.

A **National Project Coordinator** also appointed by the National Executing Agency was responsible for the day to day coordination of project activities to ensure implementation of the project activities as set out in the project document. The NPC was also responsible for the preparation of progress and financial reports of the project, as well as of the annual Project Implementation Report (PIR).

A **Project Management and Monitoring Committee** (PMMC) was constituted to provide technical support to the National Project Director and the National Project Coordinator. A **Project Coordination Unit** (PCU) provided the required operational and administrative and technical support for implementation of the project activities. Figure 2 below shows the project's execution arrangements

Figure 2 Decision Making Flow-chart and Organizational Chart - India



o Project Cost and Financing

The project in **Turkey** falls under the medium-size project (MSP) category, with an overall project budget of **US\$1,292,650** that comprised of a GEF allocation of US\$542,650 and an expected counterpart funding from the government of Turkey of US\$ 550,000 in cash and US\$ 200,000 in-kind.

The project in **India** falls under the full-size project (FSP) category, with an overall project budget of **US\$ 8,727,273** comprising US\$ 2,727,273 from the GEFand an expected counterpart funding from the government of India of US\$900,000 in cash and US\$5,100,000 in kind, amounting to a total of US\$ 6,000,000.

Table 4. Estimated project budget by component (USD) - Turkey

Component	GEF	Co-Financing	Total
1 Stocktaking on biosafety	5,000	5,000	10,000
2 Regulatory biosafety regime	14,000	17,000	31,000
3 System for handling of requests, risk assessment, decision-making and risk management of LMOs	128,000	176,500	304,500

Component	GEF	Co-Financing	Total
4 Monitoring and inspection system for LMOs	272,650	350,000	622,650
5 Public awareness and participation for biosafety	53,000	101,500	154,500
M&E	20,000	25,000	45,000
Project Management	50,000	75,000	125,000
TOTAL	542,650	750,000	1,292,650

Table 5. Estimated project budget by component (USD) - India

	Project (B)	
GEF financing	2,727,273	
Co-financing	6,000,000	
Total	8,727,273	

Implementation Issues

Turkey: Delays in implementation of some project components, especially the technical studies, have mainly been related to delays in receiving during the transition to UNOJA⁸¹ funds form UN Environment. To counter the risks associated with these challenges, project extension was made to extend the technical duration of the project up to December 2016 to allow for review, finalisation, translation and publishing of guidelines on application procedures, legal issues, risk assessment, socio-economic assessment, emergency measures, traceability, control and inspection of LMOs and organisation of relevant meetings. Another project extension was granted to extend the project to end in August 2017 to allow for the completion of outstanding activities. In spite of these revisions to the project document and budget, the total cost of the project has remained unchanged.

India: The project did not experience any major setbacks. Most notable implementation issue was a delayed start of the by 1.5 years. The project has however progressed well and has completed most of the project activities with the help of project partners and the Project Coordination Unit (PCU). No-cost extensions were required to re-phase the budget and complete outstanding activities and outputs before closing the project, for example: state level training workshops; development of an E-Learning Module on ERA of GE Plants; establishment of an e-Monitoring mechanism; various reports from agencies under the 'Handling, Transport, Packaging and Identification' thrust area; finalization of the Risk Communication Strategy; and development and distribution of outreach materials developed under the project.

b. SECTION 2. OBJECTIVE AND SCOPE OF THE EVALUATION

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) as far as possible, and when verification is not possible, the single source will be mentioned (whilst anonymity is still protected). Analysis leading to evaluative judgements should always be clearly spelled out.

⁸¹ UN+MOJA is a complete re-working of the way the United Nations Secretariat manages its administration, in both business processes and Information Technology solutions. A new central administrative system, UMOJA replaces multiple and fragmented legacy systems such as IMIS, Mercury and Sun.

The "Why?" Question. As this is a terminal evaluation and similar interventions are envisaged for the future, particular attention should be given to learning from the experience. Therefore, the "Why?" question should be at the front of the consultants' minds all through the evaluation exercise and is supported by the use of a theory of change approach. This means that the consultants need 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. This should provide the basis for the lessons that can be drawn from the project.

Baselines and counterfactuals. In attempting to attribute any outcomes and impacts to the project intervention, the evaluators 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, trends and counterfactuals in relation to the intended project outcomes and impacts. It 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, trends or counterfactuals 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.

Communicating evaluation results. A key aim of the evaluation is to encourage reflection and learning by UN Environment staff and key project stakeholders. The consultant should consider how reflection and learning can be promoted, both through the evaluation process and in the communication of evaluation findings and key lessons. Clear and concise writing is required on all evaluation deliverables. Draft and final versions of the main evaluation report will be shared with key stakeholders by the Evaluation Office. There may, however, be several intended audiences, each with different interests and needs regarding the report. The Evaluation Manager will plan with the consultant(s) which audiences to target and the easiest and clearest way to communicate the key evaluation findings and lessons to them. This may include some or all of the following; a webinar, conference calls with relevant stakeholders, the preparation of an evaluation brief or interactive presentation.

o Objective of the Evaluation

In line with the UN Environment Evaluation Policy⁸² and the UN Environment Programme Manual⁸³, the Terminal Evaluation (TE) is undertaken at 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 has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote operational improvement, learning and knowledge sharing through results and lessons learned among UN Environment and the project's main partners. Therefore, the evaluation will identify lessons of operational relevance for future project formulation and implementation [especially for the second phase of the project, if applicable].

Key Strategic Questions

In addition to the evaluation criteria outlined from para. 8 below, the evaluation will address the **strategic questions** listed below. These are questions of interest to UN Environment and to which the project is believed to be able to make a substantive contribution:

1. To what extent were these projects able to assist Turkey and India to establish and consolidate a fully **functional and responsive regulatory regime** that responds to their obligations under the Cartagena Protocol on Biosafety as well as their national needs for a viable and profitable National Biosafety Framework?

⁸² http://www.UN Environment.org/eou/StandardsPolicyandPractices/UN ENVIRONMENTEvaluationPolicy/tabid/3050/language/en-US/Default.aspx

⁸³ http://www.UN Environment.org/QAS/Documents/UN ENVIRONMENT_Programme_Manual_May_2013.pdf . *This manual is under revision.*

- 2. To what extent were these projects able to develop **institutional and technical capacity**, **awareness and participation** amongst the key actors to ensure that biosafety becomes part of their permanent action?
- 3. To what extent was the project able to assist Turkey and India establish and consolidate a functional national monitoring system for Biotechnology to follow up on the releases of Living Modified Organisms (LMOs) and their possible effects on the environment?
- 4. To what extent are the **outcome indicators verifiable**, and record progresses towards the achievement of the development objectives, as well as the obligations under the Cartagena Protocol?

Evaluation Criteria

All evaluation criteria will be rated on a six-point scale. Sections A-I below, outline the scope of the criteria and a link to a table for recording the ratings is provided in Annex 1). A weightings table will be provided in excel format (link provided in Annex 1) to support the determination of an overall project rating. The set of evaluation criteria are grouped in nine categories: (A) Strategic Relevance; (B) Quality of Project Design; (C) Nature of External Context; (D) Effectiveness, which comprises assessments of the achievement of outputs, achievement of outcomes and likelihood of impact; (E) Financial Management; (F) Efficiency; (G) Monitoring and Reporting; (H) Sustainability; and (I) Factors Affecting Project Performance. The evaluation consultant can propose other evaluation criteria as deemed appropriate. The following criteria apply to **each** project (i.e. **Turkey** and **India**)

A. Strategic Relevance

The evaluation will assess, in line with the OECD/DAC definition of relevance, 'the extent to which the activity is suited to the priorities and policies of the target group, recipient and donor'. The evaluation will include an assessment of the project's relevance in relation to UN Environment's mandate and its alignment with UN Environment's policies and strategies at the time of project approval. Under strategic relevance an assessment of the complementarity of the project with other interventions addressing the needs of the same target groups will be made. This criterion comprises four elements:

i. Alignment to the UN Environment Medium Term Strategy84 (MTS) and Programme of Work (POW)

The evaluation should assess the project's alignment with the MTS and POW under which the project was approved and include reflections on the scale and scope of any contributions made to the planned results reflected in the relevant MTS and POW.

ii. Alignment to UN Environment /GEF/Donor Strategic Priorities

Donor, including GEF, strategic priorities will vary across interventions. UN Environment strategic priorities include the Bali Strategic Plan for Technology Support and Capacity Building⁸⁵ (BSP) and South-South Cooperation (S-SC). The BSP relates to the capacity of governments to: comply with international agreements and obligations at the national level; promote, facilitate and finance environmentally sound technologies and to strengthen frameworks for developing coherent international environmental policies. S-SC is regarded as the exchange of resources, technology and knowledge between developing countries. GEF priorities are specified in published programming priorities and focal area strategies.

iii. Relevance to Regional, Sub-regional and National Environmental Priorities

The evaluation will assess the extent to which the intervention is suited, or responding to, the stated environmental concerns and needs of the countries, sub-regions or regions where it is being implemented. Examples may include: national or sub-national development plans, poverty reduction strategies or Nationally Appropriate Mitigation Action (NAMA) plans or regional agreements etc.

