Evaluation Office of UN Environment

# Terminal Evaluation Report on Completion and Strengthening of the Cuban National Biosafety Framework for the Effective Implementation of the Cartagena Protocol

March 2017


**Evaluation Office of UN Environment**

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Completion and Strengthening of the National Biosafety Framework of Cuba for the Effective Implementation of the Cartagena Protocol - Cuba Evaluation
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## ABOUT THE EVALUATION[1]

**Joint Evaluation:** No

**Report Language(s):** English

**Evaluation Type:** Terminal Project Evaluations

**Brief Description:** This report is a terminal evaluation of a UN Environment-GEF project implemented between 2010 and 2016.The project's overall development goal was general objective was to address the technical, legal, infrastructural and biosafety management gaps faced by National Competent Authorities (NCAs), to ensure the successful implementation of the Cartagena Protocol for Biosafety (CPB) in Cuba. The project aimed to close these final gaps through the combination of institutional coordination mechanisms, improved capacities to control transboundary movements of LMOs, expanded biosafety training, and infrastructural capacities to detect/identify living modified organisms (LMOs). 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. The evaluation has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UN Environment, the GEF and their executing partner CBS - and the relevant agencies of the project participating country.

**Key words:** Biosafety; Biodiversity; Cartagena Protocol; Cuba; Biotechnology; Living Modified Organisms, Genetically Modified Organisms; Genetic Engineering; Environmental Regulations; Environmental Law; TE; Terminal Evaluation; GEF; GEF Project

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

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## PROJECT IDENTIFICATION TABLE

| | | | |
|---|---|---|---|
| ***UNEP PIMS ID:*** | | ***IMIS number:*** | *GFL 2328 2716 4B74* |
| ***Sub-programme:*** | *Environmental Governance* | ***Expected Accomplishment:*** | *Pow Accomplishment 2014-2015: b) Provision of legal and technical support to Governments to develop and enforce laws and strengthen institutions to achieve internationally agreed environment* |
| ***UNEP approval date:*** | *20 November 2010* | ***PoW Output(s):*** | *2) Legal technical assistance provided to support initiatives by countries to implement, monitor and achieve compliance with, and enforcement of, international environmental obligations, including those set out in multilateral environmental agreements* |
| ***GEF project ID:*** | *3643* | ***Project Type:*** | *MSP* |
| ***GEF OP #:*** | *GEF 4 BD-SP-6* | ***Focal Area(s):*** | *Biosafety* |
| ***GEF approval date:*** | *4 October 2010* | ***GEF Strategic Priority/Objective:*** | *BD3* |
| ***Expected Start Date:*** | *1 November 2010* | ***Actual start date:*** | *1 November 2010* |
| ***Planned completion date:*** | *30 November 2015* | ***Actual completion date:*** | *June 2016* |
| ***Planned project budget at approval:*** | *USD 900,091* | ***Total expenditures reported as of [June 2016]:*** | *USD 1,848,996.28* |
| ***GEF Allocation:*** | *USD 900,091* | ***GEF grant expenditures reported as of [June 2016]:*** | *USD 810,022.10* |
| ***PPG GEF cost:*** | *USD 9,000* | ***PPG co-financing:*** | *USD 24,254* |
| ***Expected MSP/FSP co-financing:*** | *USD 1,018,552* | ***Secured MSP co-financing [June 2016]:*** | *USD 1,038,974.18* |
| ***First Disbursement:*** | *10 December 2010* | ***Date of financial closure:*** | *30 June 2016* |
| ***No. of revisions:*** | *7* | ***Date of last revision:*** | *June 2016* |
| ***Date of last Steering Committee meeting:*** | *May 2015* | | |
| ***Mid-term review/ evaluation (planned date):*** | *April 2013* | ***Mid-term review/ evaluation (actual date):*** | *May 2013* |
| ***Terminal Evaluation (actual date):*** | *October 2016 – February 2017* | | |

*Source: Terminal Evaluation of "Completion and Strengthening of the National Biosafety Framework of Cuba for the Effective Implementation of the Cartagena Protocol" – Terms of Reference*

# ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| BCH | Biosafety Clearing House |
| CENSA | National Center of Animal and Plant Health |
| CIGB | Center for Genetic Engineering and Biotechnology |
| CITMA | Ministry of Science, Technology and the Environment |
| CNSV | National Center of Plant Health |
| CP | Cartagena Protocol on Biosafety |
| CPHEM | Provincial Centers of Hygiene, Epidemiology and Microbiology |
| CSB | National Centre for Biological Safety |
| DT | CITMA Territorial Delegations |
| FSP | Full Size Project |
| GEF | Global Environment Facility |
| GM | Genetically Modified |
| GMO | Genetically Modified Organism |
| IMV | Institute of Veterinary Medicine |
| INHA | Institute for Nourishment and Food Hygiene |
| INSTEC | Institute of Applied Sciences and Technology |
| LMO | Living Modified Organism |
| M&E | Monitoring and Evaluation |
| MCN | National Coordination Mechanism |
| MES | Ministry of Higher Education |
| MINAG | Ministry of Agriculture |
| MINCEX | Ministry of Foreign Trade |
| MINSAP | Ministry of Public Health |
| MOP | Meeting of the Parties to the Protocol |
| NBF | National Biosafety Framework |
| NCA | National Competent Authority |
| OACE | Central Administration State Agencies |
| ORASEN | Office for Environmental Regulation & Nuclear Safety |
| PIPE | Program of Information and Public Education |
| PIR | Project Implementation Review |
| PPG | Project Preparation Grant |
| UNDP | United Nations Development Programme |
| UN Environment | United Nations Environment (UNEP) |
| UNSA | National Unit of Environmental Health |

# EXECUTIVE SUMMARY

1. The general findings of the Terminal Evaluation indicate that "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol" was successful in achieving almost all of its outputs and expected outcomes, with satisfactory to highly satisfactory performance levels that demonstrated good project management practices.

2. The project was strategically relevant both globally and nationally. Project objectives were aligned with the UN Environment 2010-2013 Medium-Term Strategy's crosscutting priority of global, regional and national environmental governance, and the third objective of capacity building and technology transfer to support the Bali Strategic Plan (BSP). They were also consistent with UN Environment's 2010-11 Programme of Work and Expected Accomplishment of enhanced State capacities to implement environmental obligations, in this case the Cartagena Protocol on Biosafety. National relevance was reinforced by the project's focus on closing the final capacity gaps, building on the advances of earlier GEF-UN Environment biosafety projects. By supporting Cuba's first national biosafety coordination mechanism and seeking to strengthen LMO detection capabilities, the project addressed fundamental aspects of the national biosafety framework that had been lacking.

3. The project was very effective in delivering its planned outputs and outcomes. Twenty-seven of 29 outputs (93%) were fully completed, as were 89% of project activities. Some main outputs of the project included:

- The establishment of Cuba's first national biosafety coordination mechanism and information system, enabling systematic communications and quicker decision-making processes;
- A national biosafety training system that expands the range of higher biosafety education and extends it to the provinces;
- Recognition of the Center for Biological Safety (CSB) as the leading national authority for biosafety by the Ministry of Foreign Trade (MINCEX) and other government entities, and;
- Increased regulation of LMO imports and exports by Customs personnel, accompanied by the inclusion of LMO data in the Declaration of Conformity.

4. The approval of new NCA biosafety mandates, based on the restructuring of CITMA and ORASEN, was pending at the time of the evaluation, perhaps in anticipation of possible changes to Cuba's governance framework that were under discussion at senior government levels. In addition, laboratory infrastructure and equipment for LMO detection and identification were not delivered. Low levels of Internet connectivity discouraged online networking and greater use of the BCH, despite increased office bandwidth and Internet memory.

5. The project was effective in reaching its expected outcomes and immediate objectives. Evaluation findings indicate that three out of four outcomes were achieved to a high degree. The National Coordination Mechanism has helped national authorities reach agreements on how to manage LMO requests and establish a "one stop" system that streamlines decision processes, binding the pronouncements of national authorities. Formats have been standardized and the sequence of steps required for LMO decisions are now understood by NCAs.

6. There are early indications of impact: LMO importers need to submit one folder of documents instead of dealing separately with different institutions and paperwork requirements. Decisions on imported transgenic grains that required several months in the past, are now taken within 30 days and the deadline for reaching LMO decisions was significantly reduced. Before the project, Customs would retain GM biological samples or other LMOs for up to 45 days in the absence of clear guidelines, and then destroy them; this no longer happens. LMO information is now required in the Declaration of Conformity form.

7. Biosafety training was expanded nationally and articulates a network of universities, specialized institutions and decentralized CITMA training facilities. Biosafety education is presently offered at doctorate, post-graduate and undergraduate levels with specializations that are not available elsewhere in the region. The national biosafety training system is expected to fully meet Cuba's capacity needs by 2020, and has the potential of offering a regional biosafety training "hub" with potential opportunities for cost recovery.

8. The fourth outcome of having greater NCA operational capacities in biosafety was not fully reached because the laboratory equipment, reactives and other items needed for LMO detection and identification did not arrive due to delays in their procurement. However, this initiative would be continued through the proposed follow-up project that was recently forwarded to GEF, and its achievement is likely if there is continued support.

9. The evaluation considers that the project results have a high likelihood of sustainability – institutionally and financially – due to the close "fit" of project objectives with CSB's corporate biosafety plan, the technical capacities of the institutions, and Cuba's policy commitment to the implementation of the CP. CSB's mandates for biosafety, biological agents and exotic species are core components of Cuba's state security policy. The national policy commitment is also driven by an important biotechnology sector that contributes to Cuba's export economy and foreign exchange earnings. The project led the drafting of the 2016-2020 National Action Plan for Biosafety that was submitted to the State Council for approval.

10. The project was cost-effective in its implementation. Project delivery was consistently high and over 90% of project activities and outputs were completed as planned. The final project audit indicated a financial delivery rate of 96% between November 2010 and June 2016 with a final unspent budget of US$ 12,000 that included costs of the Terminal Evaluation. Management costs were low because the CSB executed the project using its own staff. A senior CSB manager and a compact group of experienced technical staff led the project team. As a result there were lower expenditures on external consultants and technical services than is often the case. UN Environment raised the project's efficiency by

managing all international procurement and forwarding the equipment or other goods received to CSB through the UNDP Country Office. This practice has provided a timely and efficient option that avoids excessive bureaucracy or the U.S. economic embargo. There were few cases of delayed procurement or disbursement; the most extended delay being the Umoja "blackout" that suspended payments to the project for several months.

11. The evaluation highlighted the following factors that influenced project performance and results:

- High levels of preparation and readiness on the part of CSB, with prior experience as NEA for GEF-UNEP projects;
- Good project design that was achievable in terms of expectations, timelines and resource allocations;
- High levels of country ownership on the part of the NEA; and
- Mechanisms for stakeholder participation and adaptive management, i.e. Technical Committee and National Coordination Mechanism.

12. As national executing agency, CSB managed the project effectively and efficiently. The evaluation findings indicate commendable performance on the part of the National Project Coordinator and technical team that managed the components. There were substantive results and high delivery. Work plans and responsibilities were understood and adhered to, and budget revisions were periodically made to re-program finances. The implementation process was monitored by the project team and CSB personnel, who met as a separate committee (*Grupo de Apoyo*) for this purpose several times a year.

13. Communications were important to the project and the third component was partly devoted to public awareness through the PIPE, with an e-newsletter, informative folders, a video and TV spots. Data was not available on the number of persons exposed to PIPE, and awareness raising is difficult to measure. Communication and awareness were also promoted through events directed at national authorities and other stakeholders. The project organized 59 events between technical meetings and workshops. Communications between NCAs benefited from face-to-face MCN meetings and data flows that link the various authorities for LMO decisions. Unfortunately, Cuba's low Internet connectivity restricted opportunities for online communications and networking; this affected access to the BCH, online communications, and the uploading of data to ANUBIS and the BCH.

14. Budget delivery was high. According to the final project audit, 96% of the GEF budget had been spent between November 2010-June 2016 leaving a balance of US$ 12,000. Funds were efficiently managed by the project team. Unspent budgets were reprogrammed with annual budget revisions. Funds were transferred between budget lines to meet changing needs and accommodate more training. The suspension of financial transactions during the Umoja "blackout" lasted several months and was ultimately compensated with the project's extension. Delays in the procurement of laboratory equipment and reactives for LMO detection prevented the full achievement of the project's

fourth outcome. However, these setbacks did not detract from what was a generally efficient performance.

15. The guidance provided by the UN Environment Task Manager and Financial Management Officer was useful and very much appreciated, particularly during the project's start-up phase and as a regular source of advice on administrative and reporting issues. The Task Manager facilitated links with other biosafety projects, and national project coordinators from the LAC region were brought together at annual meetings to exchange experiences and discussed project issues of common interest. Likewise, the 2012 regional workshop for project administrators offered useful guidance on Anubis and financial management guidelines..

16. Project monitoring was satisfactory, in particular due to the NEA's initiative. Because the project team was composed of CSB staff, emerging challenges were anticipated and remedial actions taken in a timely manner by the NEA. Internal monitoring was practiced by the project Support Group *("Grupo de Apoyo")* that met three times a year to review progress, discuss relevant issues and adjust work plans. NCAs were also involved in monitoring and adaptive management through the Technical Committee that met twice yearly.

17. The lessons of the project highlight the National Coordination Mechanism (MCN) as an innovative approach to inter-institutional coordination that had not existed before the project and that could be replicated by other government authorities that oversee inter-institutional processes. The institutional stability and group dynamics within CSB were instrumental in enabling the technical and managerial expertise that went into the project's execution. Early consultations with NCAs and biotechnology representatives for the design phase strengthened their commitment to the project and its objectives. The national biosafety training system that was developed with project support could establish Cuba as a regional hub for biosafety training and South-South cooperation.

18. In its recommendations, the evaluation strongly endorses the continuity of GEF-UN Environment technical support to further consolidate the institutional coordination and training arrangements that were supported by the project, and in particular to establish laboratory infrastructure for independent LMO detection and identification. There is also need to raise biosafety awareness among productive sectors that could be affected by increased imports/exports of transgenic grain or other GM products in the future; in this respect, CSB should continue to encourage the participation of the National Association of Agricultural Producers (ANAP) and NGOs that can inform civil society and monitor the environmental impact of biosafety policies. Finally, it is recommended that the new project proposal include an internal mid-term review to adjust to anticipated governance reform measures that could decentralize or otherwise affect institutional functions.

19. The following table summarizes the project performance ratings that are based on the evaluation criteria and presented in in Section IV. "Conclusions":

**Figure 1**

**Summary of Project Performance Ratings**

| **Evaluation Criteria** | **Performance Rating** |
|---|---|
| Strategic Relevance | Highly Satisfactory (HS) |
| Achievement of Outputs | Highly Satisfactory (HS) |
| Effectiveness/Attainment of objectives and outcomes | Satisfactory (S) |
| Sustainability and Replication | Highly Likely (HL) |
| Efficiency | Highly Satisfactory (HS) |
| *Factors Affecting Performance:* | |
| Preparation and Readiness | Highly Satisfactory (HS) |
| Project Implementation and Management | Highly Satisfactory (HS) |
| Stakeholder Participation and Public Awareness | Satisfactory (S) |
| Country Ownership and Driven-ness | Highly Satisfactory (HS) |
| Financial Planning and Management | Highly Satisfactory (HS) |
| UN Environment Supervision and Backstopping | Highly Satisfactory (HS) |
| Monitoring and Evaluation | Highly Satisfactory (HS) |
| **OVERALL PROJECT RATING** | **Highly Satisfactory (HS)** |

# I. INTRODUCTION

20. The UN Environment-GEF project "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol" was executed over a five and a half year period by the National Center for Biosafety (CSB) with a US$ 900,091 grant from the Global Environment Facility (GEF) and US$ 1,018,552 in co-financing from the Government of Cuba. As the designated GEF implementing agency, UN Environment was responsible for providing technical guidance and oversight to the project, and managing the disbursement of GEF funds. The project started in November 2010 and finished in June 2016 (seven months later than initially planned).

21. The general objective was to address the technical, legal, infrastructural and biosafety management gaps faced by National Competent Authorities (NCAs), to ensure the successful implementation of the Cartagena Protocol for Biosafety (CPB) in Cuba. The project aimed to close these final gaps through the combination of institutional coordination mechanisms, improved capacities to control transboundary movements of LMOs, expanded biosafety training, and infrastructural capacities to detect/identify living modified organisms (LMOs).

22. The overall objective was backed by four specific objectives that were the basis of the projects components:

- To reinforce the National Coordination Mechanism, focusing on decision-making and setting standards and criteria.
- To strengthen the framework for LMO import and export in accordance with the CP.
- To design and implement a System of Human Resources Training in Biosafety.
- To increase the scientific, technological, and infrastructure capacities of the National Competent Authorities.

23. The National Center for Biodiversity (CSB) was the national executing agency (NEA) for the project. This was based on its role as lead authority for Cuba's national biosafety framework and national authority to the Cartagena Protocol on Biosafety. CSB is organizationally part of the Ministry of Science, Technology and Environment (CITMA) and is under the Office for Environmental Regulation and Nuclear Safety (ORASEN). The National Competent Authorities (NCAs)[2] that are responsible for managing the national biosafety framework were both partners and beneficiaries of the project.

## 1.1 Objectives, Approach and Limitations of the Evaluation

24. The project was scheduled to undergo a Terminal Evaluation (TE) on completion of project activities, following UN Environment evaluation policies and GEF guidelines for implementing agencies. The Inception Report was the first step of the TE process. The

[2] These are the CSB, Ministry of Public Health (MSP), Interior Ministry (MININT), Ministry of Exterior Commerce (MINCEX), Ministry of Superior Education (MES), Ministry of the Armed Forces (MINFAR), Customs, and the National Center for Plant Health (associated with the Ministry of Agriculture).

evaluation was expected to assess project performance according to criteria of relevance, effectiveness, efficiency, sustainability, stakeholder participation, national ownership, financial management and monitoring among others. Through this assessment, the evaluation will provide evidence of results and contribute to learning, feedback and knowledge sharing between UN Environment, GEF and national partners, with lessons that are relevant for future initiatives.

25. The evaluation approach combined the following:

- A desk review of documentation that included the project document, Project Implementation Reviews (PIRs), annual progress reports, minutes of Technical Committee meetings, audits and budget revisions, the Final Project Report, and information related to the national coordination mechanism (MCN), information flows, and biosafety training system. The desk review took place during September and October 2016, contributing to the evaluation Inception Report (the evaluation's first deliverable).
- A one-week country mission was scheduled in October to interview the project team and focal points from CSB, ORASEN, CITMA, NCAs represented on the MCN and other institutions that participated in the project.
- A skype interview was held with the UN Environment Task Manager to capture her views as the IA representative closest to the project (October 2016).
- This was followed by the "triangulation" of data collected from the desk review, country interviews and skype interview. This helped the evaluator to (i) systematize perceptions of project performance by different stakeholder groups (NEA, project team, NCAs, trainees), (ii) compare these with the reported data on project implementation and financial delivery, and (iii) articulate a set of findings that were developed into the body of this report, base on the evaluation criteria in the ToRs (December 2016-January 2017 [3]).
- The draft version of the Terminal Report will be submitted to UN Environment for internal review with the NEA and other partners, and subsequently revised based on the feedback that is received. The revised draft will represent the final version of the project's Terminal Evaluation Report and will be submitted to UN Environment in March 2017.

26. Country interviews were organized around guiding questions that were drawn from the evaluation Terms of Reference. Due to the volume of questions and duration of the country visit, however, the evaluator was unable to ask all questions to the targeted respondents, and instead integrated these questions in a manner that covered the principal evaluation criteria. [4]

27. Terminal evaluations are generally scheduled shortly before or after the termination of project activities, which makes it difficult to assess final outcomes or the likelihood of

[3] The interim period between the country visit and drafting the TE report was devoted to another UNEP assignment (final evaluation of "Sustainable Forest Management in the Transboundary Gran Chaco Americano Ecosystem").

[4] The evaluator was unable to interview representatives of environmental NGOs or the National Association of Agricultural Producers (ANAP). Although their participation in the project was very limited, the evaluation would have benefitted from a non-governmental perspective on the project and biosafety issues affecting Cuba.

sustainability. Two outputs remain pending that, if finalized, would influence the level of outcome achievement. Likewise, the benefits derived from biosafety training, public awareness campaigns, improved information flows or laboratory equipment for LMO detection often require a gestation period in order to achieve their full impact, and some project initiatives are still in process of consolidation. However, the timing of the evaluation and country visit – which took place several months after the project's termination - was beneficial in this respect. Likewise, the evaluation benefited from comprehensive and very detailed information that was provided by interviewed participants and through PPT presentations prepared by the project team.

# II. THE PROJECT

## A. Context

28. Cuba is one of the leading countries in the region in terms of biosafety management and enforcement. Its NBF is supported by enabling legislation that was approved 14 years ago and has been improved over time. The ratification of the Cartagena Protocol in 2002 was a consequence of the high profile achieved by Cuba's biotechnology sector, whereby the Government of Cuba recognized biosafety as a necessary accompaniment to this sector's growth. This has led to the formulation and periodic updating of the "*Implementation Plan for the Cartagena Protocol*" - a strategic 'roadmap' that addresses challenges and capacity needs - and inclusion of biosafety issues within national environmental strategies. The Implementation Plan has allowed Cuba to better understand its position in relation to the fulfillment of its CP obligations, assess national performance, and identify gaps that require corrective actions.

29. The present capacities of the NBF, institutionally and systemically, are the result of an extended support process in which UN Environment-GEF played an important role: In 1998 the Cuban National Centre for Biosafety (CSB) participated in a pilot project for the development of a National Biosafety Framework (NBF), under the "first generation" of GEF support to the Cartagena Protocol. Between 2002 and 2007, Cuba participated in a series of demonstration projects for the implementation of NBFs. These projects have helped Cuba consolidate its national biosafety system through the design and adoption of a regulatory instrument for LMO risk evaluation and assessment prior to their liberation into the environment. GEF-UN Environment support was also received to establish the national Biosafety Clearinghouse (BCH), and train national personnel in uploading information to the BCH. This has enabled higher level of security towards the potential impacts of LMOs on human health and the environment, compared to former periods.

30. Despite recognized advances, there were continuing capacity needs that required continued support. This was influenced by a several factors: The momentum generated by Cuba's biotechnology sector and the government's supportive policies towards biosafety; the evolution of international regulatory instruments; the difficulties of accessing technology and foreign exchange as result of the U.S. economic blockade; the decline of the Soviet Union and *períodos especiales* of economic austerity.

