# Mid-Term Review of the UNEP-GEF Project

Creation of Additional Biosafety Capacities that Lead to a Full Implementation of the Cartagena Protocol on Biosafety in Cuba (GEF Project ID: 9860)

03 April 2020 – 31 March 2025

## DRAFT MAIN MID-TERM REVIEW REPORT


**UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division**

**UNEP Latin American and the Caribbean Office**

**JANUARY 2024**

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This report has been prepared by an external consultant as part of a Mid-Term Review, which is a management-led process to assess performance at the project's mid-point. The UNEP Evaluation Office provides templates and tools to support the review process. The findings and conclusions expressed herein do not necessarily reflect the views of Member States or the UN Environment Programme Senior Management.

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Creation of Additional Biosafety Capacities that Lead to a Full Implementation of the Cartagena Protocol on Biosafety in Cuba

GEF Project ID: 9860

(16th January 2024)

## ACKNOWLEDGEMENTS

This Mid-Term Review was prepared for UNEP Latin America and the Caribbean Office by Noel D. Jacobs Sr.

The reviewer would like to express their gratitude to all persons met and who contributed to this review, as listed in Annex II.

The review team would like to thank the project team and in particular Task Managers Thais Narciso, Tea Garcia-Huidobro, and Robert Erath for their contribution and collaboration throughout the review process. Sincere appreciation is also expressed to the Project Steering Committee who took time to provide comments to the draft report. The evaluator would also like to thank the Government of Cuba.

Special acknowledgements to Tanya Romay Fernandez of the Office of Environmental Regulation and Security for her commitment and invaluable support during the MTR process.

The review consultant hopes that the findings, conclusions, and recommendations will contribute to the successful finalisation of the current project and to the continuous improvement of similar projects in other countries and regions.

## BRIEF EXTERNAL CONSULTANT BIOGRAPHY

Noel Jacobs Sr has 19 years of experience working as an International Development Consultant in project design, management, and evaluation primarily in biodiversity, climate change, marine resources, protected areas, land degradation, sustainable tourism, Blue Economy, and policy development. He has successfully designed many GEF projects and has conducted numerous Mid-Term Evaluations of GEF and non-GEF projects. He also has extensive experience as an Institutional Development Consultant, focusing on Institutional Assessments, Organizational Re-structuring, Development of Organizational Policies, Strategic Plans, and Operational Guidelines and Manuals for Organizations and Projects. Mr. Jacobs has worked extensively as a consultant in more than 30 countries in a multitude of sectors including Tourism, Marine Fisheries, Coastal Zone Management, Environment, Climate Change, Aviation, Cultural Heritage, Health, among others. His analytical skills and ability to effectively apply the multi-sector approach in project planning and policy development has proven to be a tremendous asset in the delivery of services to a wide diversity of clients in Latin America and the Caribbean and beyond.

## ABOUT THE REVIEW

**Joint Review:** No

**Report Language:** English

**Review Type:** Mid-Term Review

**Brief Description:** This report is a management-led Mid Term Review of a UNEP/GEF project implemented between 2020 and 2025. The project's overall development goal was to further complete the process of implementation of the Cartagena Protocol on Biosafety (CPB) through the creation of additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms (LMOs) and the socio-economic considerations of importance for Cuba related to them. The review 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 review 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 UNEP, the GEF and the relevant agencies of the project participating country.

**Key words:** Genetically Modified Organisms, Cartagena Protocol on Biosafety, Living Modified Organisms, capacity, national reference laboratories, detection and identification, national system for monitoring and surveillance, certification and accreditation, socio-economic considerations.

**Primary data collection period:** 20 October 2023 to 08 December 2023.

**Field mission dates:** 03-08 December 2023

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## LIST OF ACRONYMS

| | |
|---|---|
| BD | Biodiversity |
| CBD | Convention on Biological Diversity |
| CENATOX | National Centre for Toxicology |
| CENSA | National Centre for Agricultural Health |
| CICDC | Scientific Investigations Centre for Civil Defence |
| CITMA | Ministry of Science, Technology and Environment |
| CPB | Cartagena Protocol on Biosafety |
| CSB | National Centre of Biological Safety |
| EA | Executing Agency |
| GEB | Global Environmental Benefit |
| GEF | Global Environment Facility |
| GMO | Genetically Modified Organisms |
| HYPR | Half-Year Progress Report |
| LMO | Living Modified Organisms |
| MTR | Mid Term Review |
| M&E | Monitoring and Evaluation |
| M&S | Monitoring and Surveillance |
| NPC | National Project Coordinator |
| NSB | National Standardization Office |
| ONARC | National Accreditation Office of the Republic of Cuba |
| ORSA | Office of Environmental Regulation and Security |
| PDQ | Project Design Quality |
| PIR | Project Implementation Review |
| PMU | Project Management Unit |
| PSC | Project Steering Committee |
| SEC | Socio-Economic Considerations |
| SDG | Sustainable Development Goal |
| SOP | Standard Operating Procedures |
| ToC | Theory of Change |
| ToR | Terms of Reference |
| UNEP | United Nations Environment Programme |
| UNDP | United Nations Development Programme |
| USD | United States Dollar |