⁸⁴ UN Environment's Medium Term Strategy (MTS) is a document that guides UN Environment's programme planning over a four-year period. It identifies UN Environment's thematic priorities, known as Sub-programmes (SP), and sets out the desired outcomes, known as Expected Accomplishments (EAs), of the Sub-programmes.

⁸⁵ http://www.UN Environment.org/GC/GC23/documents/GC23-6-add-1.pdf

iv. Complementarity with Existing Interventions

An assessment will be made of how well the project, either at design stage or during the project mobilization, took account of ongoing and planned initiatives (under the same sub-programme, other UN Environment sub-programmes, or being implemented by other agencies) that address similar needs of the same target groups. The evaluation will consider if the project team, in collaboration with Regional Offices and Sub-Programme Coordinators, made efforts to ensure their own intervention was complementary to other interventions, optimized any synergies and avoided duplication of effort. Examples may include UNDAFs or One UN programming. Linkages with other interventions should be described and instances where UN Environment's comparative advantage has been particularly well applied should be highlighted.

<u>Factors affecting this criterion may include</u>: stakeholders' participation and cooperation; responsiveness to human rights and gender equity and country ownership and driven-ness.

B. Quality of Project Design

The quality of project design is assessed using an agreed template during the evaluation inception phase, ratings are attributed to identified criteria and an overall Project Design Quality rating is established. This overall Project Design Quality rating is entered in the final evaluation ratings table as item B. In the Main Evaluation Report a summary of the project's strengths and weaknesses at design stage is included.

<u>Factors affecting this criterion may include (at the design stage)</u>: stakeholders participation and cooperation and responsiveness to human rights and gender equity, including the extent to which relevant actions are adequately budgeted for.

C. Nature of External Context

At evaluation inception stage a rating is established for the project's external operating context (considering the prevalence of conflict, natural disasters and political upheaval). This rating is entered in the final evaluation ratings table as item C. Where a project has been rated as facing either an Unfavourable or Highly Unfavourable and unexpected external operating context, the overall rating for Effectiveness may be increased at the discretion of the Evaluation Consultant and Evaluation Manager together. A justification for such an increase must be given.

D. Effectiveness

The evaluation will assess effectiveness across three dimensions: achievement of outputs, achievement of direct outcomes and likelihood of impact.

i. Achievement of Outputs

The evaluation will assess the project's success in producing the programmed outputs (products and services delivered by the project itself) and achieving milestones as per the project design document (ProDoc). Any *formal* modifications/revisions made during project implementation will be considered part of the project design. Where the project outputs are inappropriately or inaccurately stated in the ProDoc, a table should be provided showing the original formulation and the amended version for transparency. The achievement of outputs will be assessed in terms of both quantity and quality, and the assessment will consider their usefulness and the timeliness of their delivery. The evaluation will briefly explain the reasons behind the success or shortcomings of the project in delivering its programmed outputs and meeting expected quality standards.

<u>Factors affecting this criterion may include:</u> preparation and readiness and quality of project management and supervision⁸⁶.

⁸⁶ In some cases 'project management and supervision' will refer to the supervision and guidance provided by UN Environment to implementing partners and national governments while in others, specifically for GEF funded projects, it will refer to the project management performance of the executing agency and the technical backstopping provided by UN Environment.

ii. Achievement of Direct Outcomes

The achievement of direct outcomes is assessed as performance against the direct outcomes as defined in the reconstructed⁸⁷ Theory of Change. These are the first-level outcomes expected to be achieved as an immediate result of project outputs. As in 1, above, a table can be used where substantive amendments to the formulation of direct outcomes is necessary. The evaluation should report evidence of attribution between UN Environment's intervention and the direct outcomes. In cases of normative work or where several actors are collaborating to achieve common outcomes, evidence of the nature and magnitude of UN Environment's contribution should be included.

<u>Factors affecting this criterion may include:</u> quality of project management and supervision; stakeholders' participation and cooperation; responsiveness to human rights and gender equity and communication and public awareness.

iii. Likelihood of Impact

Based on the articulation of longer term effects in the reconstructed TOC (i.e. from direct outcomes, via intermediate states, to impact), the evaluation will assess the likelihood of the intended, positive impacts becoming a reality. The Evaluation Office's approach to the use of TOC in project evaluations is outlined in a guidance note available on the EOU website (http://www.unep.org/evaluation/) and is supported by an excel-based flow chart called, Likelihood of Impact Assessment (see Annex 1). Essentially the approach follows a 'likelihood tree' from direct outcomes to impacts, taking account of whether the assumptions and drivers identified in the reconstructed TOC held. Any unintended positive effects should also be identified and their causal linkages to the intended impact described.

The evaluation will also consider the likelihood that the intervention may lead, or contribute to, unintended negative effects. Some of these potential negative effects may have been identified in the project design as risks or as part of the analysis of Environmental, Social and Economic Safeguards.⁸⁸

The evaluation will consider the extent to which the project has played a catalytic role or has promoted scaling up and/or replication⁸⁹ as part of its Theory of Change and as factors that are likely to contribute to longer term impact.

Ultimately UN Environment and all its partners aim to bring about benefits to the environment and human well-being. Few projects are likely to have impact statements that reflect such long-term or broad-based changes. However, the evaluation will assess the likelihood of the project to make a substantive contribution to the high level changes represented by UN Environment's Expected Accomplishments, the Sustainable Development Goals⁹⁰ and/or the high level results prioritised by the funding partner.

<u>Factors affecting this criterion may include:</u> quality of project management and supervision, including adaptive project management; stakeholders participation and cooperation; responsiveness to human rights and gender equity; country ownership and driven-ness and communication and public awareness.

⁸⁷ UN Environment staff are currently required to submit a Theory of Change with all submitted project designs. The level of 'reconstruction' needed during an evaluation will depend on the quality of this initial TOC, the time that has lapsed between project design and implementation (which may be related to securing and disbursing funds) and the level of any changes made to the project design. In the case of projects pre-dating 2013 the intervention logic is often represented in a logical framework and a TOC will need to be constructed in the inception stage of the evaluation.

⁸⁸ Further information on Environmental, Social and Economic Safeguards (ESES) can be found at http://www.UN Environment.org/about/eses/

Scaling up refers to approaches being adopted on a much larger scale, but in a very similar context. Scaling up is often the longer term objective of pilot initiatives. *Replication* refers to approaches being repeated or lessons being explicitly applied in new/different contexts e.g. other geographic areas, different target group etc. Effective replication typically requires some form of revision or adaptation to the new context. It is possible to replicate at either the same or a different scale.

⁹⁰ A list of relevant SDGs is available on the EO website www.UN Environment.org/evaluation

E. Financial Management

Financial management will be assessed under three broad themes: *completeness* of financial information, *communication* between financial and project management staff and *compliance* with relevant UN financial management standards and procedures. The evaluation will establish the actual spend across the life of the project of funds secured from all donors. This expenditure will be reported, where possible, at output level and will be compared with the approved budget. The evaluation will assess the level of communication between the Task Manager and the Fund Management Officer as it relates to the effective delivery of the planned project and the needs of a responsive, adaptive management approach. The evaluation will verify the application of proper financial management standards and adherence to UN Environment's financial management policies. Any financial management issues that have affected the timely delivery of the project or the quality of its performance will be highlighted.