31. To better face the challenges of modern biotechnology and fulfill its obligations to the Cartagena Protocol, the Cuba's National Capacity Self-Assessment (NCSA) exercise prioritized the need for better institutional coordination, strengthened controls of transboundary LMOs, improved biosafety training and education, and better scientific capacity and infrastructure for LMO detection and risk analysis. These priorities were identified through the analysis of the following threats, root causes and barriers:

**Figure 2**

**Threats, Root Causes and Barriers to Biosafety in Cuba**

| Threats | Root Causes | Barriers |
|---|---|---|
| Adverse effects on ecosystems and human and animal health due to the non-regulated introduction of LMOs | Failures in the biosafety system, specifically the incorrect application of the authorization process. | Many authorities with different procedures do not act in a harmonized way.<br><br>Border Control does not address the entry and exit of LMOs from the perspective of biosafety. |
| Unauthorized entry of LMOs de-stabilizing the implementation and improvement of the biosafety system | Coordination mechanisms between competent authorities linked with LMOs are not effective | No harmonized legislation.<br>Inter-institutional communication is ineffective and insufficient. |
| Unauthorized entry of LMOs de-stabilizing the implementation and improvement of the biosafety system | Coordination mechanisms between competent authorities linked with LMOs are not effective | No harmonized legislation.<br>Inter-institutional communication is ineffective and insufficient. |
| Unauthorized entry of LMOs de-stabilizing the implementation and improvement of the biosafety system | Lack of infrastructure for specialized scientific and technical services to support regulatory actions | Limited financial resources.<br>Low technology means all information must be printed which leads to high updating costs. |
| Decision makers and society in general lack a culture of security and precaution. | Insufficient training of the main actors involved and of biotechnology users (society) in general | No training strategy designed that covers all sectors involved.<br>Insufficient education for all ages.<br>Limited financial resources. |

*Source: "Completion and Strengthening of the National Biosafety Framework of Cuba for the Effective Implementation of the Cartagena Protocol" - Project Document (2010)*

32. Based on these needs, Cuba's Center for Biological Safety (CBS) proposed the present project, that was national in scale and aimed to address these capacity gaps. The proposed project sought to (i) expand the scale of stakeholders involved in Cuba's national biosafety framework from the aforementioned NCAs to include specialized government sector agencies, regional branches of CITMA, regional universities (Havana, Holguin, Cienfuegos), provincial governments and NGOs; (ii) balance NCA capacities to facilitate their effective participation, (iii) establish the laboratory infrastructure required for LMO detection and identification (iii) ensure future capacity development through a comprehensive training system. While ambitious in its outcomes and institutional scope,

the TE considers that the project was feasible in relation to Cuba's operating environment and the baseline capacities and expertise of participating institutions. The project's feasibility was reinforced by the PPG support that was used to organize consultative workshops with the various stakeholders.

## B. Objectives and Components

33. The main objective of the project was to address the technical, legal, infrastructural and biosafety management gaps faced by the country's National Competent Authorities to ensure the successful and sustainable implementation of the Cartagena Protocol in Cuba. This was supported by four immediate objectives that provided the foundation for the project's four components:

- Reinforce the National Coordination Mechanism, focusing on decision-making and setting standards and criteria;
- Strengthen the framework for LMO import and export in accordance with the CP;
- Design and implement a System of Human Resources Training in Biosafety;
- Increase the scientific, technological, and infrastructure capacities of the National Competent Authorities.

34. The four components with their associated outcomes and outputs are described below:

**Figure 3**

**Project Components, Outcomes and Outputs**

| Components | Expected outcomes | Outputs |
|---|---|---|
| 1. Reinforcement of the National Coordination Mechanism, with emphasis on decision-making needs, and setting norms and standards | 1.1. Greater capacity for implementing, coordinating and harmonizing the country's biosafety legislation with the administrative processes of the Cartagena Protocol and other relevant legislation | 1.1.1 A strengthened National Coordination Mechanism through discussions and definitions of the Technical Advisory Committee and agreements on how to maintain it functioning<br><br>1.1.2 A National Strategy on Biosafety and its Action Plan for the years 2011-2014<br><br>1.1.3 An Action Plan for Capacity Building in Biosafety that covers LMO control, among other topics<br><br>1.1.4 Regulation for applying the CPB's Advance Informed Agreement<br><br>1.1.5 Legal and technical proposals for harmonizing legislation to cover transport, transit, storage and distribution of LMOs, as well as coordinated decision making, and other possible gaps found in the legislation<br><br>1.2.1 Web site on biosafety with information relevant to decision making<br><br>1.2.2 Data bases with information on LMO inspections, |

| | | |
|---|---|---|
| | 1.2. Improved information management related to biosafety | authorizations, biosafety entities, and legal and technical biosafety documents<br><br>1.2.3 Information flow mechanisms established as part of National Coordination Mechanism for Biosafety |
| 2. Strengthening of the framework for import and export of LMOs in accordance with the Cartagena Protocol | 2.1. The National Competent Authority is granted competency to certify border control officers in biosafety<br><br>2.2. Biosafety is integrated into border control activities | 2.1.1. New competences acknowledged and granted to the National Competent Authority<br><br>2.1.2 Guidelines (manual) for including transboundary issues such as transport, handling, identification, packaging and transit of LMOs in certification courses<br><br>2.2.1 Border control officers certified in biosafety by the National Competent Authority<br><br>2.2.2 Control of product imports and exports at the border includes biosafety considerations<br><br>2.2.3 Documentation for the identification and border control of LMOs subject to transboundary movements |
| 3. Design and implementation of a System for Human Resources Training in Biosafety | 3.1. An integral and coordinated training system is created for biosafety management and CP implementation<br><br>3.2. The human resources that form part of the National Biosafety System receive up-to-date training in biosafety management and CPB implementation<br><br>3.3. Comprehensive and coordinated training on the CPB's Biosafety Clearing House (BCH)<br><br>3.4 Greater public awareness with respect to biosafety in Cuba<br><br>3.5 Increased the potential for regional human resources training in biosafety | 3.1.1 A Training Program for Human Resources in Biosafety is elaborated with curricular contents approved by the MES<br><br>3.1.2 A Training System that integrates State institutions in biosafety training and has assured funding<br><br>3.2.1 Specialized Courses in Biosafety delivered to biosafety-related professionals and specialists<br><br>3.2.2 Masters degrees in biosafety granted to biosafety-related specialists and personnel from entities that handle biological risk<br><br>3.2.3 International training in biosafety for staff that conform the National Biosafety System<br><br>3.3.1. Personnel from competent authorities and territorial authorities trained in BCH use<br><br>3.4.1 Program for Public Information and Education (PIPE) re-elaborated, giving biosafety more prominence, approved, and its implementation initiated<br><br>3.4.2 Educational and dissemination materials<br><br>3.5.1 Regional Human Resources Training Program in Biosafety proposal elaborated<br><br>3.5.2 Project proposal for implementing the Program and delivering regional training |
| 4. Increase in the scientific, technological and infrastructural capacities of the National Competent | 4.1 Greater capacity in the National Competent Authorities to connect to, and participate in, the BCH<br><br>4.2 Available capacity for LMO detection and | 4.1.1 National BCH node, hosted on an institutional web site and accessible from other institutional web sites<br><br>4.1.2 Focal Point access to the BCH Central Portal and national records uploaded online<br><br>4.2.1. Formalization of an inter-institutional agreement |

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| Authorities | identification is strengthened<br><br>4.3 Strengthened capacity to deliver training and scientific education in biosafety | for rendering LMO detection and identification services<br><br>4.2.2. Laboratory capacity for detecting and identifying LMOs, including<br><br>4.3.1. Setting up of specialized and fully equipped classrooms and areas for training in biosafety<br><br>4.3.2 Infrastructural capacity (technology, library, etc.) renewed in National Competent Authority and Territorial Branches |

## C. Target Areas/Groups

35. The project was national in scale and covered the territory of Cuba. The target groups were government and non-government agencies with biosafety mandates or interests, the national university system, and the general public (in relation to the PIPE public awareness program. Specific stakeholders included:

- The Center for Biological Safety (CSB)
- Office for Environmental Regulation and Nuclear Safety (ORASEN)
- Ministry of Science, Technology and Environment (CITMA)
- Ministry of External Trade and Foreign Investment (MINCEX)
- Ministry of Transportation (MITRANS)
- Ministry of Agriculture (MINAG)
- Ministry of Public Health (MINSAP)
- Centre of Genetic Engineering and Biotechnology (CIGB)
- National Centre of Agriculture & Livestock Sanitation (CENSA)
- National Civil Defense General Staff (affiliated to MINFAR)
- General Customs of the Republic of Cuba (AGR)
- Faculty of Biology of the University of Havana (affiliated to MES)
- University of Holguín
- University of Cienfuegos
- National Center of Plant Health (affiliated to MINAG)
- National Institute of Veterinary Medicine (affiliated to MINAG)
- INSTEC (Institute of Applied Sciences and Technology)
- ACPA (NGO)
- Fundación Antonio Núñez Jiménez (NGO)

## D. Milestones/Key Dates in Project Design and Implementation

- Project Approval: October 2010
- Project Commencement: November 2010
- First Disbursement: December 2010
- Mid-Term Evaluation: May 2013
- TE Evaluation: October 2016-March 2017 [5]
- Planned Project Completion: November 2015

[5] The evaluator devoted part of this period to field visits related to another TE, as agreed with UNEP's Evaluation Office.

- Actual Project Completion: June 2016
- Financial Closure: December 2016

## E. Implementation Arrangements

36. UN Environment was the GEF-designated Implementing Agency (IA) for the project. In this capacity, it was responsible for overall project supervision to ensure consistency with GEF-UN Environment policies/procedures, providing guidance as needed and liaising with the NEA on substantive and administrative matters. The UN Environment Task Manager (TM) and Financial Management Officer (FMO) assisted the project team on management aspects in addition to UN Environment-GEF procedures and reporting requirements. The TM and FMO were responsible for clearing and forwarding financial and progress reports to GEF. UN Environment additionally approved all substantive reports and played an important support role in the direct procurement of international goods nonwithstanding the U.S. economic embargo.

37. As National Executing Agency (NEA), the Center for Biological Safety was responsible for overall project management, coordination, planning and monitoring. It also ensured the alignment of project execution with national policies, and bore ultimately responsible for project performance and delivery. Specific attributions included the approval of annual work plans and budgets, designation of the project team and periodic reporting to UN Environment and GEF.

38. National Competent Authorities [6] were both drivers and beneficiaries of the project through their participation in the Technical Committee and National Coordination Mechanism, and as recipients of project training, technical assistance and equipment. CSB and INSTEC in particular had substantive roles: CSB was the national executing agency and also led efforts to harmonize biosafety norms, standards and other regulations under the first project component. INSTEC designed the curricula for human resource training in biosafety and was very much involved in strengthening national LMO detection capacities under the third and fourth components. Likewise, CITMA's territorial branches provided decentralized training venues that extended biosafety training to the provinces. Cuba's General Customs also played an important role through its increased involvement in monitoring transboundary LMO movements under the second component.

## F. Project Financing

- GEF allocation: US$ 900,091
- GEF PPG allocation: US$ 9,000
- Government of Cuba co-financing: US$ 1,018,552
- PPG co-financing: US$ 24,254
- Total project cost (w/PPG): US$ 1,951,897

[6] Which included representation by CSB, Customs, IMV, Vegetable Health, Ministry of Public Health, Ministry of Interior, Ministry of Superior Education, Ministry of Agriculture, Ministry of Armed Forces, CITMA, MININT, MINFAR, MES, CSB and MINAG, as well as CIGB, IPK and CNAP.

## G. Project Partners

**Figure 4**

**Project Partners and Intended Roles**

| Partner | Role (as in PRODOC) | Were they Involved in implementation ? (Yes/No) | Involvement |
|---|---|---|---|
| 1. Institute of Nourishment and Food Hygiene (MINSAP). | To harmonize the process of decision-making about LMOS and necessity of capacity building. | Yes | Coordinate the authorization process |
| 2. Institute of Veterinary Medicine (affiliated to MINAG) | To harmonize the process of decision-making about LMOS and necessity of capacity building.<br>Border control | Yes | Coordinate the authorization process |
| 3. National Center for Plant Health (affiliated to MINAG) | To harmonize the process of decision-making about LMOS and necessity of capacity building.<br>Border control | Yes | Coordinate the authorization process |
| 4. Ministry of Foreign Trade | Border control, recognition of the national authority and art. 18. | Yes | To demand biosafety requirements in the trade to the importers and to specify them in contracts |
| 5. Maritime Security Division | LMOs transit and transport | No | |
| 6. National Civil Defense General Staff (affiliated to MINFAR) | Emergencies | Yes | Inclusion of biosafety in the emergency plans. Identification and detection of LMOs |
| 7. General Customs of the Republic of Cuba (AGR) | Border control | Yes | Establishment of the necessary procedures to execute the control in a first stage. |
| 8. Faculty of Biology of the University of Havana (affiliated to MES) | System of human resources formation | Yes | Execution of courses |
| 9. National Center of Animal and Plant Health (affiliated to MES) | Investigations | Yes | Representative of Search Institutions. |
| 10. Environmental Management Head Office (affiliated to CITMA) | To draw up policies and strategies | Yes | National environmental strategy of biodiversity and other policy guiding documents. |
| 11. International Collaboration Head Office (affiliated to CITMA) | CPB and GEF focal points. | Yes | Link with GEF |

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|---|---|---|---|
| 12. Center of Genetic Engineering and Biotechnology (affiliated to BioCUBAFARMA) | Representative of industry | Yes | Regulation documents, technical guides and training. |
| 13. NGOs (ACPA, Fundación Antonio Núñez Jiménez) | Public presentation | Low Participation | Public Education Program (PIPE) |
| 14. INSTEC | System of human resources formation | Yes | Execution of courses Design of the System and Program of Training. |
| 15. ANAP | National Association of Agricultural Producers | Low participation | Public Education Program |

## H. Changes in Design during Implementation

39. There were no changes to the project's design and the implementation process was based on the results framework of the project document. There were adjustments to activities and budget lines in response to changing circumstances that did not affect the expected deliverables or project budget. This reflected the project's good design as well good adaptive management and project ownership on the part of the NEA.

## I. Reconstructed Theory of Change (ToC) for the Project

40. The Theory of Change (ToC) analyses the causal pathways that link project outputs (goods and services delivered by the project) to outcomes (changes resulting from the use made by key stakeholders of project outputs) and towards impact (long term changes in environmental benefits and living conditions). The ToC also serves to identify intermediate changes that need to take place in order to proceed from project outcomes to impact; these are called 'intermediate states'. ToC also defines external factors that influence change along the major pathways and how outputs progress towards outcomes. These external factors are either drivers (when the project has a certain level of control) or assumptions (when the project has no control).

41. As seen in Figure 5, the analysis of the project's design and likelihood of impact was based on the mapping of causal pathways, and the extent to which related outputs and outcomes were connected sequentially in the implementation process. The identification of pathways for this project indicated that most outputs led to their respective outcomes, with several examples of over-arching outcomes that link different project components.

42. There was a high degree of articulation between the various elements of the project's design. The first three outcomes – the national biosafety coordination mechanism, the framework for LMO import/export, and the biosafety training system – were connected to the overall objective, yet also fed horizontally into the fourth outcome of greater NCA operational capacity. Hence while all outcomes needed to be reached in order to fulfill the project's overall objective, the higher-order outcome of greater NCA operational

capacities represented the “intermediate stage” that had to be reached in order to enable the achievement of the overall objective. Likewise, the project design internally linked associated outputs (i.e. output 1.1i-v, 2.1i-ii) that were sequentially connected on the impact pathways.

43. The overall objective of “addressing the technical, legal, infrastructural and biosafety management gaps faced by the country’s NCAs to ensure the successful and sustainable implementation of the CP in Cuba” was reflected in four technical components with outcomes that were identical to the immediate objectives. The lack of differentiation between objectives and outcomes departed from standard design practice (where outcomes usually feed into immediate objectives that are directly connected to the overall objective or goal) but this did not weaken the project’s design.

44. The outputs followed logical sequences towards their outcomes, and were designed in a manner that articulated related outputs (i.e. 1.1i, 1.1ii) with shared deliverables. For the first outcome, the availability of a LMO database (output 1.2ii) was a requisite for developing the web site and information flow (output 1.2i. 1.2iii), and provided an important input to the design of proposals for harmonizing legislation (1.1). From a ToC perspective this illustrated an impact/causal pathway that followed the implementation sequence connecting outputs 1.2ii>1.2i and 1.1; 1.2i>1.2iii>outcome 1; and 1.1>outcome 1.

45. The second outcome started with the collection of documentation on transboundary LMOs (2.2iii) and definition of NCA competencies (2.1i), both of which were needed to elaborate guidelines for the regulation of transboundary LMOs (output 1.2ii). The new guidelines and competencies would in turn enable the certification of border control officers (2.2i), and implementation of LMO border control. This impact pathway followed the sequence of ouptuts 2.2iii and 2.1i>2.1ii >2.2i; and 2.2i>2.2ii>outcome.

46. The third outcome was concerned with establishing a comprehensive training system. The impact pathway began with the design and formal approval of the biosafety training program with curricular content (output 3.1i), which established the basis for the main output of having a funded training system in place that articulates different state

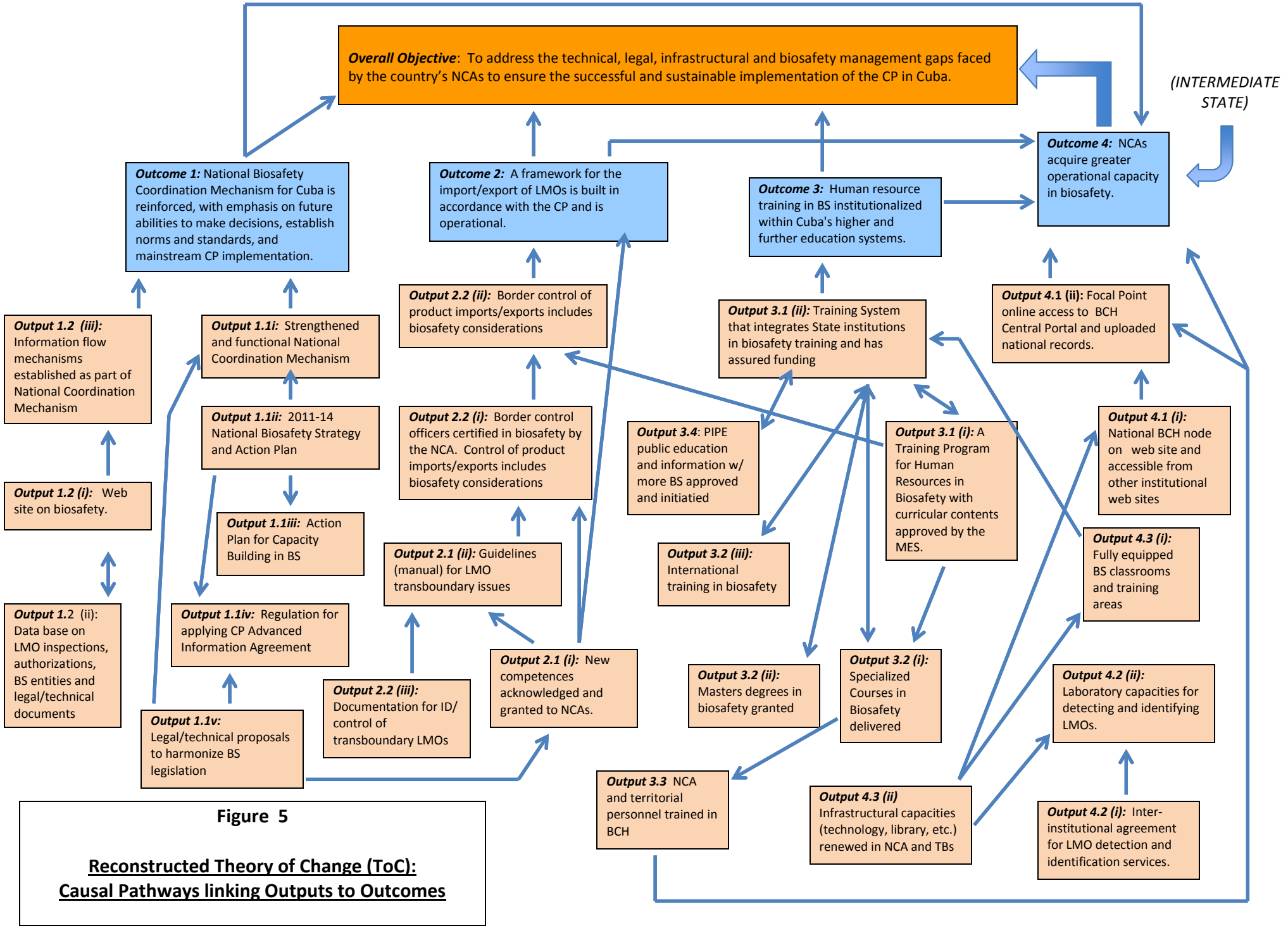


**Figure 5**

**Reconstructed Theory of Change (ToC):**
**Causal Pathways linking Outputs to Outcomes**

institutions (3.1ii). The training system provides the enabling framework for initiatives such as PIPE (3.4).

47. The ToC analysis identified the following drivers that have moved the implementation process forward, and the assumptions that influenced design and outcome yet were largely outside the project team's control:

48. ***Impact Drivers****:*

- Cuba's adhesion to the Cartagena Protocol on Biosafety.
- A dynamic and growing biotechnology sector that generates demand for biosafety services.
- Government commitment to an effective national biosafety system, as reflected in national plans and policies.
- NCAs have well-developed baseline capacities that allow them to participate effectively in project execution and internalize project benefits.

49. ***Assumptions***:

- The project timeframe and budget are sufficient to deliver all outputs and achieve intended outcomes (the NEA and project team can shift GEF funds between budget lines but not increase the approved amount or extend the project).
- There is political will to approve, finance and apply the Biosafety Training System and National Coordination Mechanism.
- NCAs and anticipating government institutions are motivated to participate fully in the project.
- Staff continuity is high within the project team, NEA and NCAs.
- Financial disbursements to the project are timely and efficient (in spite of the US economic blockade and introduction of the new Umoja system).

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# III. EVALUATION FINDINGS

## A. Strategic Relevance

50. The project assisted in the creation of Cuba's first biosafety coordination mechanism linking National Competent Authorities (NCAs), an integrated information system that streamlines LMO decision-making, a national training framework, and improved laboratory capabilities for LMO analysis. The project objectives were aligned with UN Environment's 2010-2013 Medium-Term Strategy (MTS) as reflected in the cross-cutting priority of global, regional and national environmental governance to address common environmental priorities,

and the third objective of capacity building and technology transfer in support of the Bali Strategic Plan's (BSP) implementation. There was also consistency with the UN Environment's 2010-11 Programme of Work (PoW) and Expected Accomplishment (EA) of enhanced State capacities to implement environmental obligations and achieve priority targets/objectives.

51. Project design also supported GEF's Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1) under SP-6 ("Building Capacity for the Implementation of the CPB") of Biodiversity Strategic Objective 3 (SO3), which was part of the "Focal Area Strategies and Strategic Programming for GEF-4" that was approved in July 2007. It also addressed the need for national biosafety frameworks to implement the CPB, as emphasized in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol (adopted at COP-MOP-3).