# PROJECT IDENTIFICATION TABLE

**Table 1. Project Summary**

| | | | |
|---|---|---|---|
| **UNEP Sub-programme:** | Programme of Work 2021-2022<br><br>Subprogramme 3: Healthy and productive ecosystems<br><br>Subprogramme 4: Environmental governance | **UNEP Division/Branch:** | Ecosystems Division, GEF Biodiversity and Land Degradation Unit, Biodiversity and Land Branch. |
| **Expected Accomplishment(s):** | National capacities for LMO identification and detection strengthened and supporting decision-making processes.<br><br>National system for monitoring and surveillance established and operational.<br><br>Socio-economic considerations as per article 26 are considered in decision-making. | **Programme of Work Output(s):** | Two national laboratories: Centre for Scientific Research for the Civil Defence (CICDC)<br><br>and National Centre for Agricultural Health equipped to play a role as national reference laboratories.<br>(accredited by the NC ISO / IEC 17025:2000)<br><br>Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment.<br><br>Detailed analysis of the socio-economic considerations of importance for Cuba related to LMO impacts completed. |
| **SDG(s) and indicator(s)** | **SDG 2 – Zero Hunger**<br><br>Target 2.5 By 2020, maintain the genetic diversity of seeds, cultivated plants, and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional, and international levels, and promote access to and fair and equitable sharing of benefits arising.<br><br>Indicator 2.5.1: Number of plant and animal genetic resources for food and agriculture secured in either medium- or long-term conservation | | |

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| | facilities.<br><br>Indicator 2.5.2: Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction | | |
| **GEF Core Indicator Targets** (identify these for projects approved prior to GEF-7) | **Corporate Result 6.** Enhance capacity of countries to implement MEAs (multilateral environmental agreements) and mainstream into national and sub-national policy, planning financial and legal frameworks.<br><br>**Replenishment Targets**<br><br>Development and sectoral planning frameworks integrate measurable targets drawn from the MEAs in at least 10 countries.<br><br>Project Target: *Number of Countries: 1*<br><br>Functional environmental information systems are established to support decision-making in at least 10 countries.<br>Project Target: *Number of Countries: 1* | | |
| **Dates of previous project phases:** | NA | **Status of future project phases:** | NA |

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|---|---|
| **Project Title:** | Creation of additional Biosafety Capacities that lead to a Full Implementation of the Cartagena Protocol on Biosafety in Cuba |

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|---|---|
| **Executing Agency:** | Office of Environmental Regulation and Security (ORSA) of the Ministry of Science, Technology and Environment |

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| **Project partners:** | CICDC: Centre for Scientific Research for the Civil Defence (CICDC)<br><br>CENSA: National Centre for Agricultural Health<br><br>CENATOX: National Toxicology Centre<br><br>UNDP Cuba<br><br>EMIDICT: Specialized Importer, Exporter and Distributor for Science and Technology (company in charge of equipment imports) |

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|---|---|
| **Geographical Scope:** | National |

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|---|---|
| **Participating Countries:** | Cuba |

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|---|---|---|---|
| **GEF project ID:** | 9860 | **IMIS number*[1]:** | GFL-11207-14AC0003-SB-014367 |
| **Focal Area(s):** | Biodiversity | **GEF OP #:** | |
| **GEF Strategic Priority/Objective:** | BD-2 Program 5 | **GEF approval date*:** | 17 July 2017 |
| **UNEP approval date:** | 24 March 2020 | **Date of first disbursement*:** | 8 June 2020 |
| **Actual start date[2]:** | 3 April 2020 | **Planned duration:** | 60 months |
| **Intended completion date*:** | 31 March 2025 | **Actual or Expected completion date:** | N/A |
| **Project Type:** | Medium-sized Project (MSP) | **GEF Allocation*:** | USD 1,826,484 |
| **PPG GEF cost*:** | - | **PPG co-financing*:** | - |
| **Expected MSP/FSP Co-financing*:** | USD 1,920,443 | **Total Cost*:** | USD 3,746,927 |
| **Mid-term Review/eval. (planned date):** | January 2023 | **Terminal Evaluation (planned date):** | N/A |
| **Mid-term Review/eval. (actual date):** | N/A | **No. of revisions*:** | 3 |
| **Date of last Steering Committee meeting:** | 4 May 2022 | **Date of last Revision*:** | 17 May 2022 |
| **Disbursement as of 30 June 2023*:** | USD 1,131,901.22 | **Date of planned financial closure*:** | 30 April 2026 |
| **Date of planned completion*:** | 31 March 2025 | **Actual expenditures reported as of 31 March 2023:** | USD 680,973.11 |