Factors affecting this criterion may include: preparation and readiness and quality of project management and supervision.

F. Efficiency

In keeping with the OECD/DAC definition of efficiency, the evaluation will assess the cost-effectiveness and timeliness of project execution. Focussing on the translation of inputs into outputs, cost-effectiveness is the extent to which an intervention has achieved, or is expected to achieve, its results at the lowest possible cost. Timeliness refers to whether planned activities were delivered according to expected timeframes as well as whether events were sequenced efficiently. The evaluation will also assess to what extent any project extension could have been avoided through stronger project management and identify any negative impacts caused by project delays or extensions. The evaluation will describe any cost or time-saving measures put in place to maximise results within the secured budget and agreed project timeframe and consider whether the project was implemented in the most efficient way compared to alternative interventions or approaches.

The evaluation will give special attention to efforts by the project teams to make use of/build upon preexisting institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. to increase project efficiency. The evaluation will also consider the extent to which the management of the project minimised UN Environment's environmental footprint.

<u>Factors affecting this criterion may include:</u> preparation and readiness (e.ge. timeliness); quality of project management and supervision and stakeholders participation and cooperation.

G. Monitoring and Reporting

The evaluation will assess monitoring and reporting across three sub-categories: monitoring design and budgeting, monitoring implementation and project reporting.

i. Monitoring Design and Budgeting

Each project should be supported by a sound monitoring plan that is designed to track progress against SMART⁹¹ indicators towards the achievement of the projects outputs and direct outcomes, including at a level disaggregated by gender or groups with low representation. The evaluation will assess the quality of the design of the monitoring plan as well as the funds allocated for its implementation. The adequacy of resources for mid-term and terminal evaluation/review should be discussed if applicable.

ii. Monitoring Implementation

The evaluation will assess whether the monitoring system was operational and facilitated the timely tracking of results and progress towards projects objectives throughout the project implementation period. It will also consider how information generated by the monitoring system during project implementation was used to adapt and improve project execution, achievement of outcomes and ensure sustainability. The evaluation should confirm that funds allocated for monitoring were used to support this activity.

⁹¹ SMART refers to indicators that are specific, measurable, assignable, realistic and time-specific.

iii. Project Reporting

UN Environment has a centralised Project Information Management System (PIMS) in which project managers upload six-monthly status reports against agreed project milestones. This information will be provided to the Evaluation Consultant(s) by the Evaluation Manager. Some projects have additional requirements to report regularly to funding partners, which will be supplied by the project team (specifically the Project Implementation Reviews and Tracking Tool). The evaluation will assess the extent to which both UN Environment and donor reporting commitments have been fulfilled.

<u>Factors affecting this criterion may include:</u> quality of project management and supervision and responsiveness to human rights and gender equity (e.g. disaggregated indicators and data).

H. Sustainability

Sustainability is understood as the probability of direct outcomes being maintained and developed after the close of the intervention. The evaluation will identify and assess the key conditions or factors that are likely to undermine or contribute to the persistence of achieved direct outcomes. Some factors of sustainability may be embedded in the project design and implementation approaches while others may be contextual circumstances or conditions that evolve over the life of the intervention. Where applicable an assessment of bio-physical factors that may affect the sustainability of direct outcomes may also be included.

i. Socio-political Sustainability

The evaluation will assess the extent to which social or political factors support the continuation and further development of project direct outcomes. It will consider the level of ownership, interest and commitment among government and other stakeholders to take the project achievements forwards. In particular the evaluation will consider whether individual capacity development efforts are likely to be sustained.

ii. Financial Sustainability

Some direct outcomes, once achieved, do not require further financial inputs, e.g. the adoption of a revised policy. However, in order to derive a benefit from this outcome further management action may still be needed e.g. to undertake actions to enforce the policy. Other direct outcomes may be dependent on a continuous flow of action that needs to be resourced for them to be maintained, e.g. continuation of a new resource management approach. The evaluation will assess the extent to which project outcomes are dependent on future funding for the benefits they bring to be sustained. Secured future funding is only relevant to financial sustainability where the direct outcomes of a project have been extended into a future project phase. The question still remains as to whether the future project outcomes will be financially sustainable.

iii. Institutional Sustainability

The evaluation will assess the extent to which the sustainability of project outcomes is dependent on issues relating to institutional frameworks and governance. It will consider whether institutional achievements such as governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. are robust enough to continue delivering the benefits associated with the project outcomes after project closure.

<u>Factors affecting this criterion may include:</u> Stakeholders participation and cooperation; responsiveness to human rights and gender equity (e.g. where interventions are not inclusive, their sustainability may be undermined); communication and public awareness and country ownership and driven-ness.

I. <u>Factors and Processes Affecting Project Performance</u>

(These factors are rated in the ratings table, but are discussed as cross-cutting themes as appropriate under the other evaluation criteria, above).

i. Preparation and Readiness

This criterion focuses on the inception or mobilisation stage of the project. The evaluation will assess whether appropriate measures were taken to either address weaknesses in the project design or

respond to changes that took place between project approval, the securing of funds and project mobilisation. In particular the evaluation will consider the nature and quality of engagement with stakeholder groups by the project team, the confirmation of partner capacity and development of partnership agreements as well as initial staffing and financing arrangements. (Project preparation is covered in the template for the assessment of Project Design Quality).

ii. Quality of Project Management and Supervision

In some cases 'project management and supervision' will refer to the supervision and guidance provided by UN Environment to implementing partners and national governments while in others, specifically for GEF funded projects, it will refer to the project management performance of the executing agency and the technical backstopping and supervision provided by UN Environment.

The evaluation will assess the effectiveness of project management with regard to: providing leadership towards achieving the planned outcomes; managing team structures; maintaining productive partner relationships (including Steering Groups etc.); communication and collaboration with UN Environment colleagues; risk management; use of problem-solving; project adaptation and overall project execution. Evidence of adaptive project management should be highlighted.

iii. Stakeholder Participation and Cooperation

Here the term 'stakeholder' should be considered in a broad sense, encompassing all project partners, duty bearers with a role in delivering project outputs and target users of project outputs and any other collaborating agents external to UN Environment. The assessment will consider the quality and effectiveness of all forms of communication and consultation with stakeholders throughout the project life and the support given to maximise collaboration and coherence between various stakeholders, including sharing plans, pooling resources and exchanging learning and expertise. The inclusion and participation of all differentiated groups, including gender groups, should be considered.

iv. Responsiveness to Human Rights and Gender Equity

The evaluation will ascertain to what extent the project has applied the UN Common Understanding on the human rights based approach (HRBA) and the UN Declaration on the Rights of Indigenous People. Within this human rights context the evaluation will assess to what extent the intervention adheres to UN Environment's Policy and Strategy for Gender Equality and the Environment.

The report should present the extent to which the intervention, following an adequate gender analysis at design stage, has implemented the identified actions and/or applied adaptive management to ensure that Gender Equity and Human Rights are adequately taken into account. In particular, the evaluation will consider to what extent project design (section B), the implementation that underpins effectiveness (section D), and monitoring (section G) 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; (iii) the role of women in mitigating or adapting to environmental changes and engaging in environmental protection and rehabilitation.

v. Country Ownership and Driven-ness

The evaluation will assess the quality and degree of engagement of government / public sector agencies in the project. The evaluation will consider the involvement not only of those directly involved in project execution and those participating in technical or leadership groups, but also those official representatives whose cooperation is needed for change to be embedded in their respective institutions and offices. This factor is concerned with the level of ownership generated by the project over outputs and outcomes and that is necessary for long term impact to be realised. This ownership should adequately represent the needs and interests of all gender and marginalised groups.

vi. Communication and Public Awareness

The evaluation will assess the effectiveness of: a) communication of learning and experience sharing between project partners and interested groups arising from the project during its life and b) public awareness activities that were undertaken during the implementation of the project to influence attitudes or shape behaviour among wider communities and civil society at large. The evaluation should

consider whether existing communication channels and networks were used effectively, including meeting the differentiated needs of gender and marginalised groups, and whether any feedback channels were established. Where knowledge sharing platforms have been established under a project the evaluation will comment on the sustainability of the communication channel under either sociopolitical, institutional or financial sustainability, as appropriate.

c. SECTION 3. EVALUATION APPROACH, METHODS AND DELIVERABLES

The Terminal Evaluation will be an in-depth evaluation 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 as appropriate to determine project achievements against the expected outputs, outcomes and impacts. It is highly recommended that the consultant(s) maintains close communication with the project team and promotes information exchange throughout the evaluation implementation phase in order to increase their (and other stakeholder) ownership of the evaluation findings.