52. Relevance at the country level was reinforced by its complementarity with earlier biosafety projects, building on the progress that was achieved. As its name suggested, "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol" was the most recent initiative in the cycles of UN Environment-GEF project support that started in 1998 with the design of Cuba's national biosafety framework. The project was part of a broader cooperation context and built on the cumulative improvements that were achieved over the years, with the aim of closing the remaining capacity gaps and strengthening systemic performance through improved information flows and coordination mechanisms. The project's rationale and design were based on past empirical experience, and for the most part focused on specific capacity needs that were deliverable within the project timeframe. By supporting the creation of Cuba's first inter-institutional biosafety coordination mechanism (which is also used for CSB mandates for control of biological agents and exotic species), the project addressed an essential element of a functional national biosafety framework that was lacking. The support provided for laboratory infrastructure, reactives and other materials were extremely relevant to Cuba's material needs given the difficulties raised by the US trade embargo.

53. Gender balance was not explicit in the design of this project. However, CSB ensured that women were well represented in the project team - 7 of 9 participants were female – and training activities; several of the doctoral and masters candidates identified in the project reports were women. Human rights and indigenous people's issues were not relevant due the nature of the project and Cuba's demographic characteristics. South-south cooperation was sought at the project level by sending trainees to events in other Latin American countries, providing training to students from other countries (Latin America and Africa) and through collaboration with the University of West Indies – Trinidad, which executes a regional UN Environment-GEF biosafety project for the Anglophone Caribbean. Likewise, the UN Environment Task Manager organized annual meetings of national biosafety project coordinators from the LAC region that were highly appreciated and considered a good practice.

## B. Achievement of Outputs

54. The project's four technical components foresaw the delivery of 29 outputs and 46 activities. Project performance was highly satisfactory in this respect and almost all of the planned outputs were delivered. According to project reports, 27 (93%) of 29 outputs were fully completed, as were 89% of the programmed activities; the findings of the evaluation interviews support this statement. Two outputs were not achieved - the approval of NCA competencies (output 2.1) is pending in anticipation of changes to Cuba's governance framework that are currently being discussed; and improved laboratory infrastructure and capacities for LMO analysis (output 4.2) were not delivered due to procurement delays. Low levels of Internet connectivity affected online networking and discouraged use of the BCH, in spite of the expanded bandwidth and internet SHDL memory that were installed by ORASEN.

55. The following table summarizes the final status of project outputs:

**Figure 6**

**Achievement of Project Outputs**

| *Output* | *Level of Achievement* | *Evaluator's Comments* |
|---|---|---|
| 1.1 (i) A strengthened National Coordination Mechanism through discussions and definitions of the Technical Advisory Committee and agreements on how to maintain it functioning | ***Completed*** *The* first National Coordination Mechanism (MCN) was created from the project's technical advisory committee, linking National Competent Authorities (NCAs) with biosafety mandates. The MCN also facilitates coordination on biological agents and exotic species, which are under CSB's mandate. The MCN has held 10 meetings between 2011-2016 and made coordinated decisions on LMOs; the meetings are well documented. | The MCN has helped to clarify institutional roles and responsibilities for biosafety. It has facilitated agreements on procedures for the analysis of LMOs, and enabled the creation of a "single window" system to streamline LMO decisions in a coordinated manner. To an extent, the MCA(N)has helped in balancing biosafety awareness and capacities among institutions. The MCN approach is considered innovative and may be replicated by other cross-institutional government initiatives. |
| 1.1(ii) A National Strategy on Biosafety and its Action Plan for the years 2011-2014. | ***Completed.*** The 2011-2014 Biosafety Action Plan was formulated and incorporated to the national biodiversity strategy. The Plan has guided CSB BS work plans and activities during the 2011-2014 period. Cuba's updated National Environment Strategy (EAN) included a biodiversity component for the 2015-2020 period. | The 2015-2018 Biosecurity Action Plan was also drafted, yet remains under review with approval pending. This is due to an ongoing process of state reform that is expected to generate institutional changes within Cuba's public sector. |
| 1.1 (iii) An Action Plan | ***Completed.*** A capacity building | While not approved at ministerial |

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| for Capacity Building in Biosafety that covers LMO control, among other topics. | action plan was approved by CSB in its capacity as coordinator of capacity development for biosafety. | levels, the plan helped to focus the training needs and priorities of both the CSB and institutions on the MCN. It was socialized with the other institutions at workshops. The Plan identified the project idea that was later developed into a new proposal for GEF's sixth cycle. |
| 1.1 (iv) Regulation for applying the CP's Advance Informed Agreement | ***Completed.*** Proposed regulations were drafted that cover administrative aspects of the Informed Agreement and suggest a procedure for Cuba. A Resolution was sent to CITMA for approval. | Official approval was pending and outside the project's immediate control. |
| 1.1 (v) Legal and technical proposals for harmonizing legislation on transport, transit, storage and distribution of LMOs, coordinated decision making, and other gaps in the legislation. | ***Completed*** Biosafety legislation was updated and draft resolutions submitted to CITMA for approval. Proposals to harmonize decision-making among MCN authorities were proposed as internal Standardised Operating Procedures (SOPs) for internal institutional approval. MINCEX now recognizes CSB as lead biosafety authority for trade, under an amendment to the Harmonized System Product (SACLAP) concerning equipment and biological samples. | Same as above. The procedures are being applied to an extent between MCN members. |
| 1.2 (i) Web site on biosafety with information relevant to decision making | ***Completed.*** The project designed a biosafety information system (SIISB) that integrates a set of databases and legal/technical information. This system was designed with links to official sites of other MCN authorities, to access biosafety information for decision-making. | The SIISB is well designed, user-friendly and opens to pages containing information on CSB, biosafety inspections, authorizations, safeguards, projects and legislation. However, institutional access to the SIISB is conditioned by low internet connectivity. CITMA has helped to improve the bandwidth, and the SIIB will be connected to partner institutions via government Intranet. |

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| 1.2 (ii): Data base on LMO inspections, authorizations, BS entities and legal/technical documents | ***Completed*.** The SIISB contains databases of inspections, authorizations, list of entities and facilities biohazardous, along with a database on relevant legal/technical documents, guides and manuals. | Same as above. |
| 1.2 (iii) Information flow mechanisms established as part of National Coordination | ***Completed*.** Information flow mechanisms were designed and are used by MCN participants, contributing to more timely and | The improved flow of information between MCN authorities has helped to streamline LMO analysis and decisions. This has shortened |

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| Mechanism for biosafety | efficient biosafety decisions.<br>The project developed four databases addressing Inspections, Authorizations, Institutions and Legal/ Technical Documents that are currently running and being fed data. | the timeline considerably and enabled fuller participation of customs officials in monitoring transboundary LMO. However, internet connectivity is a problem and the system largely relies on government intranet and e-mail. |
| 2.1 (i) New competences acknowledged and granted to the National Competent Authority | ***Partially Completed.*** It was not possible to complete the accreditation process during the project because the national accreditation body (ONARC) adopted ISO NC / IEC 17020: 2012 leading to modifications and adjustments to accreditation documents. NCAs need to formally approve the MCN and related biosafety function internally before they can provide certification. Project reports mentioned the limited experience of the national accrediting entity ONARC with regulatory/inspector bodies.<br>There were delays in securing an external evaluator to give accreditation to the trained customs officials. The accreditation of the laboratories was not realized due to delays in the assgining an international evaluator by ILAC (Interamerican Cooperation Accredited Laboratories). | The accreditation of trained customs officials and laboratories is pending and is expected to occur in the near future, or alternatively under the proposed follow-up project that was presented to GEF. |
| 2.1 (ii) Guidelines (manual) for including transboundary issues such as transport, handling, identification, packaging and transit of LMOs in certification courses | ***Completed*** A manual for border inspectors was designed and has been used for training courses targetting Customs officials. It was subsequently revised and scheduled for publication. | The guidelines have benefited customs inspectors who are now aware of the procedures, shortening the time for handling and processing GM products. |
| 2.2 (i) Border control officers certified in biosafety by the National Competent Authority | ***Partially completed.*** 4 editions of the training course for border control officers have been held. 112 participants from 10 institutions were trained - doctors, agronomists, veterinarians and customs agents - at four annual courses. Certification was provided by the relevant NCA, although credentials for officials are pending. | Courses are included as part of the annual core training for customs personnel at the *Colegio de Formación Aduanera*.<br>Approximately 25 customs agents are receiving biosafety training each year.<br><br>There were delays in securing an external evaluator to give accreditation to the trained customs |

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| | | officials. |
| 2.2 (ii) Control of product imports and exports at the border includes biosafety considerations | ***Completed.*** An agreement was reached with the Ministry of Foreign Trade (MINCEX) to apply the format of declaration of conformity according to ISO/IEC standards, which obliges exporters to declare the actual or possible presence of LMOs in their products, and provide accompanying information in line with MOP I and III decisions. | Interviewed customs officials emphasized that trained inspectors are now better informed of biosafety issues, and know which institutions to contact. Institutional coordination has particularly improved with Animal and Vegetable Health. The MCN and information flow developed by the project were helpful in this regard. Control processes of biological/laboratory samples are quicker with lower likelihood of degradation, as had occurred with previous imported samples. |
| 3.1 (i) A Training Program for Human Resources in Biosafety is elaborated with curricular contents approved by the MES. | ***Completed.*** A national-scale human resource training program in biosafety was developed by CBS and the Higher Institute of Applied Sciences Technology (INSTEC) with the participation the Faculty of Biology of the University of Havana, the universities of Cienfuegos (central region) and Holguin (eastern region), all of which now have equipped classrooms with project support. The program encompasses post-graduate degrees (Doctorate in Biosafety and Risk Management; Masters in Biosafety) directed at academic faculty; post-graduate diplomas in design of facilities with biological risk, biological risk management, and biosafety for health and pharmaceutical facilities; and various under-graduate elective courses.<br><br>The program integrates and expands on existing biosafety training courses, including the existing Master's program. The training program meets the requirements of the Ministry of Higher Education of Cuba (MES) and requires formal approval by MES and INSTEC; the approval process is presently underway. | The evaluator notes that although formal approval of the training system is pending on the part of MES and INSTEC, the output was completed on the project's side. The design of the training program benefitted from peer reviews by specialized institutions (MES, INSTEC, the Council of Scientific Faculties, CSB) and subsequent adjustments to content as in the case of the VI edition of the Master's program. Biosafety training faculty were identified and assigned.<br><br>Postgraduate training has been ongoing. A total of 105 degrees have been awarded or are anticipated under the V (graduated in 2015 and 2016) and VI editions (graduating in 2019) of the Masters program in Biosafety. |
| 3.1 (ii) A Training System that integrates | ***Completed.*** The training system links CSB, INSTEC, MINCEX, MES, | Same as above. According to the project team, funding is assured for |

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| State institutions in biosafety training and has assured funding. | MINAL, CITMA's decentralized training facilities, and the Universities of Havana, Holguín and Cienfuegos. | the training program from the State budget. |
| 3.2 (i) Specialized Courses in Biosafety delivered to biosafety-related professionals and specialists | ***Completed.*** A total of 19 specialized courses were implemented in classrooms equipped by the project. These included 2 courses for biosafety officers, 5 on biosafety inspections, 5 of authorizations, 4 for border inspectors and 3 courses on biosafety facilities design aimed at architects, engineers and construction professionals. | Achievement levels were highly satisfactory and initial targets were surpassed. 490 (98%) of the 498 participants successfully completed the courses.<br>The strategy of offering postgraduate biosafety courses within the core training programs of different entities (INSTEC, Customs) and university faculties, offers a cost-effective arrangement in comparison to having separate programs. |
| 3.2 (ii) Masters degrees in biosafety granted to biosafety-related specialists and personnel from entities that handle biological risk. | ***Completed*** The master's course completed its fifth edition and has commenced the sixth. A total of 105 degrees have been awarded or are anticipated under the V (graduated in 2015 and 2016) and VI editions (graduating in 2019) of the masters. | The existing biosafety Master's program and didactic materials were revised and a new version is now being offered, based on the recommendations of a peer review. |
| 3.2 (iii) International training in biosafety for staff that conform the National Biosafety System | ***Completed*** A total of 18 specialists from the national authority have been trained in 26 workshops and conferences abroad. Topics included LMO risk analysis, GIS systems, biotechnology in agriculture, | Many of the participants will support the human resource development program as trainers and faculty. |
| Output 3.3 (i) Personnel from competent authorities and territorial authorities trained in BCH use | **Completed.** Three workshops were held on the use of the BCH, directed at NCAs, scientific and academic institutions (including provincial delegations), and NGOs. | The workshops were organized in cooperation with the BCH II project. |
| 3.4 (i) Program for Public Information and Education (PIPE) re-elaborated, giving biosafety more prominence, approved, and its implementation initiated | ***Completed*** The revised PIPE was approved at the 5$^{th}$ MCN meeting, and coordinated with MES. Workshops were held to plan PEP implementation with the media, NGOs and educational institutions. Dissemination activities were conducted and educational materials developed. | PIPE implementation is in its initial stages, involving the dissemination of biosafety information through the mass media. |

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| 3.4 (ii) Educational and dissemination materials | ***Completed*** A set of folding brochures, an electronic newsletter and video addressing different biosafety issues were developed, in addition to an e-book outlining updated LMO risk assessment guidelines. Animated biosafety spots have been presented on television. | The design of an online component is restricted by limited internet connectivity. |
| 4.1 (i) National BCH node is hosted on an institutional web site and accessible from other institutional web sites. | ***Completed.*** Web page was designed and is operational. | Despite improvements in bandwidth, the capacity of NCAs to use the BCH continues to be limited by internet connectivity problems that are outside the project's control. |
| 4.1 (ii) Focal Point accesses to the BCH Central Portal and national records uploaded online. | ***Completed.*** ORASEN allocated funds to improve offce bandwidth from 128 kb to 256 kb, and co-financed 1 meg internet SHDL. This is expected to enable CSB and NCAs to upload/update information to the BCH. | Same as above. |
| 4.2 (i) Formalization of an inter-institutional agreement for rendering LMO detection and identification services. | ***Completed.*** Agreements were reached with the National Center for Agricultural Health (CENSA) and Center for Scientific Research of civil Defense (CICDC) to utilize laboratory facilities for LMO detection and identification services. | These agreements are expected to enable independent LMO detection/identification by NCAs, without depending on the Cuban Center for Genetic Engineering & Biotechnology (CIGB) – a producer of GMOs – for this service. |
| 4.2 (ii) Laboratory capacities for detecting and identifying LMOs. | ***Partially completed.*** The output was not fully achieved due to delays in the procurement of laboratory reactives and other inputs needed for LMO detection. | The delays were internal to the Cuban government and not UN Environment. The strengthening of laboratory capacities is a main component of the proposed follow-up project. |
| 4.3 (i) Setting up of specialized and fully equipped classrooms and areas for training in biosafety. | ***Completed.*** Three regional classrooms have been equipped at the Higher Institute of Science and Advanced Technologies (INSTEC) in Cuba's western region, the University of Cienfuegos for the central region and University of Holguin for the eastern region. | The output significantly facilitates access of provincial students and government staff to biosafety training that was previously offered in Havana only. The improved classrooms are already being used for training, spreading biosafety capabilities both territorially and institutionally in anticipation of expected state reform/decentralization measures. in 2017. |
| 4.3 (ii) Infrastructural capacities (technology, library, etc.) renewed in National Competent Authority and | Completed. Several CITMA territorial branches have been used for postgraduate courses aimed at provincial students and government technical staff. Computers were | Same as above. The support provided for the acquisition of equipment is highly valued by project partners given the difficulties generated by the U.S. trade embargo |

| | | |
|---|---|---|
| Territorial Branches. | acquired for NCAs at central and provincial levels, the capacity of servers improved, and equipment such as printers and photocopiers purchased. | and limited availability of foreign exchange. |

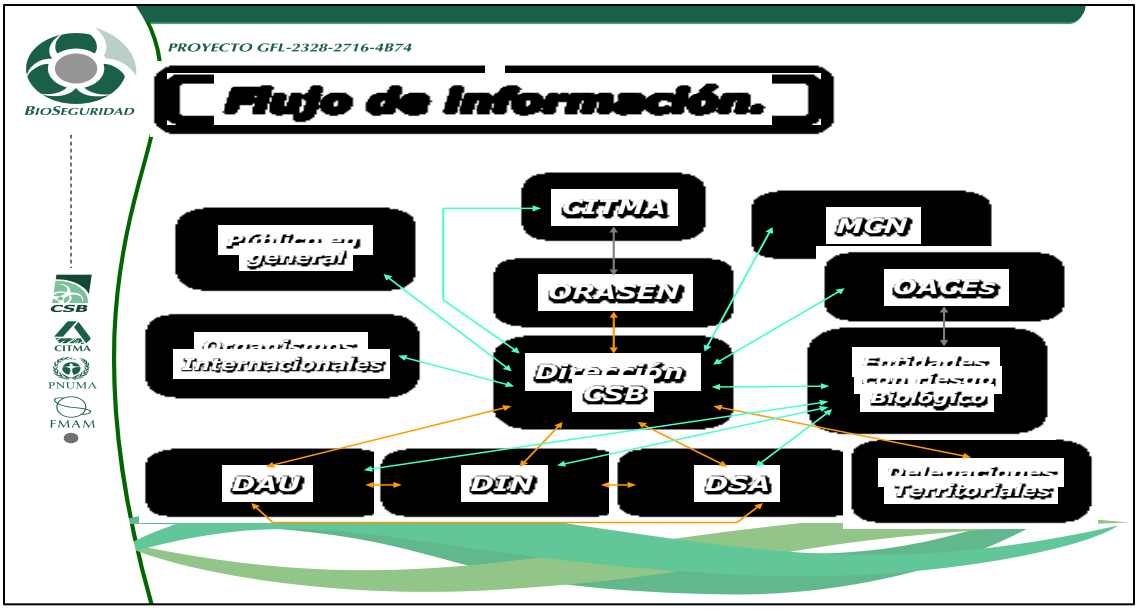
**Figure 7**

**The Integrated Biosafety Information System (SIIB): Home Page**


*Source: CSB PPT presentation (2016)*

**Figure 8**

**Integrated Biosafety Information System: Information Flow between Institutions**




*Source: CSB PPT presentation (2016)*

**Figure 9**

**The National Biosafety Training System: Academic Structure**

| | | |
|---|---|---|
| **Academic Faculty Development** | | ✓ Doctorate in Biosafety<br>✓ Specialty in Biosafety<br>✓ Masters in Biosafety |
| **Post-graduate level** | 5 Diplomas (720 hrs+)<br><br>12 post-graduate courses | ✓ Design of facilities with biological risks<br>✓ Biological risk management<br>✓ Biological risk evaluation<br>✓ Biosafety for health facilities<br>✓ Biosafety for medical/pharmaceutical industry |
| **Undergraduate level** | 3 elective courses | |

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

### C.1 Direct outcomes from reconstructed TOC

56. The project was effective in its progress towards expected outcomes, three of four of which were achieved to a high degree (in relation to their indicators). This section assesses the extent to which the four outcomes were reached, and how the impact pathways connecting outputs to outcomes influenced this. For reference, the pathways are illustrated in Figure 8 "Reconstructed Theory of Change (ToC): Causal Pathways linking Outputs to Outcomes" in Section 1.I.

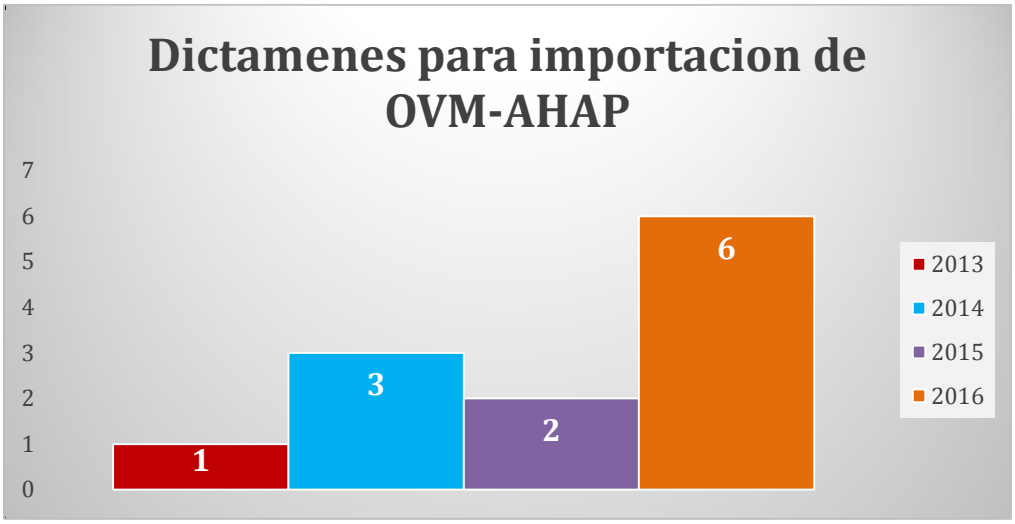
| ***Outcome 1:*** | ***Indicators:*** | ***Achievement Rating:*** |
|---|---|---|
| *The National Biosafety Coordination Mechanism for Cuba is reinforced, with an emphasis on future abilities to make decisions, establish norms and standards, and mainstream CP implementation.* | ✓ *Greater capacity for implementing, coordinating and harmonizing the country's biosafety legislation with the administrative processes of the Cartagena Protocol (CP) and other relevant legislation*<br>✓ *Improved information management related to biosafety* | *Highly Satisfactory* |

57. The first outcome was achieved through the delivery of outputs 1.1 (National Coordination Mechanism) and 1.2 (integrated information system) that are situated at the top of the causal pathway and lead directly to the outcome. The establishment of a National Coordination Mechanism (MCN) linking NCAs has been an important milestone of Cuba's biosafety framework that raises capabilities for informed LMO decision-making and fulfilling its obligations under the Cartagena Protocol. The MCN has enabled sustained institutional dialogue between the CSB, Ministry of Public Health (MSP), Interior Ministry (MININT), Ministry of Exterior Commerce (MINCEX), Ministry of Superior Education (MES), Customs, the Center for Biological Engineering Research (CIGB) and National Center for Plant Health, among others.

58. The MCN is functional and has met twice yearly since 2011. During this period 74 requests for grain imports were handled, of which 12 led to LMO decisions while 62 were discontinued because the products did not contain modified organisms (Figures 9 and 10). Combined, the numbers indicate a marked increase in requests that underscore the greater involvement of Customs and benefits of the MCN. According to interviewed participants, the MCN has also helped to balance biosafety awareness and capacities among NCAs that had limited prior involvements, i.e. Customs and MINCEX. The coordination mechanism is multi-functional and cost-effective because it also convenes for biological agents and exotic species, which are within CSB mandates.