[1] Fields with an * sign (in yellow) should be filled by the Fund Management Officer

[2] Only if different from first disbursement date, e.g., in cases were a long time elapsed between first disbursement and recruitment of project manager.

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|---|---|---|---|
| **Total co-financing realized as of 31 December 2022** | USD 556,487.74 | **Actual expenditures entered in IMIS as of 31 December 2022*:** | N/A |
| **Leveraged financing:** | | | |

# EXECUTIVE SUMMARY

## Project background

1. The use of Genetically Modified Organisms has been controversial over the years since they have the potential to contribute to human wellbeing in fields like agriculture, bioremediation, and climate change, amongst others. However, their safe use is imperative to minimize possible risks to the environment and human health. Based on this, the Cartagena Protocol on Biosafety calls for international standards on the use of Genetically Modified Organisms under a precautionary principle. Cuba has made significant efforts towards having a functional biosafety system. Nonetheless, the complexity of such enterprise requires additional efforts to allow the country to take advantage of use of GMOs as well as to minimize the possible negative effects that they could have. Barriers to achieving a functional biosafety system in the country include lack of monitoring and surveillance capacity to enforce national regulations in relation to Living Modified Organisms, in the field and at port level, limited financial resources for capacity building in monitoring and surveillance, there is no technical capacity or systems at customs to manage biosafety issues, and lack of information and understanding regarding the economic, legal, and social impacts of Living Modified Organisms. To address these challenges, the Government of Cuba sought and obtained funding from the Global Environment Facility for the project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" and "GEF ID 9860". The project was approved by the GEF in July 2017, but with actual start date of 03 April 2020 for a planned duration of 60 months.

## This Review

2. This Mid-Term Review covers the implementation of the project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" (GEF ID 9860) for the period 3rd April 2020 to 30th November 2023. The Project is funded by the Global Environment Facility and the Mid-Term Review was carried out in the period October 2023 – January 2024. The review 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 review 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 United Nations Environment Programme, the Global Environment Facility, and the relevant agencies of the project participating country. The project is managed from the United Nations Environment Programme's GEF Biodiversity and Land Degradation Unit, Ecosystems Division, via the Latin America and Caribbean Office. Coordination and overall project supervision are the responsibility of the United Nations Environment Programme as Implementing Agency of the Global Environment Facility and the Office of Environmental Regulation and Security is the project's Executing Agency.

3. The project aligns with the Global Environment Facility's and United Nations Environment Programme's strategic programs, applicable at the time of project design. The project is consistent with the GEF Biodiversity Focal Area (BD-2 Program 5), and with UNEP's Subprogramme 3: Healthy and productive ecosystems and Subprogramme 4:

Environmental governance; Expected Accomplishments: (1) National capacities for Living Modified Organisms identification and detection strengthened and supporting decision-making processes, (2) National system for monitoring and surveillance established and operational, (3) Socio-economic considerations as per article 26 are considered in decision-making; and with Programme of Work Outputs (1) Two national laboratories: Centre for Scientific Research for the Civil Defence and National Centre for Agricultural Health equipped to play a role as national reference laboratories, (2) Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment, and (3) Detailed analysis of the socio-economic considerations of importance for Cuba related to the impacts of Living Modified Organisms.

4. The project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" seeks to further complete the process of implementation of the Cartagena Protocol on Biosafety through the creation of additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms and the socio-economic considerations of importance for Cuba related to them, by strengthening the capacity of national laboratories to perform the role of national reference laboratories, develop tools and Standard Operating Procedures for Living Modified Organisms detection, training of relevant personnel, strengthen monitoring and surveillance with operating guidelines, equipment, and field detection strategies, and support to the integration of socio-economic considerations of the impact of Living Modified Organisms into decision-making.