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

(a) A desk review of:

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 (including project design approvals/endorsement, GEF Secretariat Project Review sheet, approved project document (ProDoc), Annual Work Plans and Budgets or equivalent, revisions to the project (Project Document Supplement), the logical/results framework and its budget;

Project reports such as six-monthly progress reports including the Project Implementation Reviews and Tracking Tool etc., quarterly financial expenditure reports, progress reports from collaborating partners, relevant meeting minutes, relevant correspondence, etc.

Project outputs, as applicable, based on the results framework;

Any other documentation deemed relevant for the accurate assessment of the project's implementation.

(b) Interviews (individual or in group) with:

UN Environment Task Manager (TM) - Alex Owusu-Biney;

Project management team based in the project countries;

UN Environment Fund Management Officer (FMO) - Paul Vrontamitis;

Sub-Programme Coordinator – Cristina Zucca;

Project partners – relevant government ministries, national and local non-governmental organizations, private sector, universities and research institutes;

Other relevant resource persons.

Surveys - as deemed appropriate, and based on the stakeholders analysis

Field visits to the relevant project participants and pilot sites in Turkey.

Other data collection tools as will be found appropriate to supplement information for these evaluations.

Evaluation Deliverables and Review Procedures

The consultant will prepare and submit the following deliverables for each project (Turkey and India):

- Inception Report: (see Annex 1 for links to all templates, tables and guidance notes) containing an assessment of project design quality, a draft reconstructed Theory of Change of the project, project project stakeholder analysis, evaluation framework and a tentative evaluation schedule.
- Draft and Final Evaluation Report: (see links in Annex 1) containing an executive summary that
 can act as a stand-alone document; detailed analysis of the evaluation findings organised by
 evaluation criteria and supported with evidence; lessons learned and recommendations and an
 annotated ratings table.

• Evaluation Brief: a 2-page summary of key evaluation results for wider dissemination through the EOU website.

Detailed Review Procedure

Review procedure for the evaluation report. The evaluation team will submit a draft report to the Evaluation Manager and revise the draft in response to their comments and suggestions. Once a draft of adequate quality has been peer-reviewed and accepted, the Evaluation Manager will share the cleared draft report with the Project Manager, who will alert the Evaluation Manager in case the report contains any blatant factual errors. The Evaluation Manager will then forward revised draft report (corrected by the evaluation team where necessary) to other project stakeholders, for their review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions as well as providing feedback on the proposed recommendations and lessons. Any comments or responses to draft reports will be sent to the Evaluation Manager for consolidation. The Evaluation Manager will provide all comments to the evaluation team for consideration in preparing the final report, along with guidance on areas of contradiction or issues requiring an institutional response.

Based on a careful review of the evidence collated by the evaluation consultants and the internal consistency of the report, the Evaluation Manager will provide an assessment of the ratings in the final evaluation report. Where there are differences of opinion between the evaluator and the Evaluation Manager on project ratings, both viewpoints will be clearly presented in the final report. The Evaluation Office ratings will be considered the final ratings for the project.

The Evaluation Manager will prepare a **quality assessment** of the first and final drafts of the main evaluation report, which acts as 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 template listed in Annex 1.

At the end of the evaluation process, the Evaluation Office will prepare a **Recommendations Implementation Plan** in the format of a table, to be completed and updated at regular intervals by the Task Manager. The Evaluation Office will track compliance against this plan on a six monthly basis.

o The Consultant

For this evaluation, one consultant will work under the overall responsibility of the Evaluation Office represented by an Evaluation Manager (Pauline Marima), in consultation with the UN Environment Task Manager (Alex Owusu-Biney), Fund Management Officer (Paul Vrontamitis⁹²) and the Sub-programme Coordinator of the Environmental Governance Sub-programme (Cristina Zucca). The consultant will liaise with the Evaluation Manager on any procedural and methodological matters related to the evaluation. It is, however, the consultant's individual responsibility to arrange for their travel, visa, obtain documentary evidence, plan meetings with stakeholders, organize online surveys, and any other logistical matters related to the assignment. The UN Environment Task Manager and project teams will, where possible, provide logistical support (introductions, meetings etc.) allowing the consultant to conduct the evaluation as efficiently and independently as possible.

The consultant will be hired the over the period August /2017 to January/2018 during which time the evaluation deliverables listed in Section 11 'Evaluation Deliverables' above should be submitted.

S/he should have: an advanced university degree in sciences, evaluation experience preferably using a Theory of Change approach, at least 15 years' experience in environmental management or a related field, with a preference for specific expertise in the area of biosafety and biodiversity. Knowledge of English language along with excellent writing skills in English is required. Experience in managing partnerships, knowledge management and communication is desirable for all evaluation consultants.

The consultant will be responsible, in close consultation with the Evaluation Office of UN Environment, for overall management of these evaluations and timely delivery of their outputs, described above in Section 11 Evaluation Deliverables, above. The consultant will ensure that all evaluation criteria and questions are adequately covered. Detailed guidelines for the Evaluation Consultant can be found on

⁹² Ruth Irungu supports Paul Vrontamitis in the fund management of the projects

the Evaluation Office of UN Environment website: (<a href="http://web.unep.org/evaluation/working-us/working-u

Specific Responsibilities:

The Consultant will be responsible, in close consultation with the Evaluation Office of UN Environment, for overall management of the evaluation and timely delivery of its outputs, described in Section 11 Evaluation Deliverables, above. The consultant will ensure that all evaluation criteria and questions are adequately covered. S/he will be responsible for the evaluation design, data collection and analysis, and report-writing. More specifically:

Inception phase of the evaluation, including:

- preliminary desk review and introductory interviews with project staff;
- draft the reconstructed Theory of Change of the project;
- prepare the evaluation framework;
- develop the desk review, interview protocols, data collection and analysis tools;
- plan the evaluation schedule;
- prepare the Inception Report, incorporating comments received from the Evaluation Office.

Data collection and analysis phase of the evaluation, including:

- conduct further desk review and in-depth interviews with project implementing and executing agencies, project partners and project stakeholders;
- conduct an evaluation mission to Cameroon visit the project locations, interview project partners and stakeholders, including a good representation of local communities. Ensure independence of the evaluation and confidentiality of evaluation interviews.
- regularly report back to the Evaluation Office on progress and inform of any possible problems or issues encountered and;
- keep the Project/Task Manager informed of the evaluation progress and engage the Project/Task Manager in discussions on emerging findings throughout the evaluation process.

Reporting phase, including:

- draft the Main Evaluation Report, ensuring that the evaluation report is complete, coherent and consistent with the Evaluation Office guidelines both in substance and style;
- liaise with the Evaluation Office on comments received and finalize the Main Evaluation Report, ensuring that comments are taken into account
- prepare a Response to Comments annex for the main report, listing those comments not accepted by the Evaluation Consultant and indicating the reason for the rejection; and
- prepare a 2-page summary of the key evaluation findings and lessons;

Managing relations, including:

- maintain a positive relationship with evaluation stakeholders, ensuring that the evaluation process is as participatory as possible but at the same time maintains its independence;
- communicate in a timely manner with the Evaluation Office on any issues requiring its attention and intervention.

o Schedule of the evaluation

The table below presents the tentative schedule for the evaluation.