**Figure 10**

**Decisions on LMO Importations involving the MCN: 2013-2016**



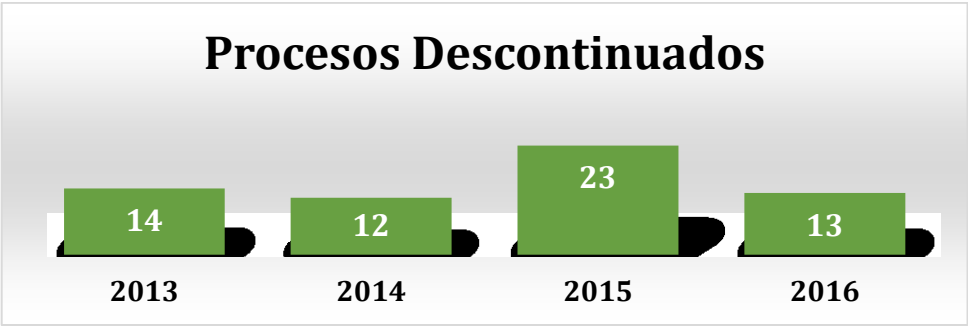

*Source: CSB PPT presentation (2016)*

> *"I didn't expect the project to go as far as it did."*
>
> *- CIGB focal point to the project*

59. The MCN has helped national authorities reach agreements on how to proceed with the analysis of LMOs and establish a "one stop" system that streamlines decision processes and articulates the pronouncements of different authorities in a coordinated manner. Dossiers are now handled by the relevant NCA according to the type of LMO involved. Formats have been standardized and the sequence of steps required for LMO analysis and decisions are now understood by all NCAs.

**Figure 11**

**Discontinued LMO Applications: 2013-2016**




*Source: CSB PPT presentation (2016)*

60. As a result, decision-making has become more agile. Decisions on imported transgenic grains that required several months are now taken within 30 days, and the deadline for reaching decisions was reduced from 10 to 3 months. Before the project, Customs would retain LMO materials for up to 45 days in the absence of clear guidelines and then destroy them; CIGB had lost imported biological samples in this manner with detrimental effects on research. After the MCN and information flow were introduced the timelines were reduced considerably. Presently, LMO importers need to submit one folder of documents instead of dealing separately with different institutions and paperwork requirements.

61. This is a notable improvement over the pre-project situation, when an importer had to be accredited by MINCEX and get separate approvals from CSB, the Sanitary Register of Foodstuffs and Institute of Plant Health (or Animal Health depending on the product). The MCN enables the permanent regulation of imported soya and maize for animal feed by CIGB, which has 63 ongoing LMO licenses that require annual renewal.

*"This is the first coordination mechanism that articulates different institutions in the country. Cuba has 28 regulated organisms, yet only CITMA has this internal coordination approach. The MCN and information flow have become references on a national scale."*

*"Our previous national control system was dispersed and fragmented. Now the various permits and authorizations for GM imports are linked under the new system."*

*- MINCEX focal point to the MCN*

62. The first component also sought to harmonize the biosafety regulations. While there were advances, the full impact is likely to be felt in the coming months: Biosafety legislation was updated and draft resolutions submitted to CITMA for approval. Proposals for harmonizing decision-making processes are also being considered within the Standardised Operating Procedures (SOPs) of specific NCAs. The current Law on Public Health did not consider biosafety functions or their regulation, and the MSP recently approved modifications that include legislation on Inoculation, food security and consumer protection; the revised version was submitted to Cuba's State Council for final review and approval. National authorities have agreed to require biosafety authorizations for imported grain. Proposed regulations for the Advanced Informed Agreement were drafted, revised and cleared by ORASEN, and are presently with CITMA's legal department. Likewise, a proposals for merging different regulations that address the confined use of LMOs are also with CITMA's legal department. If approved, the revisions will improve the cohesiveness of Cuba's biosafety legal and regulatory frameworks.

63. Although the MCN is functional the mechanism needs to be approved internally by each NEA in order to be formalized. The MSP and other national authorities have started this process. A final report on the proposed resolutions for the MCN was sent to the Ministry (CITMA) for approval and circulation. The dynamics of the MCN are considered innovative for Cuba's public sector and interest has been expressed in applying the mechanism to other institutions that have common mandates and coordination needs.

64. NCA respondents consider that the improved information flow has contributed to more timely decisions and strengthened the functions of the MCN. The Integrated Biosafety Information System (SIISB) encompasses authorizations, inspections, legal and technical information, and links to the BCH and websites of other authorities. The system contains four databases on inspections, authorizations, institutional responsibilities and legal/ technical documents are currently running and being fed data. MCN members use the SIISB; however, access is affected by connectivity problems. Although the NCAs are presently connected by government intranet, data cannot be uploaded to the Internet. A related limitation is the inability to register digital signatures online, although this is not considered a major constraint at present.

| ***Outcome 2:*** | ***Indicators:*** | ***Achievement rating:*** |
|---|---|---|
| *A framework for the import and export of LMOs is built in accordance with the CP and is operational* | ✓ *The National Competent Authority is granted competency to certify border control officers in biosafety*<br>✓ *Biosafety is integrated into border control activities* | *Satisfactory* |

65. The second outcome was reached for the most part following the achievement of output 2.2ii (border control of product imports/exports includes biosafety considerations) that feeds directly into the outcome, output 2.1ii (guidelines for transboundary LMO issues) and output 3.2 (the national training system), all of which were connected along a common impact pathway. Biosafety practices have been progressively integrated into border control activities, although they still need to be extended to airports outside of Havana. The accreditation of customs inspectors (outputs 2.1i, 2.2i) remains pending.

66. The biosafety awareness and capacities of customs officials were strengthened considerably through the MCN, four editions of the biosafety training course that is offered annually at the School for Customs Formation, and the revised manual of biosafety functions. An agreement was reached with MINCEX to apply the format for declaration of conformity that uses ISO/IEC standards, obliging exporters to declare the actual or possible GMO presence in their products and provide accompanying information. As a result, a framework for the import/export of LMOs exists and is operational. The involvement of Customs officials in monitoring the import/export of LMOs has increased considerably and 322 requests were attended between 2012-2016.

*"The project organized itself well with highly prepared personnel."*

*"The project was formidable for Customs because it was an almost unknown topic, having this knowledge at border points has been a very important advancement."*

*- Customs focal point to the MCN*

67. The CSB was officially recognized as a competent authority for all import-export activities through resolution No. 119/2012 of the National Office of Statistics and Information (ONEI). However, both the MCN and corresponding biosafety functions must be approved internally by each NCA. As noted, the accreditation process was not completed due to the adoption of new ISO NC/IEC standards by ONARC – the national accrediting entity - that require adjustments to the current arrangement. There were also delays in securing an external evaluator to grant accreditation to the trained customs officials. And the accreditation of laboratories for LMO detection was not realized because there were delays in getting an international evaluator from the Inter-American Laboratory Accreditation Cooperation (ILAC). The combination of these delays ultimately lowered the level of outcome achievement.

| ***Outcome 3:*** | ***Indicators:*** | ***Achievement Rating:*** |
|---|---|---|
| *Human resource training in biosafety is institutionalized within Cuba's higher and further education system* | ✓ *An integral and coordinated training system is created for biosafety management and CP implementation*<br>✓ *The human resources that form part of the National Biosafety System receive up-to-date training in biosafety management and CPB implementation*<br>✓ *Comprehensive and coordinated training on the Biosafety Clearing House (BCH)*<br>✓ *Greater public awareness with respect to biosafety in Cuba*<br>✓ *Increased the potential for regional human resources training in biosafety* | *Highly Satisfactory* |

68. This component enabled CSB to expand the geographic and thematic scope of biosafety training with the participation of various technical agencies and academic institutions. From a ToC perspective, the achievement of Outputs 3.1i (approved national system for biosafety training) and 3.2 (public education program) – both of which occupied strategic positions on the impact pathways for this outcome – enabled Output 3.1ii (training system integrating State institutions in biosafety training with assured funding), which was directly connected to Outcome 3. In this respect, Output 3.1ii could be viewed as the intermediate state that must be reached in order to enable the third outcome's achievement.

69. The project has helped to establish a permanent system for capacity building that is expected to meet Cuba's biosafety needs by 2020, with the potential for offering specialized courses to other countries in the region that do not have such a comprehensive approach. The combination of doctorate, postgraduate, and undergraduate training, combined with specialized short courses, enhances sustainability perspectives by ensuring future capacities, and potentially recuperating costs through training agreements with other countries or future biosafety projects. The project has strengthened Cuba's comparative advantages as a regional "hub" for biosafety training; it is the only country in the LAC region that will offer diplomas for the design of health and pharmaceutical/ medical facilities that produce or handle LMOs.

70. The national training system articulates the universities of Havana, Holguín and Cienfuegos, CITMA's territorial branches, INSTEC and other government agencies. The resulting network strengthens Cuba's ability to decentralize biosafety management in the event that governance reform measures are introduced in the future. The training courses received high marks from interviewed participants from various NCAs, and have had impact on institutional awareness and preparedness as in the case of General Customs, which now offers a biosafety course within its core training program and has raised its involvement in the control of transboundary movements GM products, attending 322 requests between 2012-2016.

> *"For us, this has been a formidable project. Biosafety was an unknown subject within Customs, and raising awareness at border points has been a very important advance."*
>
> *- Customs focal point to the MCN*

71. Public awareness activities focused on the production and dissemination of documentaries, brochures, calendars and a newsletter. The impact of these initiatives has not been measured and any assessment to this effect may be premature. The participation of NGOs and the national farmers association (ANAP) was limited despite opportunities to do so. An influencing factor is that biodiversity topics that are of public interest and intensely debated in other countries – for example, transgenic crops and LMO labeling - are not an issue for Cuba's civil society, and awareness needs to be developed. BCH training was implemented as planned yet its impact is also difficult to assess – the number of site visits or "hits" are not tabulated, and most of the interviewed NCA representatives had not used the BCH outside the training context due to low connectivity.

| ***Outcome 4:*** | ***Indicators:*** | ***Achievement Rating:*** |
|---|---|---|
| *National Competent Authorities acquire greater operational capacity in biosafety for meeting current and future demands* | ✓ *Greater capacity in the National Competent Authorities to connect to, and participate in, the BCH*<br>✓ *Available capacity for LMO detection and identification is strengthened* | *Moderately Satisfactory* |

72. The fourth outcome was not fully achieved for reasons that were largely outside of the project's control. The implementation approach followed the progression of outputs on the main impact pathway: The institutional agreements reached under output 4.2.i enabled the selection and equipping of laboratories (output 4.3i). Likewise, providing computers and libraries to NCAs under output 4.3ii enhanced conditions for the improved BCH access foreseen by outputs 4.1.i and 4.1ii, which are directly connected to the outcome. However, overall achievement of the fourth outcome was affected by the delays that undermined the procurement of laboratory materials, and Internet connectivity limitations that discourage a greater use of the BCH by national authorities.

73. Training and institutional support have raised the capacity of NCAs to use the BCH. This is important to the functions of Cuba's MCN and offers an important tool for knowledge management. However, most of the interviewed NCA representatives have not continued to use the BCH outside of the training context. Several NCAs may need to continue developing an institutional biosafety "culture" as the MCN progresses – and IT improves – before they can make full use of the BCH.

74. Supporting lab facilities for LMO detection and equipping training classrooms were highly appreciated contributions given the difficulties of acquiring equipment and biological samples from abroad. Newly-equipped classrooms within INSTEC and participating universities are directly supporting the national training activities of the third component, offering an example of pathway linkages across components and outcomes. The agreements reached with the National Center for Agricultural Health (CENSA) and Center for Scientific Research of Civil Defense (CICDC) to use their laboratory facilities for LMO detection, are important steps towards establishing independent capabilities (until now, LMO detection was conducted by CIGB, which is also a producer). As mentioned, delays in the procurement of laboratory reactives and other inputs have prevented the laboratories from achieving the necessary capacity for LMO detection/identification. This will be continued under a proposed follow-up project that has been presented to GEF.

### C.2 Likelihood of impact using RoTI and based on reconstructed ToC

75. There is a high likelihood of impact, considering the project's advances through the causal pathways towards the outcomes and intermediate states that precede impact.

76. Almost all of the higher outputs and outcomes were reached, and several of these represented intermediate states that enable impact. For the first outcome, this intermediate state was represented by outputs 1.1 (the NCM) and 1.2 (integrated information system) that connect directly to the outcome and immediate objective. The NCM has been operational for approximately two years and has made a number of LMO decisions in this capacity, with tangible improvements in institutional coordination and efficiency. This had encouraged greater participation by Customs, MINCEX and other partners with improved results in the time required for decisions and better regulation of LMO imports and exports. There is already an impact in operational terms, although official recognition of the coordination mechanism and the associated NCA biosafety responsibilities is pending.

77. The combination of outputs that produced guidelines for regulating transboundary LMOs and training courses for border control agents, created the enabling conditions for achieving output 2.1 "border control of product imports/exports includes biosafety considerations" which leads directly to the second outcomes and immediate objective.

78. From a ToC perspective, the achievement of Outputs 3.1i (approved national system for biosafety training) and 3.2 (public education program) – both of which occupied strategic positions on the impact pathways for this outcome – enabled Output 3.1ii (training system integrating State institutions in biosafety training with assured funding), which was directly connected to Outcome 3. In this respect, Output 3.1ii could be viewed as the necessary state that must be reached in order to enable the third outcome's achievement. The project has helped to establish a permanent system for capacity building.

79. The fourth outcome - NCAs acquire greater operational capacity in biosafety for meeting current and future demands - was not fully achieved for reasons that were largely outside the project's control. The implementation approach followed the progression of outputs on the main impact pathway: The institutional agreements reached under output 4.2.i enabled the selection and equipping of laboratories (output 4.3i). Likewise, providing computers and libraries to NCAs under output 4.3ii enhanced conditions for the improved BCH access foreseen by outputs 4.1.i and 4.1ii, which are directly connected to the outcome. However, overall achievement of the fourth outcome was affected by the delays that undermined the procurement of laboratory materials, and Internet connectivity limitations that discourage a greater use of the BCH by national authorities.

### C.3 Achievement of Project Goal and Planned Objectives

80. Based on the analysis, the project's overall and immediate objectives were achieved. The project achieved its main objective of addressing the technical, legal, infrastructural and biosafety management gaps faced by the country's National Competent Authorities to ensure the successful and sustainable implementation of the Cartagena Protocol in Cuba.

81. In terms of its immediate objectives, the project reinforced the National Coordination Mechanism and improved decision-making processes (IO 1). The framework for LMO import and export was strengthened through greater involvement of the General Customs agents and the inclusion of LMO information in the required Declaration of Conformity forms (IO 2). A national system of human resource training in biosafety was designed and activated (IO 3), and the capacities of NCAs was increased, although laboratory infrastructure and equipment for LMO detection and identification needs to be established (IO 4).

## D. Sustainability and Replication

### D.1 Socio-Political Sustainability

82. This project has a high sustainability potential at different levels. CSB's mandates for biosafety, biological agents and exotic species are components of Cuba's state security policy. CSB has strong institutional presence as reflected in its broad network of partners, its lead role

in providing higher biosafety education, and status as national authority to the CPB. Cuba has demonstrated a clear policy commitment to implement the Cartagena Protocol and has the technical and organizational capabilities to do so. This policy commitment is also driven by a dynamic biotechnology sector that is an important component of Cuba's export economy and foreign exchange earnings.

83. The project helped draft two national biosafety action plans; the State Council is considering the approval of the 2016-2020 edition. There are ongoing discussions on proposed constitutional amendments that could enter into effect in 2017 and alter the government's institutional framework with a possible decentralization of functions. While this generates a sense of uncertainty, the biosafety institutional framework and mandates are not expected to change. The availability of national training improves conditions for the decentralization of biosafety functions and could assist future processes in this direction.

## D.2 Financial Sustainability

84. All project activities and outputs were delivered through public sector entities. The main project initiatives that are expected to continue - the MCN, the national biosafety training system, the PIPE – will be covered by the respective institutional budget, according to respondents. Therefore the likelihood of financial sustainability is also high.

85. There are financial constraints that could affect the replacement of equipment and other items that must be imported and paid with foreign exchange. However, the project has made an important contribution that is expected to satisfy national needs for the next years. There may be opportunities to recuperate costs and generate income by offering the biosafety training program to other countries in the region that do not offer the range of courses.

## D.3 Institutional Framework

86. The institutional and technical capacity of the CSB and other NCAs are important drivers of institutional sustainability. The CSB has had extended involvement in biosafety since Cuba adopted the Cartagena Protocol, and was NEA for earlier GEF-UN Environment projects. The national coordination mechanism is also used for CSB's other mandates for biological agents and exotic species. The formal recognition of CSB as the lead national authority on biosafety and the greater involvement of Customs and other government agencies are important milestones that strengthen the enabling institutional environment.

87. There is a community of professionals from the CBS, the University of Havana and partner institutions who have studied together and worked together for many years. The levels of staff permanence, team rapport and expertise are clearly drivers of sustainability in their own right. Practically all project activities were managed by core CSB staff, from which the

project team was drawn. This strengthens perspectives for continuity among a professional team that has worked together over an extended period.

### D.4 Environmental Sustainability

88. There are no particular environmental factors that influence the future of the project, aside from the continued development of Cuba's biotechnology sector. Confined trials of transgenic crops are limited to a maximum area of 10 hectares and are concentrated in one province of the island. The project initiatives are expected to strengthen Cuba's ability to ensure biosafety on a national scale, which is beneficial for the natural environment.

### D.5 Catalytic role and Replication

89. The project was designed to close pending gaps in Cuba's national biosafety framework by strengthening institutional coordination, information management, capacity development and laboratory infrastructure. The project targeted the national biosafety framework and did not have pilot components that were intended for replication. Indeed, Cuba's national biosafety framework has evolved well beyond the demonstration stage. However, several of the interviewed participants think that MCN and information flow are innovative approaches to inter-institutional coordination that are new in Cuba, and could be readily applied to other sectors or initiatives that involve similar dynamics. This could be useful to assist other mandates or governance processes that require coordination among stakeholders.

90. The project did have a role in catalyzing behavioral changes within NCAs that had entered with little exposure to biosafety. CSB was recognized as the lead national authority in biosafety by MINCEX and other government agencies, and was able to develop working relations with a broader range of stakeholders. The MCN, information flows and training have stimulated the interest and participation of agencies such as Customs, MINCEX and others with little or no biosafety experience.

91. Under the second component, CSB was able to reach an agreement with MINCEX to adjust the declaration of conformity format to ISO/IEC standards; this requires a declaration on the actual/possible presence of GMOs and accompanying information. The project has catalyzed a stronger budget commitment to biosafety by government. Operational costs associated with the MCN, SIISB and national training system will be covered under the government budget. Under the third component, the project had a direct role in expanding biosafety training on a national scale through participating provincial universities (Cienfuegos, Holguín) and CITMA's territorial branches.

## E. Efficiency

92. The project was cost-effective in its implementation. Project delivery was consistently high and over 90% of project activities and outputs were completed as planned. The final project audit indicated a financial delivery rate of 96% between November 2010 and June 2016 with a final unspent budget of US$ 12,000 that included the cost of the Terminal Evaluation. [7]

93. The efficient performance reflected the institutional capacity of CSB and its partners, as well as the economic approaches used Cuba's public sector in its daily operations to make the best use of limited budgets. As a result, the GEF grant and government contribution enabled a wide range of activities that in almost all cases were delivered on time and with high professional quality. The MCN, in addition to being Cuba's first biosafety coordination mechanism, is also multi-functional and is applied to biological agents and exotic species.

94. Management costs were low: CSB or government partners directly executed the various components. A senior CSB manager and a compact group of experienced technical staff led the project team. As a result there were lower expenditures on external consultants and technical services.

95. UN Environment played an important and not common support role in external procurement, by directly purchasing international equipment and other goods, and forwarding these to the project via the UNDP country office. This practice helped implementation by providing a timely and efficient option that avoided the barriers of the economic embargo. There were few exceptions to the high levels of project efficiency: Disbursements and payments were delayed by several months during the Umoja "blackout" during which financial transactions were suspended (the project was subsequently extended by six months in compensation). There were other delays in the purchasing of laboratory equipment and reactives for LMO detection that ultimately prevented the project from fully achieving the fourth outcome. In 2016, a UN Environment disbursement arrived two months late because funds were sent from Nairobi to UNDP Cuba through New York, could not be processed, and were returned.

## F. Factors and Processes affecting Project Performance and Results

### F.1 Preparation and Readiness

96. The project's effectiveness and efficiency were the result of high institutional capacities and preparedness. "Completion and strengthening of the Cuban national biosafety framework

[7] Independent Audit, CIH, S.A (2016)

for the effective implementation of the Cartagena Protocol" was the most recent initiative of a series of GEF-UN Environment projects, and builds on the achievements and lessons of these earlier experiences. The project's design and execution arrangements were part of a broader context and benefitted from the cumulative experience acquired. Another contributing factor was the stability of personnel within the CSB and other government agencies, which helps in building institutional memory, professional expertise and group rapport.

97. Project stakeholders were identified according to their mandate and functions as NCAs for the national biosafety framework. Institutional capacities were first considered during the 2011 National Capacity Self-Assessment (NCSA) process and revisited afterwards during the PPG design phase.[8] The main project components – developing the national coordination mechanism, establishing national biosafety training, harmonizing regulations – were intended to strengthen and balance institutional capacities by engaging them. These aspects may have helped to facilitate early partnership relations and have factors helped to facilitate the early establishment of partner relations within the project, and the evolution of the Technical Committee into a permanent National Coordination Mechanism (MCN). The designation of the Center for Biological Safety (CSB) as NEA was a logical choice in view of its biosafety mandates - regulating LMOs, biological agents and exotic species; being national authority to the CPB - and accumulated experience as Cuba's leading biosafety entity. The CSB subscribes to ISO 9000 quality management standards and has an established team of highly capable professionals who have participated in past GEF-UN Environment projects.

98. Project design in general was straightforward, well articulated and feasible for the approved timelines and budget. The four outcomes were achievable, in part because they built on capacities and processes that were already in place (and comparatively well-developed for the region). The achievement of outcomes was not conditioned by unrealistic design assumptions nor did they envision changes to baseline situations that were unlikely to occur. As a result, their attainment was more viable on the part of the NEA. The project's design was also sensitive to Cuba's difficulties in procuring external goods and services due to the U.S. embargo: The project was approved for a five-year period (instead of the four years that are normally given for MSPs) and a relatively high portion of the budget (32%) was earmarked for equipment and laboratory materials.

99. The project strategy addressed the institutional and systemic dimensions of capacity development. The second and fourth components were directed at raising NCA capabilities for meeting priority needs aspects - regulating LMO imports and exports, improving LMO detection and risk assessment - that are core functions of national biosafety system. Whereas the first and third components addressed systemic levels by creating institutional coordination

[8] PPG support enabled the CSB to hold two workshops with NCAs and other stakeholders that served to discuss project design, clarify institutional roles and harmonize expectations.

mechanisms, information flows and a national training system. The implementation approach encouraged synergy between the project's components and raised collective impact through institutional capacity improvements that, combined with information flows and coordination mechanisms, have improved the systemic effectiveness of Cuba's national biosafety framework.

100. One of the main obstacles that affected institutonal coordination and networking was the slow Internet connectivity. This obstacle affected institutional access to the BCH, digital communications and coordination, and the uploading of data to ANUBIS. The present IT technology does not allow clients to track the status of their LMO applications, or the use of digital signatures. Another problem was the difficulty of procuring international goods and services. UN Environment helped the project to avoid this obstacle by directly purchasing equipment and other international items from Nairobi, and sending them to the project through the UNDP Country Office.