## Key findings

5. At the mid-term, the project has done well at procuring and receiving all reagents, equipment and supplies necessary for the operation of the two reference laboratories, a Procedures Manual for the operations of the laboratories, the approval and incorporation of the laboratories into the quality management system of both entities, workshops for sharing of results with key actors from different research centres, collaboration agreements between key institutions were signed, protocols, techniques and procedures for the detection and identification of Genetically Modified Organisms were developed and approved, the definition of detection limits established, training on the requirements and implementation of the NC ISO/IEC 17025: 2017 Standard, specialist trainings in Mexico and Argentina, development of the Adverse Effects Monitoring and Surveillance System, definition of procedures for sampling and detection in the field and at the borders, training to customs officers and personnel involved in the Monitoring &Surveillance System, a study on International Regulations About Socio-economic Considerations, sensitization workshops in rural communities, and the development and dissemination of Knowledge Management products.

6. Notwithstanding the many successes described above, there are project implementation issues to be addressed. The timeline for the validation of the protocols for qualitative tests to detect and identify LMO events may need to be revisited due to technical delays. Also, the timeline for the accreditation of the laboratories in CENSA and CICDC is unclear and must be clarified. Field samplings have been hampered by a lack of fuel and questions the level of priority the project has in the broader scheme of things in the country.

A Workshop to present the Monitoring and Surveillance System is yet to be held and efforts should be made by the project before the project ends to evaluate the impacts of GMO crops (Maize and Soy) recently released in Placetas, Villa Clara and Sanguily, municipality of Venezuela in Ciego de Avila province, as a practical demonstration of the capacity acquired with the support of the project. The project is deficient in its reporting of project budget by component or outcomes and in the reporting of co-financing by source. While most outcome indicators in the Project Results Framework are appropriate, these are not disaggregated by relevant stakeholder groups including gender and minority/disadvantaged groups and gender sensitive indicators are not available, even though women seem to be majority participants in project events. While the project has made steps to engage institutional stakeholders, formal engagement and partnerships with the Private Sector and Non-government Organizations are not available. There are clear inconveniences all around in terms of the tri-partite arrangements for project payments in USD between UNEP, the Government of Cuba, and UNDP Cuba resulting in a cumbersome and inefficient system of payments to suppliers outside of Cuba.

7. The project has been successful in engaging the primary stakeholders, these being mainly specialized institutions and centres in the country that are associated with the topic of biosafety, as well as community engagements. No Gender Action Plan or Gender Marker were prepared for the project. Of note is the fact that two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 Standard in which a total of 29 students, mostly women, received the corresponding certificate. The integrated approach to human/natural systems was not defined in the project document. The project is being implemented within the framework of the Policy for the Use of Genetically Modified Organisms in Cuban Agriculture which fully embraces environmental and social safeguards. There are appropriate strategies defined and implemented for communication and dissemination of results and lesson sharing, with gender-sensitive approaches where feasible, and designed to respond to the needs of different types of audiences. Of note is the fact that since this project is funded under GEF-6, the preparation of a Stakeholder Engagement Plan and Gender Action Plan were not specific document requirements at the time of project design.

## Conclusions

8. At the mid-term the overall performance of the project at the Mid-Term is rated as **'Satisfactory'** and the likelihood of impact is **'Likely'**. Drivers to support transition from Outputs to Project Outcomes are partially in place; most assumptions for the change process from Outputs to Project Outcomes seem to hold. Even though the outcomes to achieve the Intermediate State have not been fully achieved, Likelihood of Impact is affected by the fact that consistent with the project's design, planned outcomes including the principal one for achieving the Intermediate State are not programmed to be fully achieved until the end of the project. A Summary Assessment and Rating can be found in Table 9 in Section V. The success of the project thus far has benefitted from a high level of technical and administrative capacity in the Project Management Unit and in ORSA, complemented by a competent set of specialists in CENSA, CICDC and CENATOX that are fully committed to the project's objectives and desirous of the project's success. Even with all the complexities involved, the project could not have procured and received all the equipment and supplies for the reference laboratories without the support of UNDP Cuba.

### Lessons Learned

9. Some key **lessons learned** in this Mid-Term Review include those outlined below, the full context of which is presented in Section V:

- Lesson Learned #1: Institutional Memory and Resident Capacity Proven to be Crucial Assets for Project Success.

- Lesson Learned #2: Working only with State Institutions Demands a Different Approach to Stakeholder Participation and Ownership.

- Lesson Learned #3: Project Execution Efficiency within a Cuban Context may Require a Relook at Project Implementation Policies.