Table 6. Tentative schedule for the evaluation - Turkey and India

Milestone	Tentative schedule
Kick-off meeting (via Skype)	Late August 2017

Inception Report	Early September 2017
Data collection and analysis, desk-based interviews and surveys	August - October 2017
Field Mission approx. 5 days in Turkey and approx. 5 days in India (based on meeting arrangements and available budget)	Early October 2017
Draft report to Evaluation Manager (and Peer Reviewer)	End of October 2017
Draft Report shared with UN Environment Task Manager and Project Team	November 2017
Draft Report shared with wider group of stakeholders	December 2017
Final Report	January 2018

Contractual Arrangements

Evaluation Consultants are selected and recruited by the Evaluation Office of UN Environment under an individual Special Service Agreement (SSA) on a "fees only" basis (see below). By signing the service contract with UN Environment/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, they will not have any future interests (within six months after completion of the contract) with the project's executing or implementing units. All consultants are required to sign the Code of Conduct Agreement Form

Fees will be paid on an instalment basis, paid on acceptance by the Evaluation Office of expected key deliverables. The schedule of payment is as follows:

Table 7. Schedule of Payment for the Consultant:

Deliverable	Percentage Payment
Approved Inception Report	30%
Approved Draft Main Evaluation Report	40%
Approved Final Main Evaluation Report	30%

<u>Fees only contracts:</u> Air tickets will be purchased by UN Environment and 75% of the DSA for each authorised travel mission will be paid up front. Local in-country travel will only be reimbursed where agreed in advance with the Evaluation Office and on the production of acceptable receipts. Terminal expenses and residual DSA entitlements (25%) will be paid after mission completion.

The consultant may be provided with access to UN Environment's Programme Information Management System (PIMS) and if such access is granted, the consultant agrees not to disclose information from that system to third parties beyond information required for, and included in, the evaluation report.

In case the consultant is not able to provide the deliverables in accordance with these guidelines, and in line with the expected quality standards by the UN Environment Evaluation Office, payment may be withheld at the discretion of the Director of the Evaluation Office until the consultants have improved the deliverables to meet UN Environment's quality standards.

If the consultant fails to submit a satisfactory final product to UN Environment in a timely manner, i.e. before 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 consultants' fees by an amount equal to the additional costs borne by the Evaluation Office to bring the report up to standard.

ANNEX III. EVALUATION ITINERARY, CONTAINING THE NAMES OF LOCATIONS VISITED AND THE NAMES (OR FUNCTIONS) AND OF PEOPLE MET/INTERVIEWED

Meetings held from November 27- December 1, 2017

Date	Location	Meeting	Participants
November		, <u></u>	
27, 2017	Ministry of	Meeting with NPC	- Ms Madhumita Biswas,
27,2017	Environment,	and officers from	Adviser, MoEFCC – The current
10.30 AM	Forest and	biosafety division	National Project Coordinator (NPC)
10.30 AIVI	Climate Change	biosalety division	Email: mbiswas.17@gov.in
	Cilitiate Change		- Dr Murali Krishna Chimata,
			Joint Director, MoEFCC Email:
			cm.krishna@gov.in
			- Mr Rajeev Ranjan, Asst Section Officer, MoEFCC Email:
			·
		Mosting with former	rajeev.90@gov.in
		Meeting with former NPD and former	Chri Ham Danda Caeratan
12.30 PM	India Habitat	NPC	- Shri Hem Pande, Secretary
12.30 PIVI	Centre	INPC	(Former), Department of Consumer Affairs, Ministry of Consumer Affairs,
	Centre	Mosting with former	Food and Public Distribution Email:
3.00 PM	Ministry of	Meeting with former NPD	hempande@nic.in
3.00 PIVI	Statistics and	INPU	- Dr Ranjini Warrier, Adviser
			(Former), Ministry of Environment,
	Programme Implementation		Forest and Climate Change (MoEFCC)
	Implementation		Email: warrier@nic.in
			Email: <u>warner@nic.in</u>
			- Dr Amita Prasad Additional
			Secretary, Ministry of Statistics and
			Program Implementation (Former
			NPD) Email: as-mospi@nic.in
			W b) Lindii. <u>as mospieme.m</u>
November 200	B	N.A	5 0 5 0 11 5
28, 2017	Biotech	Meeting with	- Dr O. P. Govila, Former
9.30 AM	Consortium	regulatory expert under RARM	Professor of Genetics, Indian
	India Limited		Agriculture Research Institute (IARI)
	Demontres ent of	component	and Member, Genetic Engineering
10.30 AM	Department of	Meeting with Adviser, DBT, also	Apprasial Committee (GEAC) Email:
10.30 AIVI	Biotechnology,		govilaop@gmail.com
	Ministry of Science	member of Project	Dr.S. D. Dao Mambar
	&Technology	Management and Monitoring	- Dr S. R Rao, Member Secretary, Review Committee on
	a recrimology	Committee	Genetic Manipulation (RCGM) and
12:30 PM		Committee	Adviser, Department of Biotechnology.
12.30 PIVI	University of	Mooting with	
	University of Delhi	Meeting with regulatory expert	Email: srraodbt@yahoo.com, srrao.dbt@nic.in
	Dellill	under RARM	SITAU.UDIETHU.III
		UNUEL NAKIVI	

Date	Location	Meeting	Participants
2:30 PM	Meeting at Ministry of Environment, Forest and Climate Change	component, co-chair of ERA Committee Meeting with NPC and officers from biosafety division	- Prof C R Babu, Member, Genetic Engineering Apprasial Committee (GEAC) Email: crb26@hotmail.com; crbabu26@gmail.com
			- Ms Madhumita Biswas, Adviser, MoEFCC — The current National Project Coordinator (NPC) Email: mbiswas.17@gov.in - Dr Murali Krishna Chimata, Joint Director, MoEFCC Email: cm.krishna@gov.in - Mr Rajeev Ranjan, Asst Section Officer, MoEFCC Email: rajeev.90@gov.in
November 29, 2017: 9:30 AM	Biotech Consortium India Limited (BCIL),	Meeting with project partners under component on Information Dissemination	- Ms. Namrata Singh and Ms Akansha Mehta, Science Associates, CABI South Asia, India Email: n.singh@cabi.org
11:00 AM	ICAR-National Bureau of Plant Genetic Resources (NBPGR)	Meeting with scientists from NBPGR engaged in detection of LMOs, and training of customs and plant quarantine officers. NBPGR is one of the labs strengthened under the project	- Dr Kuldeep Singh, Director, NBPGR Email: director.nbpgr@icar.gov.in - Dr. (Mrs.) Gurinderjit Randhawa, Principal Scientist & Officer Incharge, Genomic Resources Division Email: gurinder.randhawa@rediffmail.com, Gurinder.randhawa@icar.gov.in - Dr Shashi Bhalla, Principal Scientist, Division of Plant Quarantine, Officer In-charge, Prioritization, Monitoring and Evaluation (PME) Cell Email: shashi.bhalla@icar.gov.in - Dr. V. Celia Chalam, Principal Scientist, Plant Virology Laboratory, G- 116, Division of Plant Quarantines Email: celia.chalam@icar.gov.in

Date	Location	Meeting	Participants
November 30, 2017: 9:30 AM: 2:30 PM	Biotech Consortium India Limited (BCIL)	Meeting with PCU team Meeting with NPC and officers from	- Dr Vibha Ahuja, Chief General Manager, Mr Manish Sharma, Manager and Ms Sonia Kaushik, Assistant Manager Email: vibhaahuja.bcil@nic.in, manish@biotech.co.in,
6:30 PM	MOEFCC	and officers from biosafety division Meeting with Biotechnology Expert	- Ms Madhumita Biswas, Adviser, MoEFCC — The current National Project Coordinator (NPC) Email: mbiswas.17@gov.in - Dr Murali Krishna Chimata, Joint Director, MoEFCC Email: cm.krishna@gov.in - Mr Rajeev Ranjan, Asst Section Officer, MoEFCC Email: rajeev.90@gov.in - Dr. Siva Reddy; Chef Scientific Officer DBT (Biosafety Support Unit) former researcher at International Center for Genetical Engineering and Biotechnology (ICGEB)
<u>December</u> 1, 2017: 9:30 AM	Biotech Consortium India Limited (BCIL)	Meeting with PCU team Meeting with	vsreddy@gmail.com - Dr Vibha Ahuja, Chief General Manager, Mr Manish Sharma, Manager and Ms Sonia Kaushik, Assistant Manager Email: vibhaahuja.bcil@nic.in, manish@biotech.co.in,
1:00 PM	Biotech Consortium India Limited (BCIL)	industry representative Debriefing meeting with NPC and officers from	sonia@biotech.co.in - Dr. Shivendra Bajaj, Executive Director, ABLE-AG Email: shivendra@ableindia.org.in
3:00 PM	MoEFCC	biosafety division	- Ms Madhumita Biswas, Adviser, MoEFCC — The current National Project Coordinator (NPC) Email: mbiswas.17@gov.in - Dr Murali Krishna Chimata, Joint Director, MoEFCC Email: cm.krishna@gov.in - Mr Rajeev Ranjan, Asst Section Officer, MoEFCC Email: rajeev.90@gov.in