## F.2 Project Implementation and Management

101. The project was implemented and managed in a very satisfactory manner. The implementation mechanisms outlined in the project document were duly followed and a majority of the planned milestones, outputs and outcomes were fully delivered. There were few adaptations to the implementation strategy, which was well articulated and understood by the various institutions. Budget revisions were regularly made to re-program unspent funds or transfer funds between budget lines to meet emergent needs. One adaptation that was mentioned and merits recognition was UN Environment's support to the direct procurement of international goods that were purchased from Nairobi and forwarded to the project through the UNDP Country Office. This was a successful example of adaptive management that helped overcome the constraints of the economic embargo and ensure timely delivery.

102. As executing agency, CSB managed the project effectively and efficiently. The evaluation findings indicate commendable performance on the part of the National Project Coordinator and technical team who managed the components. There were substantive results and high delivery. Work plans and responsibilities were understood and adhered to. The project components were well managed by assigned coordinators who supported the NPC. The implementation process was monitored by the project team, which met as a separate committee – the *Grupo de Apoyo* - for this purpose several times a year. Project management benefitted significantly from the technical competence of CSB personnel, some of who have served as academic faculty for graduate biosafety courses. The project also benefited from CSB's past experience with earlier GEF-UN Environment

> *"The MCN has been really useful because it lets us establish work and communication practices. It's different when you actually get to know the people involved."*
>
> *- Customs focal point to the MCN*
>
> *"CSB made the effort to make sure that we all were able to know each other."*
>
> *- CIGB focal point to the project*

projects.

103. The NCA members of the Technical Advisory Committee played a substantive by approving work plans, enabling institutional coordination and implementing activities involving their institutions. The participation of NCAs in the project Technical Committee with oversight functions facilitated its transition to a permanent national biosafety coordination mechanism.

104. Given the levels of technical expertise within CSB, the UN Environment Task Manager's guidance was more focused more on compliance with Anubis, Umoja and other guidelines, and financial reporting in particular. On a programmatic level, the annual regional meetings of national biosafety project coordinators – a commendable practice started by the Task Manager - enabled periodic exchanges of experience and horizontal guidance between project coordinators.

## F.3 Stakeholder Participation, Cooperation and Partnerships

105. The project sought to promote greater partnership and cooperation between NCAs. Its implementation strategy explicitly encouraged inter-institutional participation within Cuba's national biosafety framework through the creation of the first National Coordination Mechanism (MCN), information flows for LMO decisions, and the recognition of biosafety mandates for NCAs.

106. The project's ability to catalyse stakeholder participation and cooperation for biosafety was one of its main strengths. This has helped towards balancing the capacities and engagement of the NCAs and overcoming the initial reluctance of some agencies to share information. The project's Technical Committee and its gradual transition into a permanent National Coordination Mechanism (the first of its kind in Cuba according to respondents) also encouraged greater NCA involvement by giving NCAs additional exposure to biosafety matter, and by providing a sense of ownership that was supported by more efficient communications and decision-making.

107. New partnerships were actively supported by the project. The CSB was a member of the *Group for the Analysis of Technical Obstacles to Commerce* that is sponsored by MINCEX, and has been instrumental in designing and delivering the post-graduate biosafety program offered by the University of Havana. The project helped CSB to consolidate partnerships with MINCEX and General Customs, among others, and expand on a national scale to include CITMA's territorial branches and the provincial universities Holguín and Cienfuegos. There were also joint activities with the University of West Indies – Trinidad, which is currently executing a regional GEF-UN Environment biosafety project, and a Peruvian university as well.

108. The national training system, as designed, links technical and educational institutions at national and sub-national levels; including several that lacked prior biosafety exposure. The interaction of institutions under the MCN has led to new collaboration between CENSA and CIGB

for the control of porcine pests, and CENSA's Emergency Plan now foresees using CIGB's facilities in case of urgency. The articulation of NCAs by the MCN and streamlined information flows have shortened the average time required for LMO decisions from three months to 30 days and sometimes less than that.

109. The participation of private and non-governmental partners was lacking and below expectations, in spite of the opportunities offered. There was little participation by the National Association of Agricultural Producers (ANAP) or two NGOs that were part of the project framework; the absence of these institutional channels may limit the impact of the PIPE public education program. To an extent, the attitude of these institutions reflected the lack of debate around LMOs and transgenic foods, contrary to other countries in the region where these topics are subject to intense debate. As a result, biosafety issues do not receive a high level of public recognition or interest, and civil society views are less polarized in this respect.

### F.4 Communication and Public Awareness

110. An important sub-component of the project – the Public Information and Education Program (PIPE) - was devoted to public awareness. The PIPE strategy promoted awareness raising and dissemination through traditional channels such as mass media, as domestic Internet connections are not readily available. Folders of biosafety information were printed, as were an electronic newsletter, an e- guide for LMO risk assessment, a video and TV spots. Data is not available on the number of people reached by PIPE activities, and changes in perception are difficult to measure outside of random surveying.

111. Communication and biosafety awareness were also promoted through events directed at NCAs and other stakeholders. The project organized a total of 59 events that included 25 technical meetings, 22 courses and 12 workshops. A Closing Workshop *("Taller de Cierre")* was organized by CSB in March 2016 to share project results and discuss next steps with partners.

112. Communications between NCAs also benefited from the face-to-face meetings of the MCN and improved data flows that linked the various authorities for LMO decision-making. As mentioned, Internet connectivity problems have limited opportunities for online communications and networking. This affected institutional access to the BCH, online communications, and uploading data to ANUBIS or the BCH. Cuba's present IT technology does not allow clients to track the status of their GMO applications through the SIISB, or introduce digital signatures.

### F.5 Country Ownership and Driven-ness

113. The project was driven by the CSB in its capacity as national executing agency, while institutional ownership was encouraged among NCAs through the Technical Committee and MCN. CSB assumed its role as NEA with a clear idea of the project's aims and how to achieve them. This was reinforced by strong organizational and technical capacities, prior experience with GEF-UN Environment projects, and being the national authority to the Cartagena Protocol. The entire project team was comprised of CSB personnel and there was little use of external

consultants or support staff. The project's design - and the annual work plans that were formulated for each component – were compatible with CSB's mandate and assisted its biosafety coordination needs by creating a permanent mechanism for this purpose.

114. Project work plans were shared with the Technical Committee (which subsequently developed into the MCN) for feedback and approval. The project has helped in consolidating CSB's biosafety mandate among other institutions, while encouraging the approval of biosafety functions within other NCAs. The greater interaction between government agencies with biosafety functions has clearly strengthened institutional linkages – i.e. CSB with Customs as well as MINCEX- while encouraging parallel collaboration between NCAs. The formalization of the MCN and NCA biosafety mandates would further strengthen national institutional ownership of the national biosafety framework.

### F.6 Financial Planning and Management

115. Budget delivery was high. According to the final project audit [9], 96% of the GEF budget had been spent between November 2010- June 2016 leaving a balance of US$ 12,000. The project team managed project funds efficiently. Unspent budgets were reprogrammed with annual budget revisions. Funds were transferred between budget lines to meet changing needs and provide more resources for training. Figure 11 tracks the levels of planned and actual expenditure for the GEF and government budgets. In both cases there appear to be increased expenditures starting in 2013 after the Umoja "blackout" was lifted, and a decline after 2015 when the project enters its final stage.

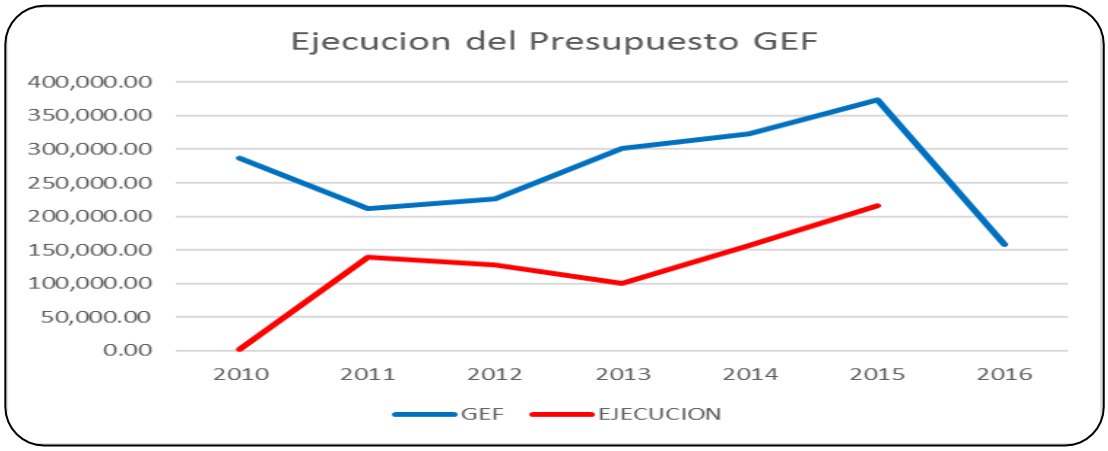
116. UN Environment played an important role in direct procurement. Computers, laboratory equipment and other goods were purchased directly from UN Environment-Nairobi and forwarded to the project via UNDP Cuba. This facilitated the international purchase of equipment by circumventing the U.S. economic embargo. There were problems with the slow activation of the financial accounting system, which took several months to become operational. The distribution of a support guide ("*Guia de Apoyo"*) for biosafety NPCs that described Umoja and UN Environment's financial procedures – an initiative of the Task Manager - was considered to be very helpful by the project's administrative staff.

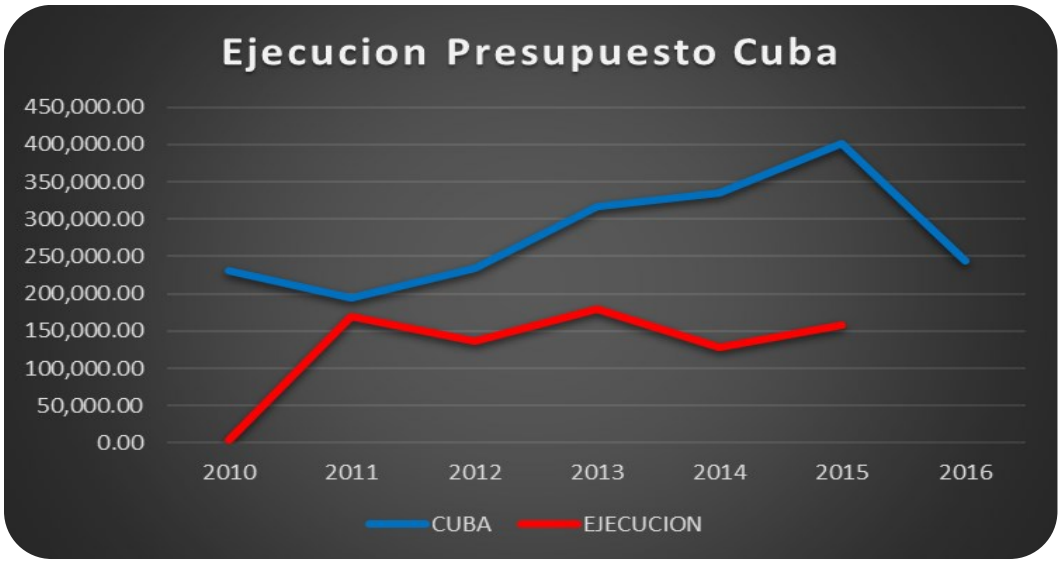
117. Despite these measures, there were administrative delays that affected financial disbursements and procurement, with effects on delivery. The suspension of financial transactions during the Umoja "blackout" lasted for several months and led to the project's extension. In 2016, funds that were disbursed by UN Environment to the project through New York could not be processed and the procedure had to be repeated. Delays in procuring laboratory equipment and reactives for LMO detection prevented the full achievement of the fourth outcome; this remains pending and will be pursued under a proposed follow-up project that will be submitted to GEF.

[9] Independent Audit, CIH, S.A (2016)

**Figure 11**

**GEF and Government Planned and Actual Budget Expenditures: 2012-2015**




*Source: CSB PPT Presentation (2016)*

## F.7 Supervision, Guidance and Technical Backstopping

118. The guidance offered by UN Environment's Task Manager and Finance Manager to the NEA was effective and highly appreciated. Both of the Task Managers who were assigned to the project have visited Cuba and were considered to be very helpful - particularly during the project's start-up phase[10] and as a regular source of advice on Umoja, Anubis and financial

[10] There was a gap of several months between Task Managers, during which the post was vacant. The lack of guidance at this early stage of the project was felt by the project coordinator and CSB.

reporting. The current TM has academic and professional background in biosafety, bringing technical expertise to the post's supervisory role. The TM conducted the Mid-Term Review and produced a report that is well written and perceptive in its analysis.

119. The Task Manager facilitated regional links with other biosafety projects: National project coordinators from the LAC region were brought together for annual meetings where they exchanged experiences and discussed issues of common interest. In 2012 UN Environment held a regional workshop in Ecuador for project administrators that explained Anubis and answered questions about financial management and reporting. One of the NPC workshops led to the documentation of lessons learned from biosafety projects.[11] This was followed by a support guide on project management and reporting. Although occasional administrative delays affected procurement, the overall guidance and technical backstopping provided by UN Environment was highly satisfactory.

## F.8 Monitoring and Evaluation

120. A Monitoring Plan and SMART indicators were included in the project document, in line with GEF-UN Environment guidelines. Monitoring and evaluation activities were allocated US$ 37,000 or 5% of the GEF grant.

121. Project monitoring was satisfactory, in particular due to the NEA's initiative. Because the project team was composed of CSB staff, emergent challenges were anticipated and remedial actions taken by on a timely basis by the NEA. Internal monitoring was practiced on a regular basis by the project Support Group *("Grupo de Apoyo")* that met three times a year to review progress, discuss pertinent issues and adjust work plans. NCAs were involved in monitoring and adaptive management to some extent through their involvement in the Technical Committee, which met twice yearly to oversee project execution and coordination.

123. Project activities and results are well documented in reports and PPT presentations prepared by the project team. These include a quantified analysis of the four technical components that presents numbers and institutional breakdown of trainees, levels of achievement of outputs indicators and outcomes, and budget expenditures by year and budget line.

124. The required reports – PIRs, quarterly expenditure reports – were submitted on time and met GEF-UN Environment guidelines. The reports of all Technical Committee meetings are on file and well documented; the meetings were well attended and offered a venue for discussions on institutional responsibilities, information flows and project work plans that have guided project implementation. The quality and detail of the documentation underlies good

[11] « *Lecciones Aprendidas en la Ejecución de Proyectos de Implementación del Marco Nacional de Bioseguridad en algunos países de Latinoamérica: Rica, Cuba, Ecuador, El Salvador, Guatemala & Perú"* (2013)

knowledge management on the part of CSB. A Closing Workshop *("Taller de Cierre")* was held to socialize the project's results, attended by national authorities, technical staff and other project participants.

125. UN Environment supported project monitoring through the Task Manager, who offered advice and guidance both on an *ad hoc* basis and through the Mid-Term Evaluation. As mentioned earlier, the annual regional NPC meetings provided opportunities for exchange and discussions on issues affecting their projects. One of the regional meetings was used to collectively document the lessons derived from other biosafety projects.

# IV. CONCLUSIONS, LESSONS LEARNED AND RECOMMENDATIONS

## A. Conclusions

**Figure 12**

**Rating Matrix of Project Performance**

| *Criterion* | *Summary Assessment* | *Rating* |
|---|---|---|
| ***A. Strategic relevance*** | The project built on a broader context of past biosafety support with the aim of filling pending gaps, prioritized through the NCSA. Cuba had no biosafety coordination mechanism or decision-making system in the past. Independent LMO detection and identification was not possible due to the lack of laboratory infrastructure. | HS |
| ***B. Achievement of outputs*** | 27 (93%) of 29 outputs were fully completed, as were 89% of the programmed activities | HS |
| ***C. Effectiveness: Attainment of project objectives and results*** | The project objective of addressing pending biosafety gaps was mostly achieved, and satisfactory results achieved under the four project components. | S |
| ***1. Achievement of direct outcomes*** | Three of four outcomes were achieved, while strengthened capacity for LMO detection and identification is pending. | S |
| ***2. Likelihood of impact*** | There is a high likelihood of impact from improved LMO decisions and information flow, as well as future capacity development. Impact will be higher once laboratory capacities for LMO detection are in place. | S |
| ***3. Achievement of project goal and planned objectives*** | The project document does not have a stated goal. Three of four immediate objectives were fully achieved. | S |
| ***D. Sustainability and replication*** | There is high likelihood of continuity of the MCN and LMO decision-making process, as well as the | HL |

| | | |
|---|---|---|
| | national training program. Formal institutional approval of MCN and NCA biosafety attributions is pending in most cases. | |
| ***1. Financial*** | Most activities will be covered under the government budget. | HL |
| ***2. Socio-political*** | Cuba has a firm commitment to biosafety, which is linked to national security and reinforced by a dynamic biotechnology sector. | HL |
| ***3. Institutional framework*** | CSB and most NCAs have high capacity levels and continuity of staff. There may be changes to the institutional framework resulting from anticipated state reform policies. The project-supported components directly support CSB's corporate objectives and lines of work. | HL |
| ***4. Environmental*** | Project results are likely to benefit the environment by strengthening the implementation of the CPB. | HL |
| ***5. Catalytic role and replication*** | The project addressed the national biosafety context and did not pilot activities for replication. It has catalysed the recognition of CSB as leading national biosafety authority and facilitated broader | S |
| ***E. Efficiency*** | The project was managed cost-effectively by CBS personnel with high program and financial delivery rates (+ 90%). | HS |
| ***F. Factors affecting project performance:*** | | |
| ***1. Preparation and readiness*** | The project built on the progress of previous GEF-UN Environment support to Cuba's national biosafety framework. Its design benefited from the lessons of past projects, the NCSA exercise and PPG support. CSB brought high technical, management and training capabilities to the project, as did other NCAs. | HS |
| ***2. Project implementation and management*** | The implementation approach was well articulated and understood by participants. The inter-institutional steering committee developed into the national coordination mechanism, while enabling conditions were established for sustained capacity building. The project was very well managed by a CSB team. | HS |
| ***3. Stakeholders participation and public awareness*** | Government stakeholders participated fully in project activities, while NGOs and ANAP (the national farmers association) did not get involved despite opportunities. | S |
| ***4. Country ownership and driven-ness*** | The project was fully driven by CSB and integrated into the national biosafety framework. The project has enabled the fuller participation of NCAs with little prior biosafety awareness or involvement. | HS |

| | | |
|---|---|---|
| ***5. Financial planning and management*** | The project was well managed financially despite some delays occasioned by the Umoja blackout and slow procurement (affecting the achievement of the project's fourth outcome) | S |
| ***6. UN Environment supervision and backstopping*** | UN Environment assumed direct procurement responsibilities to facilitate the purchase of international equipment and other items. The Task Manager provided guidance and advice that were useful to the project team. The TM organized annual regional meetings of GEF-UNEP biosafety projects for exchanges of experience and discussions on issues of common interest. | HS |
| ***7. Monitoring and evaluation*** | A CSB team met every four months to review progress and resolve project issues. The Technical Committee of NCAs met every six months and monitored the execution of project activities. A MTR was conducted by the UN Environment Task Manager. The quality and scope of project documentation by the project team has been commendable. A closing workshop was held to review achievements and discuss lessons learned with institutional partners. | HS |
| ***a. M&E Design*** | A Monitoring Plan and SMART indicators were included in the project document, meeting GEF-UNEP requirements. | HS |
| ***b. Budgeting and funding for M&E activities*** | M&E activities were allocated US$ 37,000, which represented 5% of the GEF grant. | S |
| ***c. M&E Plan Implementation*** | Internal monitoring went beyond the scope of the initial Plan with the involvement of the project Support Group and Technical Committee. | S |
| ***Overall project rating*** | ***Overall project performance and results were highly satisfactory, offering a case study of good biosafety project design and management.*** | ***HS*** |

126. **Conclusion 1: Overall project performance and results were highly satisfactory.** Project performance ranged from satisfactory to very satisfactory when assessed against the evaluation criteria. Substantive results were generated – three of four outcomes were fully reached – and 27 of 29 outputs (93%) were completed. Substance was accompanied by efficiency and more than 90% of the budget had been spent when the project's terminated in June 2016. In terms of accomplishment and cost-effectiveness, the project stands out as a "best practice" case study in project execution.

127. **Conclusion 2: The combined outcomes of the project components have raised Cuba's**

**National Biosafety Framework to a new threshold.** The project built on the progress achieved by prior UN Environment-GEF biosafety projects, and addressed pending capacity gaps that were prioritized by the National Capacity Self-Assessment (NCSA) exercise and further developed during the design phase. The establishment of the first national coordination mechanism that links the National Competent Authorities is a fundamental contribution that enables more consistent communication and involvement by government agencies on biosafety matters. This is supported by an integrated biosafety information system – the SIISB - that streamlines procedures for LMO reviews and decisions, and the implementation of a national biosafety training system that is expected to fulfill Cuba's capacity needs by 2020. These achievements are already generating impact, as reflected in significantly shorter timelines for reaching decisions on LMO requests, higher volumes of LMO import/export applications handled by Customs officials, improved access to biosafety training in the provinces, and greater equilibrium in biosafety awareness and capacity levels among NCAs. As of January 2017, all LMO imports and exports will need to present documentation identifying the LMO for the Declaration of Conformity, in accordance with NC-ISO-IEC 17050 standards.

128. **Conclusion 3: Project implementation benefited from good design, strong country ownership and high levels of NEA preparedness.** The project was part of a broader cooperation context and built on the cumulative improvements that were achieved over the years through earlier UN Environment-GEF support initiatives, with the aim of closing remaining capacity gaps through applied training and strengthening systemic performance through coordination mechanisms and information flows. The project's design drew from the findings of the National Capacity Self-Assessment (NCSA) and stakeholder workshops held during the PPG stage. As a result, project was focused and the expected outcomes achievable within the approved duration and budget. The implementation strategy linked the institutional and systemic dimensions of capacity development by supporting the establishment of institutional coordination mechanisms, information flows linking NCAs and the establishment of a national biosafety training system.

129. The Center for Biological Safety managed the project effectively and efficiently. The CSB assumed its role as NEA with a clear idea of the project's aims and how to achieve them. The high levels of preparedness were reinforced by strong organizational and technical capacities, prior experience with GEF-UN Environment projects, and CSB's role as national authority for the Cartagena Protocol.

130. Country ownership was built into project design and implementation. NCAs were familiarized with the biosafety issues addressed through their initial participation in the Technical Committee, which subsequently developed into a permanent National Coordination Mechanism with decision-making attributions. The project team was composed of CSB

personnel, and project objectives and work plans were integrated with CSB's strategic and annual plans. As a result project initiatives and results have been easily appropriated by CSB and other NCAs with a high likelihood of sustainability.