- Lesson Learned #4: Project Results can Consolidate Cuba's Strategic Positioning as a Leader in Capacity Building for LMO Detection, Identification and Management in the Central America and Caribbean Region.

### Recommendations

10. Some key **recommendations** emanating from in this Mid-Term Review include those outlined below, the full context of which is presented in Section V:

- Recommendation #1: Define the timeline for the validation of protocols for qualitative tests and for the accreditation of the two reference laboratories.

- Recommendation #2: Address the availability of fuel for project purposes at the highest political level.

- Recommendation #3: Implement practical demonstrations of the capacity acquired with the support of the project.

- Recommendation #4: Explore the feasibility and convenience of redefining the role of UNDP for the remainder of project implementation.

- Recommendation #5: Report project budget by component and co-financing by source.

- Recommendation #6: Explore elevating the level of representation on the Project Steering Committee.

- Recommendation #7: Strengthen safeguards compliance, human rights, and gender dimensions.

# I. PROJECT OVERVIEW

**Institutional Context and Implementation Arrangements**

11. This Mid-Term Review (MTR) covers the implementation of the project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" (GEF ID 9860), for the period 3rd April 2020 to 30th November 2023. The Project is funded by the Global Environment Facility (GEF) and the Mid-Term Review (MTR) was carried out in the period October 2023 – January 2024. The project is managed from UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division, via the UNEP Latin America and Caribbean Office. The project aligns with the Global Environment Facility's and United Nations Environment Programme's strategic programs, applicable at the time of project design. The project is consistent with the GEF Biodiversity Focal Area (BD-2 Program 5), and with **UNEP's Subprogramme 3**: Healthy and productive ecosystems and Subprogramme 4: Environmental governance; **Expected Accomplishments**: (1) National capacities for Living Modified Organisms (LMOs) identification and detection strengthened and supporting decision-making processes, (2) National system for monitoring and surveillance established and operational, (3) Socio-economic considerations as per article 26 are considered in decision-making; and with **Programme of Work** Outputs (1) Two national laboratories: Centre for Scientific Research for the Civil Defence and National Centre for Agricultural Health equipped to play a role as national reference laboratories, (2) Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment, and (3) Detailed analysis of the socio-economic considerations of importance for Cuba related to the impacts of LMOs.

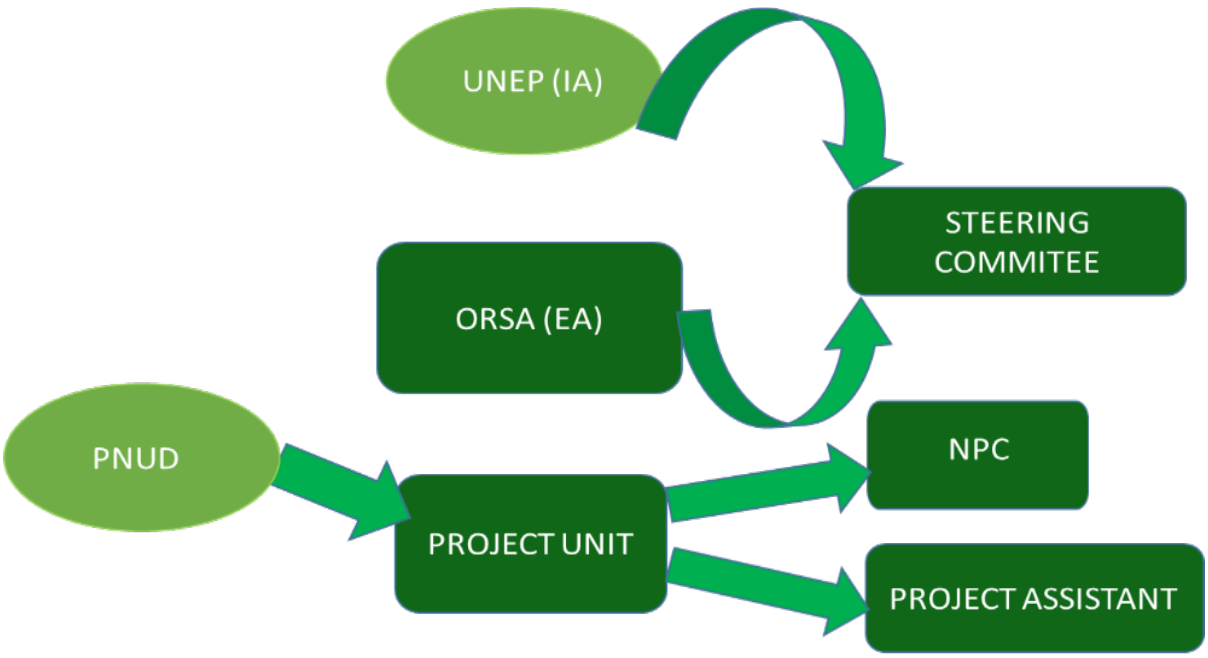
12. Coordination and overall project supervision is the responsibility of the United Nations Environment Programme (UNEP) as the GEF's Implementing Agency (IA), and the Office of Environmental Regulation and Security (ORSA) of the Ministry of Science, Technology and Environment (CITMA) is the project's Executing Agency (EA). ORSA is responsible for day-to-day project execution through the support of the Project Management Unit and the Project Coordinator. The Finance Unit of the United Nations Development Programme (UNDP) in Cuba provides procurement and financial management support to the project. UNEP's Task Manager provides continuous support and works closely with project personnel in project implementation aspects related to UNEP and the GEF implementation requirements. The Project Steering Committee (PSC) is composed of high-level representatives from ORSA, Centre for Scientific Research for the Civil Defence (CICDC), the National Centre for Agricultural Health (CENSA), the Economy Directorate of CITMA, National Centre for Toxicology (CENATOX), Directorate for International Relations, the Finance Unit of UNDP, and the UNEP Task Manager. The project's implementation arrangements are presented in Figure 1.