ANNEX IV. SUMMARY OF CO-FINANCE INFORMATION AND A STATEMENT OF PROJECT EXPENDITURE BY ACTIVITY

GEF Budget at design and expenditures by components (August 2017)93

Component/sub-component	Estimated cost at design	Actual Cost	Expenditure ratio (actual/planned)
A. Stocktaking Assessment	55,000	41,396	75.26%
B. Strengthening Regulatory & Legal			
Framework			
- Risk Assessment & Management	450,000	458,632	101.91%
- Socio Economic Assessment	150,000	151,574	101.04%
- Handling, Transport, Packaging &	165,000	155,041	96.96%
Identification of LMO			
C. Strengthening Institutional Capacity	850,000	761,021	89.53%
D. Human Resource Development	360,000	364,908	101.36%
E. Information dissemination for Enhancing Public Awareness	325,000	348,548	107.24%
F. Project coordination & Monitoring Unit	260,000	268,707	103.35%
G. Project Monitoring and Evaluation	45,000	75,450	167.67%
TOTAL	2,660,00094	2,625,277	98.7%

Co-financing Table

Co financing	Fina	own ncing		rnment		ner*		tal	Total Disbursed
(Type/Source)	Planne	1,000) Actual	Planne	1,000) Actual	Planne	1,000) Actual	Planne	1,000) Actual	(US\$1,000)
	d	Actual	d	Actual	d	Actual	d	Actual	
- Grants			900	900			900	900	900
- Loans									
- Credits									
Equity investments									
- In-kind			5,100	6,343			5,100	6,343	6,343
support									
Other (*)									
Totals			6,000	7,243			6,000	7,243	7,243

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

⁹³ Last instalment still due by UN Environment. At the time of the Evaluation 2,542,861.81 USD have been disbursed

⁹⁴ This grand total does not include the sub-budget for "Regional Network" (USD 67,273). Actually, the total GEF budget is USD 2,727,273

ANNEX V. LIST OF DOCUMENTS CONSULTED

(A) Documents consulted

- Biosafety Capacity Building Initiatives in India; Dr. Manoranjan Hota hota@nic.in; Ministry of Environment an Forests; New Delhi; https://www.google.it/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiMs MWGrtnWAhWI2xoKHXxrARYQFggnMAA&url=http%3A%2F%2Fenvfor.nic.in%2Fdivisions %2Fcsurv%2Fbiosafety%2Fcourse%2FDr%2520Manoranjan%2520Hota.ppt&usg=AOvVaw0LOto6TaPgHOyD8OdQ2yLS
- Convention on Biological Diversity, Cartagena Protocol on Biosafety, Strategic Plan of CPB 2011-20 http://bch.cbd.int/protocol/issues/cpb_stplan.shtml
- 3. GEF Project Identification Form "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India Phase II" (GEF website)
- GEF, Gender Equality Action Plan, 2015, https://www.thegef.org/sites/default/files/publications/GEF_GenderEquality_CRA_lores_0.pdf
- 5. GEF, ROtI Review of Outcomes to Impact: Practitioners Handbook, 2009, GEF
- 6. GEF, The GEF and the Sustainable Development Goals https://www.thegef.org/sites/default/files/publications/SDG_new_boilerLR_0.pdf
- 7. Project Document "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India Phase II" and its Annexes (in ANUBIS)
- 8. Project Document, Appendix 15: Applying GEF Tracking Tools in GEF -4 for Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India Phase II
- UN Environment Evaluation Office, Evaluation Criteria and Ratings Table (UN Environment, 2016)
- 10. UN Environment Evaluation Office, Evaluation Process Outline for Evaluation Consultants (UN Environment, 2016)
- 11. UN Environment Evaluation Office, Guidance on the Structure and Contents of the Inception Report (UN Environment, 2016)
- UN Environment Evaluation Office, Stakeholder Analysis in the Evaluation Process (UN Environment, 2017)
- 13. UN Environment Evaluation Office, Template for the Assessment of Project Design Quality (PDQ) (UN Environment, 2016)
- 14. UN Environment Evaluation Office, Terms of Reference of the Terminal Evaluation (2017)
- 15. UN Environment Evaluation Office, Use of Theory of Change in project evaluations (UN Environment, 2016)
- 16. UNEG / UN Evaluation Group guidance document on "Integrating Human Rights and Gender Equality in Evaluations", 2014
- 17. UNEP-GEF Toolkits for the Development of National Biosafety Frameworks http://staging.unep.org/biosafety/Documents/Drafting the NBF Formulation of the regulatory_regime.pdf

- 18. UNEP-GEF, A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects; UNEP-GEF Biosafety Unit; December 2006
- 19. UNEP-GEF, Guidance towards Implementation of NBF: Lessons Learned from UNEP Demonstration Projects; UNEP-GEF Biosafety Unit; April 2008
- 20. UNEP-GEF, Learning from experience, the global UNEP-GEF BCH Capacity building project, UNEP-GEF; UNEP-GEF Biosafety Unit; April 2008
- 21. VATIS Update, Biotechnology, Vol. 1, no 128, Oct. Dec. 2015, ISSN 0971-5622 http://bcil.nic.in/files/Publication/VATIS_October-December2015.pdf

(B) Relevant websites consulted

- Capacity Building on Biosafety India website
 http://envfor.nic.in/divisions/csurv/biosafety/biosafety regulations.htm
- Capacity Building on Biosafety: Training Needs Assessment; Project Coordinating and Monitoring Unit (PCMU) Ministry of Environment & Forests New Delhi; January, 2006 http://envfor.nic.in/divisions/csurv/biosafety/newsletter/tnareport1.pdf
- Department of Biotechnology of Ministry of Science and Technology (DBT/MS&T) http://www.dbtindia.nic.in/regulations/
- 4. fifth meeting, the COP-MOP, in decision BS-V/16, adopted the Strategic Plan for the Cartagena Protocol on Biosafety covering the period 2011 to 2020.
- 5. GEAC http://www.geacindia.gov.in/about-geac-india.aspx
- 6. India Biosafety Clearing-House http://in.biosafetyclearinghouse.net/
- 7. Ministry of Environment, Forest and Climate change, Government of India; http://www.moef.nic.in/division/cartagena-protocol-biosafety-cpb
- 8. UN Environment, Evaluation, http://www.unep.org/evaluation/

(C) List of Publications under the Project (considered by the Evaluation and partially consulted)

Phase II Capacity Building Project on Biosafety: Project Brief

Risk Assessment and Risk Management:

- Genetically Engineered (GE) Plants in the Product Development Pipeline in India: Results from a Survey conducted under the Auspices of the Phase II Capacity Building Project on Biosafety
- 3. Guidelines for the Environmental Risk Assessment of GE Plants, 2016
- 4. Environmental Risk Assessment of GE Plants: A Guide for Stakeholders, 2016
- 5. Risk Analysis Framework, 2016
- 6. Risk Communication Strategy for LMOs in agriculture, 2017
- 7. Series of Crop Specific Biology Documents
- i. Biology of Solanum lycoperscicum (Tomato)