131. **Conclusion 4: A few deliverables were not completed and will require further attention.** The most important gap is the lack the laboratory equipment and infrastructure for LMO detection/identification, which were not installed due to procurement delays; this output has since been incorporated to a new project proposal that is being formulated for submittal to GEF and UN Environment. In addition, CSB was unable to secure an available international inspector from the Inter-American Laboratory Accreditation Cooperation during the project period. Trained Customs agents had not received accreditation for biosafety enforcement due to the modifications introduced to the Declaration of Conformity for compliance with NC-ISO-IEC 17050 specifications. The 2016-2020 National Biosafety Action Plan was drafted and included in the Environmental Strategy with project support and submitted to the State Council, yet had not been approved (at the time of the evaluation mission) in anticipation of constitutional amendments and state reform measures that are presently under discussion and could affect Cuba's governance framework. One of the main obstacles affecting institutonal coordination and networking was low Internet connectivity, which undermines NCA access to the Biosafety Clearinghouse (BCH) , the uploading of data to ANUBIS, and online communications in general. Although CSB's web bandwidth and internet SDHL memory were expanded, the problem persists and will require IT solutions that are outside the scope of the project.

132. **Conclusion 5: A new biosafety project proposal has been designed that would consolidate the advances of this project.** The TE endorses this proposal and supports its approval, based on the highly satisfactory performance and results of the current project. The new project is essential to consolidate national capacities for LMO detection and identification with adequate laboratory equipment and infrastructure – an important priority that was not achieved by this project within the approved timeframe.

133. **Conclusion 6: UN Evaluation's performance as Implementing Agency was highly satisfactory and responsive to the project's needs.** UN Evaluation provided substantive guidance through its Task Manager, and assumed an uncommon role by directly purchasing international equipment and other items for the project from Nairobi, and forwarding them to CSB through the UNDP Country Office. This arrangement allowed the project to avoid delays caused by the U.S. economic embargo and ensure timely procurement (exceptions being the Umoja "blackout" that suspended financial transactions for several months, andaforementioned delays in procuring laboratory equipment). The Task Manager gave guidance on project reporting and management guidelines that were very much appreciated. The importance of the Task Manager during the project inception stage was evident when the post remained vacant for several months and the NEA was did not receive the guidance needed to understand the complex guidelines. Also appreciated were the annual meetings of NPCs from LAC that

provided a space for exchanges and discussions, including the documentation of lessons learned from other biosafety projects in the region. UN Evaluation has actively promoted networking between biosafety projects in the LAC region, and the Task Manager facilitated contact with the University of West Indies, other GEF-UN Environment biosafety projects, and national institutions in Peru and other countries.

## B. Lessons Learned

134. **Lesson 1: The National Coordination Mechanism (MCN) is the first inter-institutional mechanism of its type in Cuba and has a strong demonstration value.** Several interviewed participants mentioned the demonstration value of the MCN as a vehicle for operationalizing inter-institutional processes and coordination. The mechanism is considered to be the first of its kind in Cuba and offers a novel approach for managing over-arching processes with multiple institutions. The MCN model can offer a useful tool as Cuba discusses constitutional amendments and state reform processes that could decentralize government institutional frameworks and policy implementation.

135. **Lesson 2: Institutional stability and effective group dynamics within CSB and other government institutions have enabled the high-level technical and managerial expertise that went into the project's execution.** The externalities that often undermine the performance and sustainability of technical cooperation projects - high turnovers of government partners, weak institutional memories and low baseline capacities, disruptions caused by political elections and changes of government - were absent in Cuba. This was reflected in the levels of institutional capacity and preparedness, which in turn underscore the institutional stability of Cuba's public sector and high standards that have developed over the year (CSB subscribes to ISO 9000 management standards).

136. The project was efficiently managed by core CSB staff with little use of external consultants or support staff. This arrangement facilitated access to a community of practitioners from the CBS, the University of Havana and partner institutions who in many cases have studied and worked together for an extended period, and now occupy senior positions. Several members of the project team had participated in the execution of earlier GEF-UN Environment projects and have experience in executing international projects.

137. These combined factors have facilitated communications and coordination both within CSB and among partner institutions, enhancing project performance and strengthening the likelihood that the various support initiatives will be sustained beyond the project term. While these aspects are largely attributable to Cuba's particular system of governance and are not readily transferrable, they do offer insight into the dynamics of good governance and project management.

138. **Lesson 3: The early participation of NCAs and representatives of the biotechnology sector in the project's design strengthened institutional commitment to the project and its objectives.** The project benefited from the early involvement of leading authorities and representatives of the biotechnology sector in prioritization of needs under the National Capacity Self-Assessment that was organized in 2012, and stakeholders consultations – organized with PPG support - that shaped the project's design and harmonized institutional roles and expectations. The involvement of NCA focal points in the project's Technical Committee, which developed into a permanent National Coordination Mechanism (MCN), has additionally helped to build awareness, commitment and a common vision among participating institutions.

139. **Lesson 4: The national biosafety training system potentially enables Cuba to assume a lead role in regional capacity building and South-South cooperation.** The national biosafety training system that was developed through the project offers post-graduate modules and specialized courses that aren't available in other LAC countries, i.e. design of laboratory and pharmaceutical facilities for handling LMOs. This offers an opportunity to promote Cuba as a regional hub for biosafety training, with potential cost recovery and income generation benefits that can be re-invested to fund operating costs. The added regional exposure would be particularly important for Cuba as a lead producer of biotechnology that has advanced in implementing the CP.

## C. Recommendations

140. **Recommendation 1: The follow-up project proposal that was recently drafted by CSB would consolidate the results of this project and merits approval**. CSB has drafted a new biosafety proposal that builds on the progress achieved by this project, that was recently submitted to GEF and UN Environment for consideration. Since the proposal is not intended for general circulation, it's content is not described in this report. However, the project would extend support to establish national laboratory capacities and infrastructure for LMO detection and analysis. This is an essential component of the national biosafety framework that was planned but not achieved under the fourth project component. It is also needed to ensure independent LMO detection instead of relying on CIGB - a producer and importer of GMOs – for this service.

141. **Recommendation 2: The national system for biosafety training may offer possibilities for cost recuperation through the provision of advanced training to professionals and students of other countries**. The new project, if approved, should consider incorporating the output of developing a management or business plan for the national training system that considers medium-term demand and possibilities for cost recuperation and income generation from training international students and professionals from other LAC countries and elsewhere. This would be led by CSB and INSTEC in consultation with the universities and training

institutions, national authorities and prospective client institutions from other countries. The projections and marketing strategy for Cuba's national biosafety training system would not compete with the biosafety training offered by UWI-Trinidad, and focus instead on comparative advantages in terms of their language of instruction, content and periodicity.

142. Aside from the benefit of offering courses not available in other countries – design of medical and pharmaceutical facilities for LMO handling – the utilization of Cuba as a regional biosafety training hub may offer a cost-effective option for future rounds of GEF-UN Environment support that are simultaneously implemented in various countries.

143. **Recommendation 3: The next project should include a mid-term internal review, led by CSB, to facilitate adaptive management and adjustments to possible measures that may decentralize or otherwise affect governance functions.** The evaluator perceived a sense of uncertainty regarding anticipated changes to Cuba's governance framework that are presently under discussion at senior policy levels, and could modify present institutional arrangements. Although changes to CSB's mandates and institutional structure are unlikely, the reform measures could decentralize biosafety functions and require adaptation to the project strategy and work plan, as well as to Cuba's National Biosafety Action Plan. This review would not require external evaluators and should be conducted by CSB. However it is important that the project's design allocate the time and resources for an internal evaluation and stakeholder consultations.

144. **Recommendation 4: The PIPE public awareness program should include components directed at productive sectors are likely to be affected by increased imports/exports of transgenic grains or other GM products in the future.** The lack of participation on the part of the National Association of Agricultural Producers (ANAP) undermined the project's ability to engage this strategic sector in biosafety discussions and awareness-raising activities. It is important that ANAP participate more directly in Cuba's national biosafety framework in the future, so that it may better understand the issues and inform its constituency; this will be particularly important in the event that economic liberalization measures are introduced in the future. Likewise, the participation of NGOs in the project was below expectations despite the opportunity offered, and needs to be reinforced in the future given their potential role as a conduit for informing civil society and monitoring the environmental impact of biosafety policies.

# ANNEXES

## Annex 1

## Evaluation Terms of Reference

### Terminal Evaluation of the UNEP/GEF project

"Completion and Strengthening of the National Biosafety Framework of Cuba for the Effective Implementation of the Cartagena Protocol"

# I. PROJECT BACKGROUND AND OVERVIEW

### 1. Project General Information[12]

**Table 1. Project summary**

| | | | |
|---|---|---|---|
| **UNEP PIMS ID:** | | **IMIS number:** | GFL 2328 2716 4B74 |
| **Sub-programme:** | Environmental Governance | **Expected Accomplishment(s):** | Pow Accomplishment 2014-2015: b) Provision of legal and technical support to Governments to develop and enforce laws and strengthen institutions to achieve internationally agreed environment |
| **UNEP approval date:** | 20 November 2010 | **PoW Output(s):** | 2) Legal technical assistance provided to support initiatives by countries to implement, monitor and achieve compliance with, and enforcement of, international environmental obligations, including those set out in multilateral environmental agreements |
| **GEF project ID:** | 3643 | **Project Type:** | MSP |
| **GEF OP #:** | GEF 4 BD-SP-6 | **Focal Area(s):** | Biosafety |
| **GEF approval date:** | 4 October 2010 | **GEF Strategic Priority/Objective:** | BD3 |
| **Expected Start Date:** | 1 November 2010 | **Actual start date:** | 30 ~~1~~ November 2010 |
| **Planned completion date:** | 30 November 2015 | **Actual completion date:** | June 2016 |
| **Planned project budget at approval:** | USD 900,091 | **Total expenditures reported as of [June 2016]:** | USD 1,848,996.28 |
| **GEF Allocation:** | USD 900,091 | **GEF grant expenditures reported as of [June 2016]:** | USD 810,022.10 |

| | | | |
|---|---|---|---|
| **PPG GEF cost:** | USD 9,000 | **PPG co-financing:** | USD 24,254 |
| **Expected MSP/FSP co-financing:** | USD 1,018,552 | **Secured MSP co-financing [June 2016]:** | USD 1,038,974.18 |
| **First Disbursement:** | 10 December 2010 | **Date of financial closure:** | 30 June 2016 |
| **No. of revisions:** | 7 | **Date of last revision:** | June 2016 |
| **Date of last Steering Committee meeting:** | May 2015 | | |
| **Mid-term review/ evaluation (planned date):** | April 2013 | **Mid-term review/ evaluation (actual date):** | May 2013 |
| **Terminal Evaluation (actual date):** | September – December 2016 | | |

## 2. Project rationale

1. In 1998, the Cuban National Centre for Biosafety (CSB) participated in the Pilot Project for the development of a National Biosafety Framework (NBF). The objective was to enable participating countries to design and develop a national framework for the effective implementation of the Cartagena Protocol (CP). Between 2002 and 2007, Cuba was also part of a series of demonstration UNEP/GEF projects for the implementation of these frameworks, which contributed to the consolidation of national biosafety structures; formulation and adoption of a regulatory instrument for evaluating and assessing the risk of Genetically Modified Living Organisms (LMOs) prior to their liberation into the environment; training; information exchange; and the advance of LMO monitoring mechanisms.

2. Even before the UNEP/GEF projects, and despite the economic problems related to United States' blockade and Soviet Union's disappearance, the Cuban Government internally decided to organize biosafety and assign the hierarchy and recognition it required, in consideration of the growing biotechnology sector in the country and the evolution of international regulatory instruments. The ratification of the CP in 2002 was a consequence of the high profile reached by Cuban biotechnology.

3. In order to better face the challenges of using modern technology safely and better fulfill the obligations of the Cartagena Protocol, Cuba was deemed to require, through GEF support, at the time of project design, more effective institutional coordination. It was considered that it was necessary to strengthen its border control, to attain higher organization levels in biosafety training and education, and to improve its infrastructure for identification and detection of living modified organisms.

## 3. Project objectives and components

4. The project's overall objective is to address the technical, legal, infrastructural and biosafety management gaps faced by the country's National Competent Authorities to ensure the successful and sustainable implementation of the CP in Cuba. The specific objectives are:

1. To reinforce the National Coordination Mechanism, focusing on decision-making and setting standards and criteria.
2. To strengthen the framework for LMO import and export in accordance with the CP.
3. To design and implement a System of Human Resources Training in Biosafety.
4. To increase the scientific, technological, and infrastructure capacities of the National Competent Authorities.

5. The project is of 4 main technical components that are in keeping with the 4 specific project objectives. It contains two additional components that focus on project management and the project's monitoring and evaluation activities.

Table 2. Project components, outcomes and indicators

| Project Technical Components | Expected Outcomes | Outcome indicators |
|---|---|---|

| | | |
|---|---|---|
| 1. Reinforcement of the National Coordination Mechanism, with emphasis on decision-making needs, and setting norms and standards | The National Biosafety Coordination Mechanism for Cuba is reinforced, with an emphasis on future implementation. abilities to make decisions, establish norms and standards, and mainstream CP | 1.1. Greater capacity for implementing, coordinating and harmonizing the country's biosafety legislation with the administrative processes of the Cartagena Protocol (CP) and other relevant legislation<br>1.2. Improved information management related to biosafety |
| 2. Strengthening of the framework for import and export of LMOs in accordance with the Cartagena Protocol | A framework for the import and export of LMOs is built in accordance with the CP and is operational. | 2.1. The National Competent Authority is granted competency to certify border control officers in biosafety<br>2.2. Biosafety is integrated into border control activities |
| 3. Design and implementation of a System for Human Resources Training in Biosafety | Human resource training in biosafety I institutionalized within Cuba's higher and further education systems. | 3.1. An integral and coordinated training system is created for biosafety management and CP implementation<br>3.2. The human resources that form part of the National Biosafety System receive up-to-date training in biosafety management and CP implementation<br>3.3. Comprehensive and coordinated training on the CP's Biosafety Clearing House (BCH)<br>3.4 Greater public awareness with respect to biosafety in Cuba<br>3.5 Increased the potential for regional human resources training in biosafety |
| 4. Increase in the scientific, technological and infrastructural capacities of the National Competent Authorities | National Competent Authorities acquire greater operational capacity in biosafety for meeting current and future demands. | 4.1 Greater capacity in the National Competent Authorities to connect to, and participate in, the BCH<br>4.2 Available capacity for LMO detection and identification is strengthened<br>4.3 Strengthened capacity to deliver training and scientific education in biosafety |

## 4. Executing Arrangements

6. Specific leadership roles as well as common tasks are contemplated for project execution through three national competent authorities, namely: the CSB (National Centre for Biological Safety), the INSTEC (Institute of Applied Sciences and Technology) and two regional branches of the CITMA (Ministry of Science, Technology and the Environment).

7. CSB was the National Executing Agency and intended to lead all efforts related to setting norms, standards and criteria and other regulatory needs. INSTEC was meant to implement the system for human resources training in biosafety through which specialized curricula were meant to be delivered to relevant personnel. INSTEC was also in charge of setting up LMOs detection capacities, with its main responsibilities focused on component 3 and 4. CITMA DT was responsible for strengthening resources and capacities for biosafety within their respective jurisdictions. Their main engagement related to component 4.

8. The project appointed a coordinator, supported by a managerial support team, and established a technical advisory committee. The project also set up a steering committee (including UNEP). All these bodies intended to both oversee the project implementation and ensure its smooth execution. It should be noted that, in an effort to increase sustainability, only co-financing was used to pay for project staff, not the GEF grant. Also, the project intended to strictly adhere to the 5 year workplan and avoid any extensions.

## 5. Project Cost and Financing

9. The GEF grant amounted to 900,091.00 USD. Summed to Cuba's co-financing pledge, the total project budget came to 1,918,643.00 USD. At project design, the costs to be charged to the GEF grant were allocated by component according to the table below.

Table 3. Allocation of costs to the GEF grant by component

| Component | GEF funds (USD) | Percentage of the total |
|---|---|---|
| I | 96,225 | 11% |
| II | 37,995 | 4% |
| III | 228,680 | 25% |
| IV | 401,391 | 45% |
| V | 45,500 | 5% |
| VI | 90,300 | 10% |

### 6. Implementation Issues

10. According to the 2014 PIR, the project was on track to accomplish the main objective. Despite some difficulties with internet, purchasing procedures, etc., the project team was seen to have done a remarkable work in obtaining results and in keeping the original timeframes as much as possible. Reportedly, the project even accomplished some objectives earlier than expected and, therefore, it was considered that the team was well organized and that implementation progressed according to plans. Nonetheless, it was considered that support from other local authorities would be needed for the project to fully accomplish its main outcomes. The evaluation should consider the extent to which the project was successful in securing the necessary support.

11. It seems that Cuba was counting with access to GEF 5 funds to implement training in biosafety (activity 3.5), but no funds were available under GEF 5 for biosafety for Cuba. However, the country has networked with other countries of the region and has provided support in training activities. Eventually, the project plan was adjusted to include a proposal for GEF 6, which was successfully submitted. The evaluation should assess the extent to which the original outputs and outcomes were delivered and, if not, to what extent this has compromised the achievement of the project objective.

## II. TERMS OF REFERENCE FOR THE EVALUATION

### 1. Objective and Scope of the Evaluation

12. In line with the UNEP Evaluation Policy[13] and the UNEP Programme Manual[14], the Terminal Evaluation 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 UNEP and the main project partners. Therefore, the evaluation will identify lessons of operational relevance for future project formulation and implementation.

13. It will focus on the following sets of **key questions**, based on the project's intended outcomes, which may be expanded by the consultant as deemed appropriate:

(a) To what extent was the National Biosafety Coordination Mechanism for Cuba reinforced? To what extent did the project contribute to increase the ability of the Cuban authorities to make decisions, establish norms and standards, and mainstream the Cartagena Protocol?

(b) Was a framework for the import and export of LMOs built in accordance with the CP and is it operational?

[13] http://www.unep.org/eou/StandardsPolicyandPractices/UNEPEvaluationPolicy/tabid/3050/language/en-US/Default.aspx
[14] http://www.unep.org/QAS/Documents/UNEP_Programme_Manual_May_2013.pdf

(a) To what extent was human resource training in biosafety institutionalized within Cuba's higher and further education systems?

(b) To what extent did National Competent Authorities acquire greater operational capacity in biosafety for meeting current and future demands?

## 2. Overall Approach and Methods

14. The Terminal Evaluation of the Project will be conducted by an independent consultant under the overall responsibility and management of the UNEP Evaluation Office in consultation with the UNEP Task Manager and the Sub-programme Coordinators of the Environmental Governance Sub-programmes].

15. It 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 to determine project achievements against the expected outputs, outcomes and impacts. It is highly recommended that the consultant 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.

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

(c) A **desk review** of:

- Relevant background documentation;
- Project design documents (including minutes of the project design review meeting at approval); Annual Work Plans and Budgets or equivalent, revisions to the project (Project Document Supplement), the logical framework and its budget;
- Project reports such as six-monthly progress and financial reports, progress reports from collaborating partners, meeting minutes, relevant correspondence etc.;
- Project outputs;
- MTR of the project
- Evaluations/reviews of similar projects

(d) **Interviews (individual or in group) with**:

- UNEP Task Manager
- Project management team
- UNEP Fund Management Officer;
- Project partners, including representatives from the three national competent authorities, local authorities, civil society etc.
- Relevant resource persons;

(e) **Field visit** of the duration of one week to Cuba to meet with the project stakeholders.

## 3. Key Evaluation principles

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

18. The evaluation will assess the project with respect to **a minimum set of evaluation criteria** grouped in five categories: (1) Strategic Relevance; (2) Attainment of objectives and planned result, which comprises the assessment of outputs achieved, effectiveness and likelihood of impact; (3) Sustainability and replication; (4) Efficiency; and (5) Factors and processes affecting project performance, including preparation and readiness, implementation and management, stakeholder participation and public

awareness, country ownership and driven-ness, financial planning and management, UNEP supervision and backstopping, and project monitoring and evaluation. The evaluation consultant can propose other evaluation criteria as deemed appropriate.

19. **Ratings.** All evaluation criteria will be rated on a six-point scale. Annex 2 provides guidance on how the different criteria should be rated and how ratings should be aggregated for the different evaluation criterion categories.

20. **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.

21. **The "Why?" Question.** As this is a terminal evaluation and a follow-up project is likely [or 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 consultant's minds all through the evaluation exercise. This means that the consultant needs to go beyond the assessment of "*what*" the project performance was, and make a serious effort to provide a deeper understanding of "*why*" the performance was as it was, i.e. of processes affecting attainment of project results (criteria under category F – see below). This should provide the basis for the lessons that can be drawn from the project. In fact, the usefulness of the evaluation will be determined to a large extent by the capacity of the consultant to explain "*why things happened*" as they happened and are likely to evolve in this or that direction, **which goes well beyond the mere review of "where things stand" at the time of evaluation.**

22. A key aim of the evaluation is to encourage reflection and learning by UNEP 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.

23. Communicating evaluation results. Once the consultant has obtained evaluation findings, lessons and results, the Evaluation Office will share the findings and lessons with the key stakeholders. Evaluation results should be communicated to the key stakeholders in a brief and concise manner that encapsulates the evaluation exercise in its entirety. There may, however, be several intended audiences, each with different interests and preferences regarding the report. The Evaluation Manager will plan with the consultant 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.

## 4. Evaluation criteria

### A. Strategic relevance

24. The evaluation will assess, in retrospect, whether the project's objectives and implementation strategies were consistent with global, regional and national environmental issues and needs.

25. The evaluation will assess whether the project was in-line with the GEF Biodiversity focal area's strategic priorities and operational programme.

26. The evaluation will also assess the project's relevance in relation to UNEP's mandate and its alignment with UNEP's policies and strategies at the time of project approval. UNEP's Medium Term Strategy (MTS) is a document that guides UNEP's programme planning over a four-year period. It identifies UNEP's thematic priorities, known as Subprogrammes (SP), and sets out the desired outcomes [known as Expected Accomplishments (EAs)] of the SubProgrammes. The evaluation will assess whether

the project makes a tangible/plausible contribution to any of the EAs specified in the MTS 2010-2013 and 2014-2017. The magnitude and extent of any contributions and the causal linkages should be fully described.