**Project Parameters**

13. The project was approved as a Medium-Sized Project by the GEF on July 17th, 2017, and by UNEP on March 24th, 2020, for a period of 60 months with an intended completion date of March 2025. The project was approved with a total budget of US$3,746,927 that is divided between the GEF contribution of US$1,826,484 and co-financing of US$1,920,443

provided by ORSA, CICDC, CENSA, and CENATOX. The first disbursement of project funds was June 8th, 2020. The project took over two years to be initiated from its original date of approval due to changes in the institutional affiliation of the National Executing Authority. At the time of the MTR the project had received three (3) revisions, the last being May 17th, 2022.

**Figure 1. Project Implementation Arrangements**




**Project Objective and Logical Framework**

14. The project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" seeks to further complete the process of implementation of the Cartagena Protocol on Biosafety through the creation of additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms and the socio-economic considerations of importance for Cuba related to them, by strengthening the capacity of national laboratories to perform the role of national reference laboratories, develop tools and Standard Operating Procedures for Living Modified Organisms detection, training of relevant personnel, strengthen monitoring and surveillance with operating guidelines, equipment, and field detection strategies, and support to the integration of socio-economic considerations of the impact of Living Modified Organisms into decision- The project consists of four components, four outcomes, and thirteen outputs as summarized in Table 2.

15. The project's Logical Framework is summarized below in Table.

## Table 2. Project Logical Framework

| Components | Outputs | Outcomes |
|---|---|---|
| **C1: Creation of the necessary capacities for identification and detection of Living Modified Organisms (LMOs).** | 1.1.1: Two national laboratories -- Centro de Investigaciones Científicas de la Defensa Civil (CICDC) and Centro Nacional de Sanidad Agropecuaria (CENSA) - equipped to play a role as national reference laboratories. (certified by normative NC ISO 9001:2015 and accredited by the NC ISO / IEC 17025:2000).<br><br>1.1.2: MoU between CICDC, CENSA, and the National Competent Authority (the National Centre of Biological Safety) for the services of detection.<br><br>1.1.3: Harmonized Toolkits / Guidelines / Protocols / Standard Operating Procedures (SOPs) on LMO detection developed and/or adapted to suit Cuba´s reality and needs.<br><br>1.1.4: Personnel at CICDC and CENSA and the NCA capacitated through training programs on detection and identification of LMOs. | **O1:** National capacities for LMO identification and detection strengthened and supporting decision-making processes. |
| **C2: Creation of the necessary capacities for monitoring and surveillance of Living Modified Organisms (LMOs).** | 2.1.1: Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment.<br><br>2.1.2: Strategy for field detection (screening procedures) developed.<br><br>2.1.3: Administrative and technical guides designed for each involved institution (Veterinary and Phytosanitary borders Officers (Ministry of Agriculture) and Customs Officers (General Customs of the Republic of Cuba) and inspector from CSB) in the National Customs System.<br><br>2.1.4: Workshops for customs officers and personnel involved in M&S system on how to use the guidelines developed in 2.1.3. | **O2**: National system for monitoring and surveillance established and operational. |
| **C3: Identification of socio-economic considerations (SEC) of importance for Cuba arising from the impact** | 3.1.1: Detailed analysis of the socio-economic considerations of importance for Cuba related to LMO impacts completed. | **O3**: Socio-economic considerations as per article 26 are considered in decision-making. |