- ii. Biology of *Solanum tuberosum* (Potato)
- iii. Biology of Sorghum biocolor (Sorghum)
- iv. Biology of *Hevea brasiliensis* (Rubber)
- v. Biology of *Cicer arietinum* (Chickpea)
- vi. Biology of *Cajanus cajan* (Pigeon pea)
- vii. Biology of Brassica juncea (Indian Mustard)
- viii. Biology of Carica papaya (Papaya)
- 8. Monitoring Confined Field Trials of Regulated GE Plants: Monitoring Manual
- 9. Monitoring Confined Field Trials of Regulated GE Plants: Tools for Trainers
- 10. Review of Conformity of India's Regulatory System for GE Plants with the Cartagena Protocol on Biosafety (CPB)
- 11. Multi-country comparisons of information and data requirements for the Environmental Risk Assessment of GE Plants
- 12. Safety Assessment of GE Plants Containing Stacked Traits
- 13. Post Release monitoring of GE Crop plants
- Capacity building in communicating science and biosafety, Department of communication research (DECORE) Indian institute of mass communication (IIMC), 2015

Handling, Transport, Packaging and Identification:

- 15. Report on Stocktaking Activity, 2014
- 16. Final report on Project Phase II by ScanBi Diagnostics (2017)
- 17. Base Paper documenting gaps between the existing system and country obligations under Article 8, 10 and 18(2) of the CPB
- 18. Training Manual for strengthening capacities of enforcement agencies for transboundary movement of LMOs
- 19. Working knowledge document for strengthening capacities of enforcement agencies for trans-boundary movement of LMOs
- Report on Identity Preservation of Basmati Rice at various stages in the rice supply chain

Socio-economic considerations:

- Booklet on Resource document on Socio-economic considerations of LMOs
- 22. Resource document on Socio-economic considerations of LMOs

Public Awareness:

- 23. Biosafety Resource Kit for Genetically Engineered Plants
 - i. Cartagena Protocol on Biosafety: An Overview
- ii. Regulatory Framework for Genetically Engineered (GE) Plants in India
- iii. Frequently Asked Questions about GE plants
- iv. Confined Field Trails of GE plants

- v. Useful Resources for Safety Assessment of GMOs
- 24. Understanding Cartagena Protocol on Biosafety: A Guide
- 25. Handbook on Biosafety Clearing House: An Information Sharing Platform
- 26. Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Hindi Version
- 27. Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: Hindi Version
- 28. Resource Catalogue
 - i. Biotechnology and Biosafety Glossary of Terms
- ii. Genetically Modified Crops: An Overview
- iii. Genetically Modified Crops: Adoption & Impact
- iv. Procedure of Import and Export of GM Plant and Planting Material
- v. Role of Customs in Transboundary Movement of Plant Material including Genetically Modified Organisms
- vi. Detection Tools for GMOs: A Poster
- 29. Capacity Building in Communicating Science and Biosafety
- 30. Risk Communication Strategy for LMOs in Agriculture

Regional Cooperation:

31. Strengthening Regional Cooperation: Sharing Biosafety Project Outcomes at Regional and International Platforms

ANNEX VI. QUALITY ASSESSMENT OF THE EVALUATION REPORT

Terminal Evaluation of the UN Environment Project: "Capacity Building for Implementation of the Cartagena Protocol on Biosafety in India / Phase II"

All UN Environment evaluations are subject to a quality assessment by the Evaluation Office. This is an assessment of the quality of the evaluation product (i.e. evaluation report) and is dependent on more than just the consultant's efforts and skills. Nevertheless, the quality assessment is used as a tool for providing structured feedback to the evaluation consultants, especially at draft report stage. This guidance is provided to support consistency in assessment across different Evaluation Managers and to make the assessment process as transparent as possible.

	UN Environment Evaluation Office Comments	Final Report Rating
Substantive Report Quality Criteria		
Quality of the Executive Summary: The Summary should be able to stand alone as an accurate summary of the main evaluation product. It should include a concise overview of the evaluation object; clear summary of the evaluation objectives and scope; overall evaluation rating of the project and key features of performance (strengths and weaknesses) against exceptional criteria (plus reference to where the evaluation ratings table can be found within the report); summary of the main findings of the exercise, including a synthesis of main conclusions (which include a summary response to key strategic evaluation questions), lessons learned and recommendations.	The executive summary provides a good overview of the consultant's findings, and highlights the main conclusions, lessons and recommendations of the evaluation	5
I. Introduction A brief introduction should be given identifying, where possible and relevant, the following: institutional context of the project (subprogramme, Division, regions/countries where implemented) and coverage of the evaluation; date of PRC approval and project document signature); results frameworks to which it contributes (e.g. Expected Accomplishment in POW); project duration and start/end dates; number of project phases (where appropriate); implementing partners; total secured budget and whether the project has been evaluated in the past (e.g. midterm, part of a synthesis evaluation, evaluated by another agency etc.) Consider the extent to which the introduction includes a concise statement of the purpose of the	Brief, but captures the main introductory points (purpose and scope of the evaluation are covered in the subsequent chapter)	5

evaluation and the key intended audience for the findings? ### Evaluation Methods This section should include a description of how the *TOC at Evaluation** was designed (who was involved etc.) and applied to the context of the project? A data collection section should include: a description of evaluation methods and information sources used, including the number and type of respondents; justification for methods used (e.g. qualitative/quantitative; electronic/face-to-face); any selection criteria used to identify respondents, case studies or sites/countries visited; strategies used to increase stakeholder engagement and consultation; details of how data were verified (e.g. triangulation, review by stakeholders etc.). The methods used to analyse data (e.g. scoring; coding; thematic analysis etc.) should be described. It should also address evaluation limitations such as: low or imbalanced response rates across different groups; extent to which findings can be either generalised to wider evaluation questions or constraints on aggregation/disaggregation; any potential or apparent biases; language barriers and ways they were overcome. Ethics and human rights issues should be highlighted including: how anonymity and confidentiality were protected and strategies used to include the views of marginalised or potentially disadvantaged groups and/or divergent views. #### IThe Project This section should include: **Context: Overview of the main issue that the project is trying to address, its root causes and consequences on the environment and human well-being (i.e.) ##################################		UN Environment Evaluation	Final
### Evaluation and the key intended audience for the findings? ### I. Evaluation Methods This section should include a description of how the *TOC at Evaluation** was designed (who was involved etc.) and applied to the context of the project? A data collection section should include: a description of evaluation methods and information sources used, including the number and type of respondents; justification for methods used (e.g. qualitative/quantitative; electronic/face-to-face); any selection criteria used to identify respondents, case studies or sites/countries visited; strategies used to increase stakeholder engagement and consultation; details of how data were verified (e.g. triangulation, review by stakeholders etc.). The methods used to analyse data (e.g. scoring; coding; thematic analysis etc.) should be described. It should also address evaluation limitations such as: low or imbalanced response rates across different groups; extent to which findings can be either generalised to wider evaluation questions or constraints on aggregation/disaggregation; any potential or apparent biases; language barriers and ways they were overcome. Ethics and human rights issues should be highlighted including: how anonymity and confidentiality were protected and strategies used to include the views of marginalised or potentially disadvantaged groups and/or divergent views. #### ITHE Project This section is complete and covers all the required sub-topics in a concise manner. The discussion on stakeholders, gender and human rights are notably human rights are notably		Office Comments	
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well covered.		well covered.	

⁹⁵ During the Inception Phase of the evaluation process a *TOC* at *Design* is created based on the information contained in the approved project documents (these may include either logical framework or a TOC or narrative descriptions). During the evaluation process this TOC is revised based on changes made during project intervention and becomes the *TOC* at Evaluation.