The evaluation should assess the project's alignment / compliance with UNEP's policies and strategies. The evaluation should provide a brief narrative of the following:

1. *Alignment with the Bali Strategic Plan (BSP)*[15]. The outcomes and achievements of the project should be briefly discussed in relation to the objectives of the UNEP BSP.
2. *Gender balance*. Ascertain to what extent project design, implementation and monitoring have taken into consideration: (i) possible gender inequalities in access to and the control over natural resources; (ii) specific vulnerabilities of women and children to environmental degradation or disasters; and (iii) the role of women in mitigating or adapting to environmental changes and engaging in environmental protection and rehabilitation. Are the project intended results contributing to the realization of international GE (Gender Equality) norms and agreements as reflected in the UNEP Gender Policy and Strategy, as well as to regional, national and local strategies to advance HR & GE?
3. *Human rights based approach (HRBA) and inclusion of indigenous peoples issues, needs and concerns*. Ascertain to what extent the project has applied the UN Common Understanding on HRBA. Ascertain if the project is in line with the UN Declaration on the Rights of Indigenous People, and pursued the concept of free, prior and informed consent.
4. *South-South Cooperation.* This is regarded as the exchange of resources, technology, and knowledge between developing countries. Briefly describe any aspects of the project that could be considered as examples of South-South Cooperation.
5. *Safeguards*. Whether the project has adequately considered environmental, social and economic risks and established whether they were vigilantly monitored. Was the safeguard management instrument completed and were UNEP ESES requirements complied with?

27. Based on an analysis of project stakeholders, the evaluation should assess the relevance of the project intervention to key stakeholder groups.

## B. Achievement of Outputs

28. The evaluation will assess, for each component, the projects' success in producing the programmed outputs (products and services delivered by the project itself) and milestones as per the ProDocs and any modifications/revisions later on during project implementation, both in quantity and quality, as well as their usefulness and timeliness.

29. Briefly explain the reasons behind the success (or failure) of the project in producing its different outputs and meeting expected quality standards, cross-referencing as needed to more detailed explanations provided under Section F (which covers the processes affecting attainment of project results). Were key stakeholders appropriately involved in producing the programmed outputs?

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

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

31. The **Theory of Change** (ToC) of a project depicts the causal pathways from project outputs (goods and services delivered by the project) through outcomes (changes resulting from the use made by key stakeholders of project outputs) towards impact (long term changes in environmental benefits and living conditions). The ToC will also depict any intermediate changes required between project outcomes and

[15] http://www.unep.org/GC/GC23/documents/GC23-6-add-1.pdf

impact, called 'intermediate states'. The ToC further defines the external factors that influence change along the major pathways; i.e. factors that affect whether one result can lead to the next. These external factors are either drivers (when the project has a certain level of control) or assumptions (when the project has no control). The ToC also clearly identifies the main stakeholders involved in the change processes.

32. The evaluation will reconstruct the ToC of the project based on a review of project documentation and stakeholder interviews. The evaluator will be expected to discuss the reconstructed TOC with the stakeholders during evaluation missions and/or interviews in order to ascertain the causal pathways identified and the validity of impact drivers and assumptions described in the TOC. This exercise will also enable the consultant to address some of the key evaluation questions and make adjustments to the TOC as appropriate (the ToC of the intervention may have been modified / adapted from the original design during project implementation).

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

(f) Evaluation of the **achievement of outcomes as defined in the reconstructed ToC**. These are the first-level outcomes expected to be achieved as an immediate result of project outputs. For this project, the main question will be to what extent the project has contributed to address the technical, legal, infrastructural and biosafety management gaps faced by the country's National Competent Authorities to ensure the successful and sustainable implementation of the CP.

(g) Assessment of the **likelihood of impact** using a Review of Outcomes to Impacts (ROtI) approach[16]. The evaluation will assess to what extent the project has to date contributed, and is likely in the future to further contribute, to intermediate states, and the likelihood that those changes in turn to lead to positive changes in the natural resource base, benefits derived from the environment and human well-being. The evaluation will also consider the likelihood that the intervention may lead to unintended negative effects (project documentation relating to Environmental, Social and Economic. Safeguards)

(h) Evaluation of the **achievement of the formal project overall objective, overall purpose, goals and component outcomes** using the project's own results statements as presented in the Project Document[17]. This sub-section will refer back where applicable to the preceding sub-sections (a) and (b) to avoid repetition in the report. To measure achievement, the evaluation will use as much as appropriate the indicators for achievement proposed in the Logical Framework (Logframe) of the project, adding other relevant indicators as appropriate. Briefly explain what factors affected the project's success in achieving its objectives, cross-referencing as needed to more detailed explanations provided under Section F. Most commonly, the overall objective is a higher level result to which the project is intended to contribute. The section will describe the actual or likely **contribution** of the project to the objective.

(i) The evaluation should, where possible, disaggregate outcomes and impacts for the key project stakeholders. It should also assess the extent to which HR and GE were integrated in the Theory of Change and results framework of the intervention and to what degree participating institutions/organizations changed their policies or practices thereby leading to the fulfilment of HR and GE principles (e.g. new services, greater responsiveness, resource re-allocation, etc.)

16 Guidance material on Theory of Change and the ROtI approach is available from the Evaluation Office.

17 Or any subsequent **formally approved** revision of the project document or logical framework.

## D. Sustainability and replication

34. Sustainability is understood as the probability of continued long-term project-derived results and impacts after the external project funding and assistance ends. The evaluation will identify and assess the key conditions or factors that are likely to undermine or contribute to the persistence of benefits. Some of these factors might be direct results of the project while others will include contextual circumstances or developments that are not under control of the project but that may condition the sustainability of benefits. The evaluation will ascertain that the project has put in place an appropriate exit strategy and measures to mitigate risks to sustainability. The reconstructed ToC will assist in the evaluation of sustainability, as the drivers and assumptions required to achieve higher-level results are often similar to the factors affecting sustainability of these changes.

35. Four aspects of sustainability will be addressed:

(j) *Socio-political sustainability.* Are there any social or political factors that may influence positively or negatively the sustenance of project results and progress towards impacts? Is the level of ownership by the main stakeholders sufficient to allow for the project results to be sustained? Are there sufficient government and other key stakeholder awareness, interests, commitment and incentives to implement a comprehensive biosafety framework? Did the project conduct 'succession planning' and implement this during the life of the project? Was capacity building conducted for key stakeholders? Did the intervention activities aim to promote (and did they promote) positive sustainable changes in attitudes, behaviours and power relations between the different stakeholders? To what extent has the integration of HR and GE led to an increase in the likelihood of sustainability of project results?

(k) *Financial resources.* To what extent are the continuation of project results and the eventual impact of the project dependent on financial resources? What is the likelihood that adequate financial resources[18] will be or will become available to use capacities built by the project? Are there any financial risks that may jeopardize sustenance of project results and onward progress towards impact?

(l) *Institutional framework.* To what extent is the sustenance of the results and onward progress towards impact dependent on issues relating to institutional frameworks and governance? How robust are the institutional achievements such as governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. required to sustaining project results and to lead those to impact on human behaviour and environmental resources, goods or services?

(m) *Environmental sustainability.* Are there any environmental factors, positive or negative, that can influence the future flow of project benefits? Are there any project outputs or higher level results that are likely to affect the environment, which, in turn, might affect sustainability of project benefits? Are there any foreseeable negative environmental impacts that may occur as the project results are being up-scaled?

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

(n) *catalyzed behavioural changes* in terms of use and application, by the relevant stakeholders, of capacities developed;

[18] Those resources can be from multiple sources, such as the national budget, public and private sectors, development assistance etc.

(o) provided *incentives* (social, economic, market based, competencies etc.) to contribute to catalyzing changes in stakeholder behaviour;
(p) contributed to *institutional changes*, for instance institutional uptake of project-demonstrated technologies, practices or management approaches;
(q) contributed to *policy changes* (on paper and in implementation of policy);
(r) contributed to sustained follow-on financing (*catalytic financing*) from Governments, private sector, donors etc.;
(s) created opportunities for particular individuals or institutions ("*champions*") to catalyze change (without which the project would not have achieved all of its results).

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

## E. Efficiency

38. The evaluation will assess the cost-effectiveness and timeliness of project execution. It will describe any cost- or time-saving measures put in place in attempting to bring the project as far as possible in achieving its results within its (severely constrained) secured budget and (extended) time. It will also analyse how delays, if any, have affected project execution, costs and effectiveness. Wherever possible, costs and time over results ratios of the project will be compared with that of other similar interventions. The evaluation will also assess the extent to which HR and GE were allocated specific and adequate budget in relation to the results achieved.

39. The evaluation will give special attention to efforts by the project teams to make use of/build upon pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. to increase project efficiency. For instance, the previous biosafety projects implemented in the country.

## F. Factors and processes affecting project performance

40. **Preparation and readiness**. This criterion focusses on the quality of project design and preparation. Were project stakeholders[19] adequately identified and were they sufficiently involved in project development and ground truthing e.g. of proposed timeframe and budget? Were the project's objectives and components clear, practicable and feasible within its timeframe? Are potentially negative environmental, economic and social impacts of projects identified? Were the capacities of executing agencies properly considered when the project was designed? Was the project document clear and realistic to enable effective and efficient implementation? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities) and enabling legislation assured? Were adequate project management arrangements in place? Were lessons from other relevant projects properly incorporated in the project design? What factors influenced the quality-at-entry of the project design, choice of partners, allocation of financial resources etc.? Were any design weaknesses mentioned in the Project Review Committee minutes at the time of project approval adequately addressed?

41. **Project implementation and management**. This includes an analysis of implementation approaches used by the project, its management framework, the project's adaptation to changing

[19] Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or 'stake' in the outcome of the project. The term also applies to those potentially adversely affected by the project.

conditions and responses to changing risks including safeguard issues (adaptive management), the performance of the implementation arrangements and partnerships, relevance of changes in project design, and overall performance of project management. The evaluation will:

(t) Ascertain to what extent the project implementation mechanisms outlined in the project document have been followed and were effective in delivering project milestones, outputs and outcomes. Were pertinent adaptations made to the approaches originally proposed?

(u) Evaluate the effectiveness and efficiency of project management and how well the management was able to adapt to changes during the life of the project.

(v) Assess the role and performance of the teams and working groups established and the project execution arrangements at all levels.

(w) Assess the extent to which project management responded to direction and guidance provided by the UNEP Task Manager and project steering bodies including.

(x) Identify operational and political / institutional problems and constraints that influenced the effective implementation of the project, and how the project tried to overcome these problems.

42. **Stakeholder participation, cooperation and partnerships.** The Evaluation will assess the effectiveness of mechanisms for information sharing and cooperation with other UNEP projects and programmes, external stakeholders and partners. The term stakeholder should be considered in the broadest sense, encompassing both project partners and target users of project products. The TOC and stakeholder analysis should assist the evaluators in identifying the key stakeholders and their respective roles, capabilities and motivations in each step of the causal pathways from activities to achievement of outputs, outcomes and intermediate states towards impact. The assessment will look at three related and often overlapping processes: (1) information dissemination to and between stakeholders, (2) consultation with and between stakeholders, and (3) active engagement of stakeholders in project decision making and activities. The evaluation will specifically assess:

(y) the approach(es) and mechanisms used to identify and engage stakeholders (within and outside UNEP) in project design and at critical stages of project implementation. What were the strengths and weaknesses of these approaches with respect to the project's objectives and the stakeholders' motivations and capacities?

(z) How was the overall collaboration between different functional units of UNEP involved in the project? What coordination mechanisms were in place? Were the incentives for internal collaboration in UNEP adequate?

(aa) Was the level of involvement of the Regional, Liaison and Out-posted Offices in project design, planning, decision-making and implementation of activities appropriate?

(bb) Has the project made full use of opportunities for collaboration with other projects and programmes including opportunities not mentioned in the Project Document[20]? Have complementarities been sought, synergies been optimized and duplications avoided?

(cc) What was the achieved degree and effectiveness of collaboration and interactions between the various project partners and stakeholders during design and implementation of the project? This should be disaggregated for the main stakeholder groups identified in the inception report.

(dd) To what extent has the project been able to take up opportunities for joint activities, pooling of resources and mutual learning with other organizations and networks? In particular, how useful are partnership mechanisms and initiatives such as cooperation with local authorities to build stronger coherence and collaboration between participating organisations?

(ee) How did the relationship between the project and the collaborating partners (institutions and individual experts) develop? Which benefits stemmed from their involvement for

[20] [If the ProDoc mentions any opportunities for collaboration with other projects and programmes, present these here in the footnote]

project performance, for UNEP and for the stakeholders and partners themselves? Do the results of the project (strategic programmes and plans, monitoring and management systems, sub-regional agreements etc.) promote participation of stakeholders, including users, in environmental decision making?

43. **Communication and public awareness**. The evaluation will assess the effectiveness of any public awareness activities that were undertaken during the course of implementation of the project to communicate the project's objective, progress, outcomes and lessons. This should be disaggregated for the main stakeholder groups identified in the inception report. Did the project identify and make us of existing communication channels and networks used by key stakeholders? Did the project provide feedback channels?

44. **Country ownership and driven-ness.** The evaluation will assess the degree and effectiveness of involvement of government / public sector agencies in the project, in particular those involved in project execution and those participating in relevant bodies e.g. project Steering Committee:

(ff) To what extent have Governments assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project?

(gg) How and how well did the project stimulate country ownership of project outputs and outcomes?

(hh) [Any other project-specific questions]

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

(ii) Verify the application of proper standards (clarity, transparency, audit etc.) and timeliness of financial planning, management and reporting to ensure that sufficient and timely financial resources were available to the project and its partners;

(jj) Assess other administrative processes such as recruitment of staff, procurement of goods and services (including consultants), preparation and negotiation of cooperation agreements etc. to the extent that these might have influenced project performance;

(kk) Present the extent to which co-financing has materialized as expected at project approval (see Table 1). Report country co-financing to the project overall, and to support project activities at the national level in particular. The evaluation will provide a breakdown of final actual costs and co-financing for the different project components (see tables in Annex 3).

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

46. Analyse the effects on project performance of any irregularities in procurement, use of financial resources and human resource management, and the measures taken by UNEP to prevent such irregularities in the future. Determine whether the measures taken were adequate.

47. **Supervision, guidance and technical backstopping.** The purpose of supervision is to verify the quality and timeliness of project execution in terms of finances, administration and achievement of outputs and outcomes, in order to identify and recommend ways to deal with problems which arise during project execution. Such problems may be related to project management but may also involve technical/institutional substantive issues in which UNEP has a major contribution to make.

48. The evaluators should assess the effectiveness of supervision, guidance and technical support provided by the different supervising/supporting bodies including:

(mm) The adequacy of project supervision plans, inputs and processes;

(nn) The realism and candour of project reporting and the emphasis given to outcome monitoring (results-based project management);

(oo) How well did the different guidance and backstopping bodies play their role and how well did the guidance and backstopping mechanisms work? What were the strengths in guidance and backstopping and what were the limiting factors?

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

(pp) *M&E Design*. The evaluator should use the following questions to help assess the M&E design aspects:

- Arrangements for monitoring: Did the project have a sound M&E plan to monitor results and track progress towards achieving project objectives? Have the responsibilities for M&E activities been clearly defined? Were the data sources and data collection instruments appropriate? Was the time frame for various M&E activities specified? Was the frequency of various monitoring activities specified and adequate?
- How well was the project logical framework (original and possible updates) designed as a planning and monitoring instrument?
- SMART-ness of indicators: Are there specific indicators in the logframe for each of the project objectives? Are the indicators measurable, attainable (realistic) and relevant to the objectives? Are the indicators time-bound?
- Adequacy of baseline information: To what extent has baseline information on performance indicators been collected and presented in a clear manner? Was the methodology for the baseline data collection explicit and reliable? For instance, was there adequate baseline information on pre-existing accessible information on global and regional environmental status and trends, and on the costs and benefits of different policy options for the different target audiences? Was there sufficient information about the assessment capacity of collaborating institutions and experts etc. to determine their training and technical support needs?
- To what extent did the project engage key stakeholders in the design and implementation of monitoring? Which stakeholders (from groups identified in the inception report) were involved? If any stakeholders were excluded, what was the reason for this? Was sufficient information collected on specific indicators to measure progress on HR and GE (including sex-disaggregated data)?
- Did the project appropriately plan to monitor risks associated with Environmental Economic and Social Safeguards?
- Arrangements for evaluation: Have specific targets been specified for project outputs? Has the desired level of achievement been specified for all indicators of objectives and outcomes? Were there adequate provisions in the legal instruments binding project partners to fully collaborate in evaluations?
- Budgeting and funding for M&E activities: Determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

(qq) *M&E Plan Implementation*. The evaluation will verify that:

- the M&E system was operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period;
- PIR reports were prepared (the realism of the Task Manager's assessments will be reviewed)
- Half-yearly Progress & Financial Reports were complete and accurate;
- Risk monitoring (including safeguard issues) was regularly documented
- the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs.

## G. The Consultants' Team

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

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

## H. Evaluation Deliverables and Review Procedures

26. The consultant will prepare an **inception report** (see Annex 1(a) of TORs for Inception Report outline) containing a thorough review of the project context, project design quality, a draft reconstructed Theory of Change of the project, the evaluation framework and a tentative evaluation schedule.

27. It is expected that a large portion of the desk review will be conducted during the inception phase. It will be important to acquire a good understanding of the project context, design and process at this stage. The review of design quality will cover the following aspects (see Annex 6 for the detailed project design assessment matrix):

- Strategic relevance of the project
- Preparation and readiness;
- Financial planning;
- M&E design;
- Complementarity with UNEP strategies and programmes;
- Sustainability considerations and measures planned to promote replication and up-scaling.

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

29. The inception report will also include a stakeholder analysis identifying key stakeholders, networks and channels of communication. This information should be gathered from the Project document and discussion with the project team. See annex 1 for template.

30. The evaluation framework will present in further detail the overall evaluation approach. It will specify for each evaluation question under the various criteria what the respective indicators and data sources will be. The evaluation framework should summarize the information available from project documentation against each of the main evaluation parameters. Any gaps in information should be

identified and methods for additional data collection, verification and analysis should be specified. Evaluations/reviews of other large assessments can provide ideas about the most appropriate evaluation methods to be used.

31. Effective communication strategies help stakeholders understand the results and use the information for organisational learning and improvement. While the evaluation is expected to result in a comprehensive document, content is not always best shared in a long and detailed report; this is best presented in a synthesised form using any of a variety of creative and innovative methods. The evaluator is encouraged to make use of multimedia formats in the gathering of information eg. video, photos, sound recordings. Together with the full report, the evaluator will be expected to produce a 2-page summary of key findings and lessons. A template for this has been provided in Annex 9.

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

33. The inception report will be submitted for review and approval by the Evaluation Office before the any further data collection and analysis is undertaken.

34. **The main evaluation report** should be brief (no longer than 40 pages – excluding the executive summary and annexes), to the point and written in plain English. The report will follow the annotated Table of Contents outlined in Annex 1. It must explain the purpose of the evaluation, exactly what was evaluated and the methods used (with their limitations). The report will present evidence-based and balanced findings, consequent conclusions, lessons and recommendations, which will be cross-referenced to each other. The report should be presented in a way that makes the information accessible and comprehensible. Any dissident views in response to evaluation findings will be appended in footnote or annex as appropriate. To avoid repetitions in the report, the authors will use numbered paragraphs and make cross-references where possible.

35. **Review of the draft evaluation report**. The consultant will submit a zero draft report to the UNEP EO and revise the draft following the comments and suggestions made by the EO. Once a draft of adequate quality has been accepted, the EO will share this first draft report with the Task Manager, who will alert the EO in case the report would contain any blatant factual errors. The Evaluation Office will then forward the first draft report to the other project stakeholders, in particular the National Competent Authorities 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. It is also very important that stakeholders provide feedback on the proposed recommendations and lessons. Comments would be expected within two weeks after the draft report has been shared. Any comments or responses to the draft report will be sent to the UNEP EO for collation. The EO will provide the comments to the evaluation team for consideration in preparing the final draft report, along with its own views.

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

37. **Submission of the final evaluation report.** The final report shall be submitted by Email to the Head of the Evaluation Office. The Evaluation Office will finalize the report and share it with the interested Divisions and Sub-programme Coordinators in UNEP. The final evaluation report will be published on the UNEP Evaluation Office web-site www.unep.org/eou.

38. As per usual practice, the UNEP EO will prepare a **quality assessment** of the zero draft and final draft report, which is a tool for providing structured feedback to the evaluation consultant. The quality of the report will be assessed and rated against the criteria specified in Annex 2.

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

40. 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. After reception of the Recommendations Implementation Plan, the Task Manager is expected to complete it and return it to the EO within one month. (S)he is expected to update the plan every six month until the end of the tracking period. The tracking period for implementation of the recommendations will be 18 months, unless it is agreed to make this period shorter or longer as required for realistic implementation of all evaluation recommendations. Tracking points will be every six months after completion of the implementation plan.

## I. Logistical arrangements

41. This Terminal Evaluation will be undertaken by one independent evaluation consultant contracted by the UNEP Evaluation Office. The consultant will work under the overall responsibility of the UNEP Evaluation Office and will consult with the EO on any procedural and methodological matters related to the evaluation. It is, however, the 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 UNEP Task Manager and project team will, where possible, provide logistical support (introductions, meetings etc.) allowing the consultant to conduct the evaluation as efficiently and independently as possible.

## J. Schedule of the evaluation

42. Table 7 below presents the tentative schedule for the evaluation.

**Table 7. Tentative schedule for the evaluation**

| Milestone | Deadline |
|---|---|
| Inception Report | 30 September 2016 |
| Evaluation Mission – 1 week (Cuba) | 30 October 2016 |
| Telephone interviews, surveys etc. | 30 October 2016 |
| Zero draft report | 15 November 2016 |
| Draft Report shared with UNEP Task Manager | 20 November 2016 |
| Draft Report shared with stakeholders | 30 November 2016 |
| Final Report | 15 December 2016 |

## K. Contractual arrangements

43. The consultant will be hired under an individual Special Service Agreement (SSA). The contract will be issued based on the "fees only" system. This means that the contract stipulates consultant fees only. Air tickets will be purchased by UNEP and 75% of the DSA for each authorised travel mission will be paid up front. Local in-country travel and communication costs will be reimbursed on the production of acceptable receipts. Terminal expenses and residual DSA entitlements (25%) will be paid after mission completion.

44. Schedule of Payment:

| Deliverables | Percentage payment |
|---|---|
| Inception report | 20% of fees |

| | |
|---|---|
| Submission and approval of the draft evaluation report | 40% of fees |
| Submission and approval of the final evaluation report | 40% of fees |

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

46. The consultant may be provided with access to UNEP's Programme Information Management System (PIMS) or ANUBIS 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.

47. In case the consultant IS not able to provide the deliverables in accordance with these TORs, and in line with the expected quality standards by the UNEP Evaluation Office, payment may be withheld at the discretion of the Director of the Evaluation Office until the consultant has improved the deliverables to meet UNEP's quality standards.

48. If the consultant fails to submit a satisfactory final product to UNEP 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 consultant's fees by an amount equal to the additional costs borne by the Evaluation Office to bring the report up to standard.