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|---|---|---|
| **of LMOs, as per article 26 of the CPB.** | 3.1.2: Informative materials on socio-economic considerations produced and distributed amongst public and relevant authorities. | |
| **C4: Project Monitoring, Evaluation and Reporting.** | 4.1.1: Project reporting requirements met.<br>4.1.2: Project coordination and oversight mechanisms in place (part of M&E budget).<br>4.1.3: Project evaluations completed. | **O4**: Project implemented according to agreed terms, conditions, and timeframes. |

**Stakeholder Analysis**

16. The Project Document contains a stakeholder matrix with potential roles in project implementation. Since this project is focused on official institutions legally mandated to detect and monitor LMOs and GMOs, the stakeholder analysis has focused primarily on those institutions. The said matrix was used to develop the following Power/Interest Grid (Figure 1), with the classifications below according to required level of attention/engagement to be provided to each stakeholder, in consideration of the possible impact they may have on project outcomes:

- **High power highly interested (Manage Closely):** fully engage and make the greatest efforts to satisfy them.
- **High power, less interested (Keep Satisfied):** keep them satisfied and effectively engaged.
- **Low power highly interested (Keep Informed):** adequately inform and ensure that no major issues are arising.
- **Low power, less interested (Monitor):** monitor and engage without excessive communication.

17. Among the stakeholders identified as critical for the achievement of project outcomes is the Office of Environmental Regulation and Security within the Ministry of Science, Technology and Environment, which is the competent authority for Biosecurity in Cuba and the national authority for the Cartagena Protocol. is responsible for and coordinates the process of decision making on LMOs, including consultations with authorities of other agencies, and it establishes legal and technical standards for biosafety. The designated laboratories, namely the Centre of Scientific Research for Civil Defence (CICDC) and the National Centre for Agricultural Health (CENSA), are responsible for the identification and detection of the LMOs, under the guidance and oversight of ORSA. UN Environment administers the funding sent to the Executing Agency, participates as a member of the Steering Committee, and undertakes monitoring activities of the project, including thoe executed by UNDP Cuba in support of the project.

**Figure 2. Power/Interest Grid of Project Stakeholders**

POWER

| **Keep Satisfied** | **Manage Closely** |
|---|---|
| National Accreditation Authority of the Republic of Cuba<br><br>United Nations Development Programme<br><br>United Nations Environment Programme | The Office of Environmental Regulation and Security of the Ministry of Science, Technology and Environment<br><br>Centre for Scientific Research for the Civil Defence<br><br>National Centre for Agricultural Health<br><br>National Centre for Toxicology |
| | |
| Customs Authority of Cuba<br><br>Ministry of Agriculture | Civil Society<br><br>General Public |
| **Monitor** | **Keep Informed** |

INTEREST

## II. REVIEW METHODS

18. This MTR was conducted by an Independent International Evaluation Consultant as per the Terms of Reference developed by the project for this purpose. The MTR Report was structured as per 'Guidance on the Structure and Contents of the Main Mid Term Review Report' of the Evaluation Office of UNEP, Revised Version 9th August 2021.

**Data Collection**

19. The MTR addressed the following four (4) primary evaluation criteria: (1) Attainment of objectives and planned results; (2) Sustainability and catalytic role; (3) Processes affecting attainment of project results; and (4) Complementarity with UNEP strategies and programmes. The following specific review categories were addressed, according to their distribution across the evaluation criteria listed above: (A) Strategic Relevance; (B) Quality of Project Design; (C) Nature of External Context; (D) Effectiveness; (E) Financial Management; (F) Efficiency; (G) Monitoring and Reporting; (H) Sustainability; and (I) Factors Affecting Project Performance.

20. Evaluation questions were developed as per the guidance provided in the Terms of Reference of the MTR, inclusive of addressing the Key Strategic Questions and those required by the GEF Portal, and in consideration of the results of the Project Design Quality assessment developed during the Inception Phase. The main evaluation questions of the Terms of Reference are generally included under 'effectiveness' but are reinforced by other questions through-out the different categories of the MTR as laid out in the Evaluation Framework in Annex B of the Inception Report. All evaluation indicators were analysed using the project's reporting mechanisms (actual available outputs, PIRs, Half Year Progress Reports, technical reports, etc.), using where possible quantitative and qualitative data, validated through semi-structured interviews with project staff and other key stakeholders.