	UN Environment Evaluation	Final
	Office Comments	Report
		Rating
synopsis of the problem and situational		
analyses).		
Objectives and components: Summary of		
the project's results hierarchy as stated in		
the ProDoc (or as officially revised)		
Stakeholders: Description of groups of		
targeted stakeholders organised according		
to relevant common characteristics		
 Project implementation structure and 		
partners: A description of the		
implementation structure with diagram		
and a list of key project partners		
Changes in design during implementation:		
Any key events that affected the project's		
scope or parameters should be described		
in brief in chronological order		
Project financing: Completed tables of: (a)		
budget at design and expenditure by		
components (b) planned and actual		
sources of funding/co-financing		
IV. Theory of Change	The TOC diagram is	
A summary of the project's results hierarchy	coherent and a result of a	
should be presented for: a) the results as stated in	consultative process. The	
the approved/revised Prodoc logframe/TOC and b)	narrative is clear and	
as formulated in the TOC at Evaluation. The two	provides an explanation of	
results hierarchies should be presented as a two	the causal pathways	
column table to show clearly that, although wording and placement may have changed, the results 'goal	depicted in the diagram. Suggested edits on the	5
posts' have not been 'moved'. The TOC at Evaluation	TOC diagram were taken	3
should be presented clearly in both diagrammatic	up in the final report	
and narrative forms. Clear articulation of each	version	
major causal pathway is expected, (starting from	Version	
outputs to long term impact), including		
explanations of all drivers and assumptions as		
well as the expected roles of key actors.		
V. Key Findings	Section is well done and	
<i>y</i> g-	covers all the main aspects	
A. Strategic relevance:	of relevance prescribed in	
This section should include an assessment of the	the TOR in sufficient detail	
project's relevance in relation to UN Environment's		
mandate and its alignment with UN Environment's		,
policies and strategies at the time of project		6
approval. An assessment of the complementarity		
of the project with other interventions addressing		
the needs of the same target groups should be		
included. Consider the extent to which all four		
elements have been addressed:		

v. Alignment to the UN Environment Medium Term Strategy (MTS) and Programme of Work (POW) vi. Alignment to UN Environment/GEF/Donor Strategic Priorities viii. Relevance to Regional, Sub-regional and National Environmental Priorities viii. Complementarity with Existing Interventions B. Quality of Project Design To what extent are the strength and weaknesses of the project design effectively summarized? C. Nature of the External Context For projects where this is appropriate, key external features of the project's implementing context that may have been reasonably expected to limit the project's performance (e.g. conflict, natural disaster, political upheaval) should be described. D. Effectiveness (I) Outputs and Direct Outcomes: How well does the report present a well-reasoned, complete and evidence-based assessment of the achievement of a) outputs, and b) direct outcomes? How convincing is the discussion of attribution and contribution, as well as the limitations to attributing effects to the intervention. Ordinary of the External Context E. Nature of the External Context B. Qualitative analysis of the design are sufficiently described. Cross referencing to other sections of the report as well as references to the Project Design Quality assessment. Alone at the inception phase of the evaluation, have been used to support the assessment. No external factors were expected to reasonably limit the project's performance volupture and Direct Outcomes: How well does the report present a well-reasoned, complete and evidence-based assessment of the achievement of a) outputs, and b) direct outcomes? How convincing is the discussion of attribution and contribution, as well as the limitations to attributing effects to the intervention. Section has been completed satisfactorily. Outputs are described by component, and with sufficient evidence provided to support a detailed assessment of the delivery of outputs. Qualitative analysis of the Direct Outcomes achieved using examples that underpin the judgement on th		UN Environment Evaluation	Final
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Suggested improvements			
have been effected			

	UN Environment Evaluation Office Comments	Final Report
	especially in the clarification of findings.	Rating
(ii) Likelihood of Impact: How well does the report present an integrated analysis, guided by the causal pathways represented by the TOC, of all evidence relating to likelihood of impact? How well are change processes explained and the roles of key actors, as well as drivers and assumptions, explicitly discussed?	The narrative provides a considered analysis of the causal pathways from outcomes to intermediate states through to impact. Cross-referencing to the TOC has also been used. Improvements in the elaboration of the causal pathways form outcome to impact were noted in the final report version	5
E. Financial Management This section should contain an integrated analysis of all dimensions evaluated under financial management. And include a completed 'financial management' table. Consider how well the report addresses the following: • completeness of financial information, including the actual project costs (total and per activity) and actual co-financing used • communication between financial and project management staff and • compliance with relevant UN financial management standards and procedures.	A table summarizing financial management performance is included. Narrative accompanying the table could be improved to provide a clearer analysis of the completeness, communication and compliance aspects of financial management.	5
F. Efficiency To what extent, and how well, does the report present a well-reasoned, complete and evidence-based assessment of efficiency under the primary categories of cost-effectiveness and timeliness including: • Implications of delays and no cost extensions • Time-saving measures put in place to maximise results within the secured budget and agreed project timeframe • Discussion of making use of/building on pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc.	This section has been covered rather briefly though it covers most of the required categories of cost-effectiveness and timeliness.	4.5

	UN Environment Evaluation Office Comments	Final Report
The extent to which the management of the project minimised UN Environment's environmental footprint.		Rating
 G. Monitoring and Reporting How well does the report assess: Monitoring design and budgeting (including SMART indicators, resources for MTE/R etc.) Monitoring implementation (including use of monitoring data for adaptive management) Project reporting (e.g. PIMS and donor report) 	The section is well covered. It goes beyond reporting compliance, by also looking into the results-based monitoring. It also identifies the gaps in the overall M&E system.	5
 H. Sustainability How well does the evaluation identify and assess the key conditions or factors that are likely to undermine or contribute to the persistence of achieved direct outcomes including: Socio-political Sustainability Financial Sustainability Institutional Sustainability (including issues of partnerships) 	The assessment of sustainability identifies pertinent issues likely to undermine sustenance of outcomes. Suggestions for improvement were effected; overall the analysis has been found adequate.	5
I. Factors Affecting Performance These factors are not discussed in stand-alone sections but are integrated in criteria A-H as appropriate. To what extent, and how well, does the evaluation report cover the following crosscutting themes: • Preparation and readiness • Quality of project management and supervision ⁹⁶ • Stakeholder participation and co-operation • Responsiveness to human rights and gender equity • Country ownership and driven-ness • Communication and public awareness	Though these factors are not covered explicitly, they are adequately integrated into the report, and the ratings table provides adequate summaries on the status of each	5
VI. Conclusions and Recommendationsi. Quality of the conclusions: The key	The conclusions section adequately presents the most critical findings of	4.5

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⁹⁶ In some cases 'project management and supervision' will refer to the supervision and guidance provided by UN Environment to implementing partners and national governments while in others, specifically for GEF funded projects, it will refer to the project management performance of the executing agency and the technical backstopping provided by UN Environment.

	UN Environment Evaluation Office Comments	Final Report Rating
strategic questions should be clearly and succinctly addressed within the conclusions section? It is expected that the conclusions will highlight the main strengths and weaknesses of the project, and connect them in a compelling story line. Conclusions, as well as lessons and recommendations, should be consistent with the evidence presented in the main body of the report.	the evaluation. Responses to the key strategic questions are not explicitly discussed but one gets a good sense of the main successes and challenges in project implementation.	3
ii) Quality and utility of the lessons: Both positive and negative lessons are expected and duplication with recommendations should be avoided. Based on explicit evaluation findings lessons should be rooted in real project experiences or derived from problems encountered and mistakes made that should be avoided in the future. Lessons must have the potential for wider application and use and should briefly describe the context from which they are derived and those contexts in which they may be useful.	They are clear and anchored on actual findings. Suggested amendments were made to structure the lessons learned statements in a way that they can be coherent and have the potential for wider application.	5
iii) Quality and utility of the recommendations: To what extent are the recommendations proposals for specific actions to be taken by identified people/position-holders to resolve concrete problems affecting the project or the sustainability of its results. They should be feasible to implement within the timeframe and resources available (including local capacities) and specific in terms of who would do what and when. Recommendations should represent a measurable performance target in order that the Evaluation Office can monitor and assess compliance with the recommendations.	Mostly addressed to UN Environment and the GEF. Some improvement noted in their formulation form previous report versions. They can be utilised in the design of future projects of similar nature	4.5
VII. Report Structure and Presentation Quality		
 i) Structure and completeness of the report: To what extent does the report follow the Evaluation Office guidelines? Are all requested Annexes included and complete? ii) 	Report is complete and follows the Evaluation Office guidelines	6
iii) Quality of writing and formatting: Consider whether the report is well written (clear English language and grammar) with language that is adequate in quality and tone for an official document? Do visual aids, such as maps and graphs convey key information? Does the report follow Evaluation Office formatting guidelines?	Final report is clear and follows EO guidelines	6

	UN Environment Evaluation	Final
	Office Comments	Report
		Rating
OVERALL REPORT QUALITY RATING		S

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.