## Annex 2

## Evaluation Program

Primer día: lunes 24 de octubre del 2016

| Horario | Tema | Responsable/ Participantes | Lugar |
|---|---|---|---|
| 09:00-10:05 a.m. | Bienvenida por parte de la Directora del CSB y recorrido por el centro | Leticia Pastor/Evaluador, CSB | CSB |
| 10:00-10:30 a.m. | Presentación sobre estructura y funciones de la ORASEN | Michel Fernández/DG Orasen, Evaluador, GAA | Aula CSB |
| 10:30-11:00 a.m. | Presentación sobre estructura y funciones del CSB | Leticia Pastor/Evaluador, GAA | CSB |
| 11:00-12:00 m. | Presentación sobre resultados más relevantes del Proyecto | Juan Carlos Menéndez de San Pedro/Evaluador, GAA | Aula CSB |
| 12:00-2:00 p.m. | Ajustes a la Agenda de Trabajo de la semana. | Evaluador, GAA | Aula CSB |
| 02:00 p.m. | Almuerzo con el GAA | Evaluador, GAA | Rancho Palco |

Segundo día: Martes 25 de octubre del 2016

| Horario | Tema | Responsable/ Participantes | Lugar |
|---|---|---|---|
| 09:00-09:30 a.m. | Presentación Principales resultados Componente 1 | Lenia Arce/Evaluador, GAA | Aula CSB |
| 09:30-10:00 a.m. | Presentación Principales resultados Componente 2 | Gricel López/Evaluador, GAA | Aula CSB |
| 10:00-10:30 a.m. | Presentación Principales resultados Componente 3 | Juan Carlos Menéndez de San Pedro/Evaluador, GAA | CSB |
| 10:30-11:00 a.m. | Presentación Principales resultados Componente 4 | Juan Carlos Menéndez de San Pedro/Evaluador, GAA | Aula CSB |
| 11:00-12:00 m. | Debate | Evaluador, jefes de componentes | Aula CSB |
| 12:00-01:00 p.m. | Almuerzo | | |
| 01:00-04:30 m. | Revisión de documentos | Evaluador, GAA | Aula CSB |

Tercer día: Miércoles 26 de octubre del 2016

| Horario | Tema | Responsable/ Participantes | Lugar |
|---|---|---|---|
| 09:00-12:00 m. | Entrevista a representantes de las Autoridades Nacionales que conforman el Mecanismo de Coordinación Nacional. | Evaluador, GAA, IMV, MINSAP, INHEM, CNSV | Aula CSB |
| 12:00-01:00 p.m. | Almuerzo | | |
| 01:00-04:30 m. | Entrevista a representantes de las ONG y entidades usuarias que participan en el Mecanismo de Coordinación Nacional. | Evaluador, GAA, CIGB, CENSA, Fundación Antonio Núñez Jiménez, ACPA | Aula CSB |

Cuarto día: Jueves 27 de octubre del 2016

| Horario | Tema | Responsable/ Participantes | Lugar |
|---|---|---|---|
| 09:00-12:00 m. | Entrevista a Universidades que son parte del Sistema de Formación de RRHH en Bioseguridad. | Evaluador, GAA, INSTEC, UH (Facultad de Biología) | Aula CSB |
| 12:00-01:00 p.m. | Almuerzo | | |
| 01:00-04:30 m. | Revisión de documentos | Evaluador | Aula CSB |

Quinto día: Viernes 28 de octubre del 2016

| Horario | Tema | Responsable/ Participantes | Lugar |
|---|---|---|---|
| 09:00-12:00 m. | Entrevista a representantes de las Autoridades Nacionales que intervienen en el Control en fronteras. | Evaluador, GAA, MINCEX, AGR | Aula CSB |
| 12:00-01:00 p.m. | Almuerzo | | |
| 01:00-04:00 m. | Conclusiones preliminares | Evaluador, GAA | Aula CSB |

## Interviewed Persons

| Name | Position | Institution | E-Mail |
|---|---|---|---|
| Juan Carlos Menendez de San Pedro López | Project Coordinator | CSB | jc@orasen.co.cu |
| Lenia Arce Hernandez | Coordinator Component 1 | CSB | lenia@oraen.co.cu |
| Gricel López Fumero | Coordinator Component 2 | CSB | gricel@orasen.co.cu |
| Leticia Pastor Chirino | Coordinator Component 4 | CSB | leticiach@orasen.co.cu |
| Mayelin Periche | Financial/Administrative Assistant | CSB | maype@orasen.co.cu |
| Ileana Figueredo Echague | Secretary/Admin. Asst. | CSB | ileana@orasen.co.cu |
| Viana Barceló Pérez | Head, Inspections Dept. | CSB | viana@orase.co.cu |
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| María Victoria Luna Martinez | MCN | INHA | mvictoria@sinha.sld.cu |
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| | | | |
|---|---|---|---|
| Maria Pueyo Figueroa | MCN | CNSV | exterior@sanidadvegetal.cu |
| Mario Cruz Arias | Professor, University of Havana | University of Havana | mcruz@fbio.uh.cu |
| José Rodriguez Dueñas | Coordinator Component 3 | INSTEC | jrduenas@instec.cu |
| Angela Sosa Espinosa | MCN | CIGB | angela.sosa@cigb.edu.cu |
| Vivian Rebeca Hernandez Triana | MCN | CENSA | rebecaht@censa.edu.cu |
| Jose Valero Ramos | Senior Customs Officer, MCN | ADR | |
| Mariela Ladron de Cueva | MCN | MINCEX | |

## Annex 3

## Bibliography


- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Project Document (2010)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Project Implementation Review (PIR) Reports – 2014-2016
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Final Project Report (2016)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Reports on National Coordination Mechanism/MCN Meetings (2011-2016)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Presentations of Project Components and Results (Power Point Presentations, 2016)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Annual Budget Revisions 2011-2016
- Mid-term Review of the Project: "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol" (M. Araya-Quesada, 2013)
- *Lecciones Aprendidas en la Ejecucion de Proyectos de Implementación del Marco Nacional de Bioseguridad en Algunos Paises de Latinoamérica* (Araya, M., Azurdia, C., Cascante, M., Chávez, J., Del Cid, M., Frangakis, G., Madriz, J., Menéndez, J., López, G., Onofa, A., Rosado, A., Woolfson, J. & Yanes, J., 2013)
- *Resultados del MCN* (project papaer, no date)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": *Taller de cierre del Proyecto Completamiento y fortalecimiento del marco nacional de bioseguridad para la efectiva implementación del Protocolo de Cartagena* (2016)
- GFL-2328-2716-4B74 "Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol ": Terms of Reference (2016)

## Annex 4

## Project costs and co-financing tables

**Project Costs (GEF Budget)**

| Component/sub-component/output | Estimated cost at design | Actual Cost | Expenditure ratio (actual/planned) |
|---|---|---|---|
| 1. Reinforcement of the National Coordination Mechanism | US$ 96,225 | US$ 96,225 | 1:1 |
| 2. Strengthening of the framework for import and export of LMOs | US$ 37,995 | US$ 37,995 | 1:1 |
| 3. Design and implementation of a System for Human Resources Training in Biosafety | US$ 228,680 | US$ 228,680 | 1:1 |
| 4. Increase in the scientific, technological and infrastructural capacities of the National Competent Authorities | US$ 401,391 | US$ 401,391 | 1:1 |
| 5. M&E | US$ 45,500 | US$ 45,500 [21] | 1:1 |
| 6. Project Management | US$ 90,300 | US$ 90,300 | 1:1 |

**Co-financing**

| Co financing (Type/ThSource) | UNEP own Financing (US$1,000) | | Government (US$1,000) | | Other* (US$1,000) | | Total (US$1,000) | | Total Disbursed (US$1,000) |
|---|---|---|---|---|---|---|---|---|---|
| | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | |
| – Grants [22] | 909.091 | 909.091 | | | | | | | 810,022 |
| – Loans | | | | | | | | | |
| – Credits | | | | | | | | | |
| – Equity investments | | | | | | | | | |
| – In-kind [23] support | | | 1042.806 | 1063.228 | | | | | 1063.228 |

[21] At the time of the project's termination, US$ 810,022 had been spent. Subsequent disbursements have left a final balance of US$ 12,000. There was an unspent balance of US$ 12,000 balance at the end of the project that included costs related to the TE, which have subsequently been expended.
[22] Includes US$ 9,000 PPG project preparation grant.
[23] Includes US$ 24,254 PPG co-financing

## Annex 5

## Results and Lessons Learned

### About the Project

The project's overall objective was to address the technical, legal, infrastructural and biosafety management gaps faced by the country's National Competent Authorities to ensure the successful and sustainable implementation of the CP in Cuba. The specific objectives were:

1. To reinforce the National Coordination Mechanism, focusing on decision-making and setting standards and criteria.
2. To strengthen the framework for LMO import and export in accordance with the CP.
3. To design and implement a System of Human Resources Training in Biosafety.
4. To increase the scientific, technological, and infrastructure capacities of the National Competent Authorities.

The project was composed of 4 main technical components that were based on the specific project objectives. The project included two additional components that focus on project management and the project's monitoring and evaluation activities.

The project was implemented between November 2010 and June 2016. The project budget consisted of a US$ 900,091 grant from GEF and US$ 1,038,974.18 in government co-financing.

### Relevance

The project was relevant globally, regionally and nationally. Project objectives were aligned with UNEP's 2010-2013 Medium-Term Strategy's (MTS) cross-cutting priority of global, regional and national environmental governance to address common environmental priorities, and with the third objective of capacity building and technology transfer in support of the Bali Strategic Plan's (BSP) implementation. There was also consistency with the UNEP's 2010-11 Programme of Work (PoW) and Expected Accomplishment (EA) of enhanced State capacities to implement environmental obligations and achieve priority targets/objectives.

At the national level, the project was part of a broader cooperation context and built on the cumulative improvements achieved over the years, with the aim of closing remaining capacity gaps and strengthening systemic performance through improved information flows and coordination mechanisms. By supporting the creation of Cuba's first inter-institutional biosafety coordination mechanism the project addressed an essential element of a functional national biosafety framework that was lacking. The support provided for laboratory infrastructure, reactives and other materials were extremely relevant to Cuba's material needs given the difficulties raised by the US trade embargo.

### Performance

Overall project performance and results were highly satisfactory. Project performance ranged from satisfactory to very satisfactory when assessed against the evaluation criteria. Substantive results were

generated – three of four outcomes were fully reached – and 27 of 29 outputs (93%) were completed. Substance was accompanied by efficiency and more than 90% of the budget had been spent when the project's terminated in June 2016. In terms of accomplishment and cost-effectiveness, the project stands out as a "best practice" case study in project execution. The combined impacts of the project components have raised Cuba's National Biosafety Framework to a new threshold : The first national coordination mechanism is a fundamental contribution that enables more consistent communication and involvement by government agencies on biosafety matters. This is supported by an integrated biosafety information system – the SIISB - that streamlines procedures for LMO reviews and decisions, and the implementation of a national biosafety training system that is expected to fulfill Cuba's capacity needs by 2020.

## Factors Effecting Performance

The evaluation highlighted the following factors that influenced project performance and results:

- High levels of preparation and readiness on the part of CSB, with prior experience as NEA for GEF-UNEP projects;
- Good project design that was achievable in terms of expectations, timelines and resource allocations;
- High levels of country ownership on the part of the NEA; and
- Mechanisms for stakeholder participation and adaptive management, i.e. Technical Committee and National Coordination Mechanism.

## Key Lessons Learned

- The National Coordination Mechanism (MCN) is the first inter-institutional mechanism of its type in Cuba and has a strong demonstration value.
- Institutional stability and effective group dynamics within CSB and other government institutions have enabled the high-level technical and managerial expertise that went into the project's execution.
- The early participation of NCAs and representatives of the biotechnology sector in the project's design strengthened institutional commitment to the project and its objectives.
- The national biosafety training system potentially enables Cuba to assume a lead role in regional capacity building and South-South cooperation.

## Annex 6

**Quality Assessment of the Evaluation Report**

Evaluation Title:

| |
|---|
| Completion and strengthening of the Cuban national biosafety framework for the effective implementation of the Cartagena Protocol |

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 | Draft Report Rating | Final Report Rating |
|---|---|---|---|
| **Substantive Report Quality Criteria** | | | |
| ***Quality of the Executive Summary:***<br><br>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. | Draft report: *(Exec Summaries are not always provided at draft stage)*<br><br>Final report:<br>Very good summary | | 6 |
| ***I. Introduction***<br><br>A brief introduction should be given identifying, where possible and relevant, the following: institutional context of the project (sub-programme, 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. mid-term, part of a synthesis evaluation, evaluated by another agency etc.)<br><br>Consider the extent to which the introduction includes a concise statement of the purpose of the evaluation and the key intended audience for the findings? | Draft report:<br>Introduction is to the point<br><br>Final report:<br>Same as above | 5 | 5 |

| | | | |
|---|---|---|---|
| ***II. Evaluation Methods***<br>This section should include a description of how the *TOC at Evaluation*[24] was designed (who was involved etc.) and applied to the context of the project?<br>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.).<br>The methods used to analyse data (e.g. scoring; coding; thematic analysis etc.) should be described.<br>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.<br>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. | Draft report:<br>Methods briefly described (old ToR template)<br><br>Final report:<br>Same as above | 5 | 5 |
| ***III. The Project***<br>This section should include:<br>• *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. synopsis of the problem and situational analyses).<br>• *Objectives and components*: Summary of the project's results hierarchy as stated in the ProDoc (or as officially revised)<br>• *Stakeholders:* Description of groups of targeted stakeholders organised according to relevant common characteristics<br>• *Project implementation structure and partners:* A description of the implementation structure with diagram and a list of key project partners<br>• *Changes in design during implementation:* Any key events that affected the project's scope or parameters should be described in brief in chronological order | Draft report:<br>Context is well described<br><br>Final report:<br>Same as above | 5 | 5 |

24 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*.

| | | | |
|---|---|---|---|
| • *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***<br>A summary of the project's results hierarchy should be presented for: a) the results as stated in the approved/revised Prodoc logframe/TOC and b) as formulated in the TOC at Evaluation. *The two results hierarchies should be presented as a two column table to show clearly that, although wording and placement may have changed, the results 'goal posts' have not been 'moved'.* The TOC at Evaluation should be presented clearly in both diagrammatic and narrative forms. Clear articulation of each major causal pathway is expected, (starting from outputs to long term impact), including explanations of all drivers and assumptions as well as the expected roles of key actors. | Draft report:<br>ToC presents usual structure used by the consultants, some arrows are mis-placed/redundant but overall the causal pathways are clear<br><br>Final report:<br>Same as above, with minor improvements | 4 | 5 |
| ***V. Key Findings***<br><br>**A. Strategic relevance:**<br>This section should 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. 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:<br>1. Alignment to the UN Environment Medium Term Strategy (MTS) and Programme of Work (POW)<br>2. Alignment to UN Environment/GEF/Donor Strategic Priorities<br>3. Relevance to Regional, Sub-regional and National Environmental Priorities<br>4. Complementarity with Existing Interventions | Draft report:<br>Well covered, basically this section is not always the same after alignment issues were clarified in previous NBF evaluations (except for regional/national aspects)<br><br>Final report:<br>Same as above | 5 | 5 |
| **B. Quality of Project Design**<br>To what extent are the strength and weaknesses of the project design effectively summarized? | Draft report:<br>Good summary<br>Final report:<br>Same as above | 5 | 5 |
| **C. Nature of the External Context**<br>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. | Draft report:<br>N/A<br>Final report:<br>N/A | | |
| **D. Effectiveness**<br>**(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 | Draft report:<br>Very good summary<br>Final report:<br>Same as above | 6 | 6 |

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| attribution and contribution, as well as the limitations to attributing effects to the intervention. | | | |
| **(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?<br>How well are change processes explained and the roles of key actors, as well as drivers and assumptions, explicitly discussed? | Draft report:<br>Well described, project encounters common problem of policy adoption, well known to the consultant<br>Final report:<br>Same as above | 5 | 5 |
| **E. Financial Management**<br>This section should contain an integrated analysis of all dimensions evaluated under financial management. And include a completed 'financial management' table.<br>Consider how well the report addresses the following:<br>• *completeness* of financial information, including the actual project costs (total and per activity) and actual co-financing used<br>• *communication* between financial and project management staff and<br>• *compliance* with relevant UN financial management standards and procedures. | Draft report: well covered and detailed<br>Final report:<br>Same as above<br>*(if this section is rated poorly as a result of limited financial information from the project, this is not a reflection on the consultant per se, but will affect the quality of the evaluation report)* | 6 | 6 |
| **F. Efficiency**<br>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:<br>• Implications of delays and no cost extensions<br>• Time-saving measures put in place to maximise results within the secured budget and agreed project timeframe<br>• 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.<br>• The extent to which the management of the project minimised UN Environment's environmental footprint. | Draft report:<br>All aspects covered<br>Final report:<br>Same as above | 5 | 5 |
| **G. Monitoring and Reporting**<br>How well does the report assess:<br>• Monitoring design and budgeting *(including SMART indicators, resources for MTE/R etc.)*<br>• Monitoring implementation *(including use of monitoring data for adaptive management)*<br>• Project reporting *(e.g. PIMS and donor report)* | Draft report:<br>Good assessment<br>Final report:<br>Same as above | 5 | 5 |
| **H. Sustainability**<br>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: | Draft report:<br>All aspects considered<br>Final report:<br>Same as above | 5 | 5 |

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| • Socio-political Sustainability<br>• Financial Sustainability<br>• Institutional Sustainability *(including issues of partnerships)* | | | |
| **I. Factors Affecting Performance**<br>These factors are <u>not</u> 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 cross-cutting themes:<br>• Preparation and readiness<br>• Quality of project management and supervision[25]<br>• Stakeholder participation and co-operation<br>• Responsiveness to human rights and gender equity<br>• Country ownership and driven-ness<br>• Communication and public awareness | Draft report:<br>Good assessment, based on previous ToR structure<br><br>Final report:<br>Same as above | 5 | 5 |
| ***VI. Conclusions and Recommendations***<br><br>**i. Quality of the conclusions:** The key strategic questions should be clearly and succinctly addressed within the conclusions section?<br>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. | Draft report:<br>Conclusions highlight key points<br>Final report:<br>Same as above | 5 | 5 |
| **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. | Draft report:<br>Lessons are useful and targeted to the country as well as region<br>Final report:<br>Same as above | 5 | 5 |
| **iii) Quality and utility of the recommendations:**<br>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. | Draft report:<br>Short, targeted to follow up phase<br>Final report:<br>Same as above | 6 | 6 |
| ***VII. Report Structure and Presentation Quality*** | | | |
| **i) Structure and completeness of the report:** To | Draft report: | 6 | 6 |

[25] 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.

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| what extent does the report follow the Evaluation Office guidelines? Are all requested Annexes included and complete? | Well written report including all annexes<br>Final report:<br>Same as above | | |
| ii) **Quality of writing and formatting:**<br>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? | Draft report:<br>Well written<br>Final report:<br>Same as above | 6 | 6 |
| **OVERALL REPORT QUALITY RATING** | | 5.2 | 5.3 |

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.

At the end of the evaluation compliance of the evaluation process against the agreed standard procedures is assessed, based on the table below. *All questions with negative compliance must be explained further in the table below.*

| Evaluation Process Quality Criteria | Compliance | |
|---|---|---|
| | Yes | No |
| **Independence:** | | |
| 1. Were the Terms of Reference drafted and finalised by the Evaluation Office? | x | |
| 2. Were possible conflicts of interest of proposed Evaluation Consultant(s) appraised and addressed in the final selection? | x | |
| 3. Was the final selection of the Evaluation Consultant(s) made by the Evaluation Office? | x | |
| 4. Was the evaluator contracted directly by the Evaluation Office? | x | |
| 5. Was the Evaluation Consultant given direct access to identified external stakeholders in order to adequately present and discuss the findings, as appropriate? | x | |
| 6. Did the Evaluation Consultant raise any concerns about being unable to work freely and without interference or undue pressure from project staff or the Evaluation Office? | | x |
| 7. If Yes to Q6: Were these concerns resolved to the mutual satisfaction of both the Evaluation Consultant and the Evaluation Manager? | | |
| **Financial Management:** | | |
| 8. Was the evaluation budget approved at project design available for the evaluation? | x | |
| 9. Was the final evaluation budget agreed and approved by the Evaluation Office? | x | |
| 10. Were the agreed evaluation funds readily available to support the payment of the evaluation contract throughout the payment process? | x | |
| **Timeliness:** | | |
| 11. If a Terminal Evaluation: Was the evaluation initiated within the period of six months before or after project operational completion? Or, if a Mid Term Evaluation: Was the evaluation initiated within a six month period prior to the project's mid-point? | x | |
| 12. Were all deadlines set in the Terms of Reference respected, as far as unforeseen circumstances allowed? | | x |
| 13. Was the inception report delivered and reviewed/approved prior to commencing any travel? | x | |
| **Project's engagement and support:** | | |
| 14. Did the project team, Sub-Programme Coordinator and identified project stakeholders provide comments on the evaluation Terms of Reference? | x | |
| 15. Did the project make available all required/requested documents? | x | |
| 16. Did the project make all financial information (and audit reports if applicable) available in a timely manner and to an acceptable level of completeness? | x | |
| 17. Was adequate support provided by the project to the evaluator(s) in planning and conducting evaluation missions? | x | |
| 18. Was close communication between the Evaluation Consultant, Evaluation Office and project team maintained throughout the evaluation? | x | |
| 19. Were evaluation findings, lessons and recommendations adequately discussed with the project team for ownership to be established? | x | |
| 20. Did the project team, Sub-Programme Coordinator and any identified project stakeholders provide comments on the draft evaluation report? | x | |
| **Quality assurance:** | | |
| 21. Were the key evaluation questions in the evaluation Terms of Reference peer-reviewed? | x | |

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| 22. Were the evaluation Terms of Reference, including the key evaluation questions, peer-reviewed? | | **x** |
| 23. Was the TOC in the inception report peer-reviewed? | | **x** |
| 24. Was the quality of the draft/cleared report checked by the Evaluation Manager and Peer Reviewer prior to dissemination to stakeholders for comments? | | **x** |
| 25. Did the Evaluation Office complete an assessment of the quality of the both the draft and final reports? | **x** | |
| **Transparency:** | | |
| 26. Was the draft evaluation report sent directly by the Evaluation Consultant to the Evaluation Office? | **x** | |
| 27. Did the Evaluation Manager disseminate (or authorize dissemination) of the cleared draft report to the project team, Sub-Programme Coordinator and other key internal personnel (including the Reference Group where appropriate) to solicit formal comments? | **x** | |
| 28. Did the Evaluation Manager disseminate (or authorize dissemination) appropriate drafts of the report to identified external stakeholders, including key partners and funders, to solicit formal comments? | **x** | |
| 29. Were all stakeholder comments to the draft evaluation report sent directly to the Evaluation Office | **x** | |
| 30. Did the Evaluation Consultant(s) prepare a response to all comments? -> minor corrections only (directly in the text) | | **X** |
| 31. Did the Evaluation Office share all comments and Evaluation Consultant responses with all those who were invited to comment? | **x** | |

**Provide comments / explanations / mitigating circumstances below for any non-compliant process issues.**

| **Process Criterion Number** | **Evaluation Office Comments** |
|---|---|
| | No peer review as evaluator is very experienced and biosafety portfolio projects are very similar to each other |
| | Some delays in finalizing the report as evaluator was working on another assignment for UNEP EOU in parallel (which was agreed to with TM and other evaluation manager) |
| | |