21. Stakeholders and project beneficiaries are important sources of information to validate information in project reports, and are instrumental in reviewing the draft MTR report, and as such, are also targeted audiences of the overall MTR process. Stakeholders, and in particular project staff and members of the PSC, were engaged through one-on-one interviews, and focused at detail on the project's performance, challenges, lessons learned, and opportunities for improvement. Persons interviewed and/or engaged during the MTR process are presented in Annex 2.

22. The methodological steps for data collection in this MTR were as follows:

(a) A desk review of relevant background documentation, inter alia: relevant policies, laws and regulations, the Project Document and appendices; project design documents (including minutes of the project design review meeting at approval); Project Work Plan and Budgets; the Project Results Framework (PRF); Project Implementation Review (PIR) reports; financial reports; Auditor's Reports; reports from Steering Committee Meetings; Inception Workshop report; progress reports from collaborating partners; technical reports produced by the project; Evaluations/Reviews of similar projects; and public awareness and communication materials produced thus far by the project.

(b) One-on-one Interviews were conducted in person with representatives of ORSA, CICDC, CENSA, CENATOX, EMIDICT, UNDP, and UNEP. Semi-structured questions developed by the evaluator, based on questions in the Evaluation Framework developed during the Inception Phase, were used to secure responses and inputs from stakeholders on the four primary evaluation criteria and their respective categories. This guaranteed a more interactive process through which the interviewed respondents had more opportunities to contribute to the MTR process, without limitations to the extent of their responses. Project stakeholders who participated in one-on-one interviews were given the opportunity to provide additional information and/or clarifications where necessary. The findings derived from the desk review, one-on-interviews with stakeholders, the project team, and UNEP personnel were critically reviewed, assessed, and systematized to identify trends in the responses and perceptions on the project's results, overall performance, and perceived project challenges. This was especially useful in validating information presented in the Project PIRs, and in ensuring the proper context for articulating project lessons and recommendations for improving project implementation.

(c) A preliminary Draft MTR Report was presented to the UNEP Task Manager and the Project Team, to ensure all information sources have been accessed and to provide an opportunity to verify emerging findings. Additional discussions, information, and validation of project outputs after the preliminary draft report were instrumental in the development of the Final Main MTR Report.

23. One-on-one interviews were very much limited to representatives of the Project Team and members of the PSC, all of whom are primarily from government agencies and UNEP personnel. The fact that some key project activities are yet to be substantially developed limited the extent to which respondents in the review process were able to articulate their responses in terms of some outputs and performance of the project to date.

# III. THEORY OF CHANGE (TOC)

**Theory of Change at Review**

24. A project's intervention logic including critical assumptions and Theory of Change was not developed during project design. In the Inception Phase of this MTR a TOC at design was prepared for the project. During the main MTR process, the TOC at design was revisited after a review of project processes, documentary evidence, primarily the PIRs and one-on-one interviews with project stakeholders, to reconstruct the TOC at Evaluation. The findings in the TOC at Evaluation confirm the TOC at Design.

25. The TOC developed reflects two types of drivers: (I) long-term drivers of threats to biodiversity, and (II) drivers of positive change towards outputs (those activities and processes that the project can potentially and directly sponsor -inputs-, in support of project outputs and outcomes, while the assumptions are those conditions and circumstances that are necessary to achieve the desired project results but are outside the control of the project. The causal or impact pathways are the set of steps, consisting of activities, processes and assumptions that collectively will deliver the desired project objective. Based on assessments conducted during the MTR, the drivers, assumptions, and causal pathways were developed for the project. Drivers and assumptions are presented in the TOC Diagram in Figure 3 and the causal pathways are outlined below.

26. **Causal Pathway 1:**

This causal pathway proposes that **if** national laboratories are equipped to serve as reference laboratories, tools and Standard Operating Procedures are developed, and personnel in relevant institutions are trained, **then** the project would have strengthened national capacities for LMO identification and detection in support of decision-making processes, **because** the deficiencies and challenges affecting identification and detection would have been addressed and policy makers would be better informed to make the right decisions on LMOs.

27. **Causal Pathway 2:**

This causal pathway advocates that **if** an LMO monitoring and surveillance system is developed and the Customs System is equipped with practical guides and the necessary implementation training is delivered to customs, veterinary, and phytosanitary officers, t**hen** a functional monitoring and surveillance system for LMOs would be in place, **because** officers would have the equipment, procedures, and skills needed to take samples in support of the process to detect and identify LMOs at border points and in the field.

28. **Causal Pathway 3:**

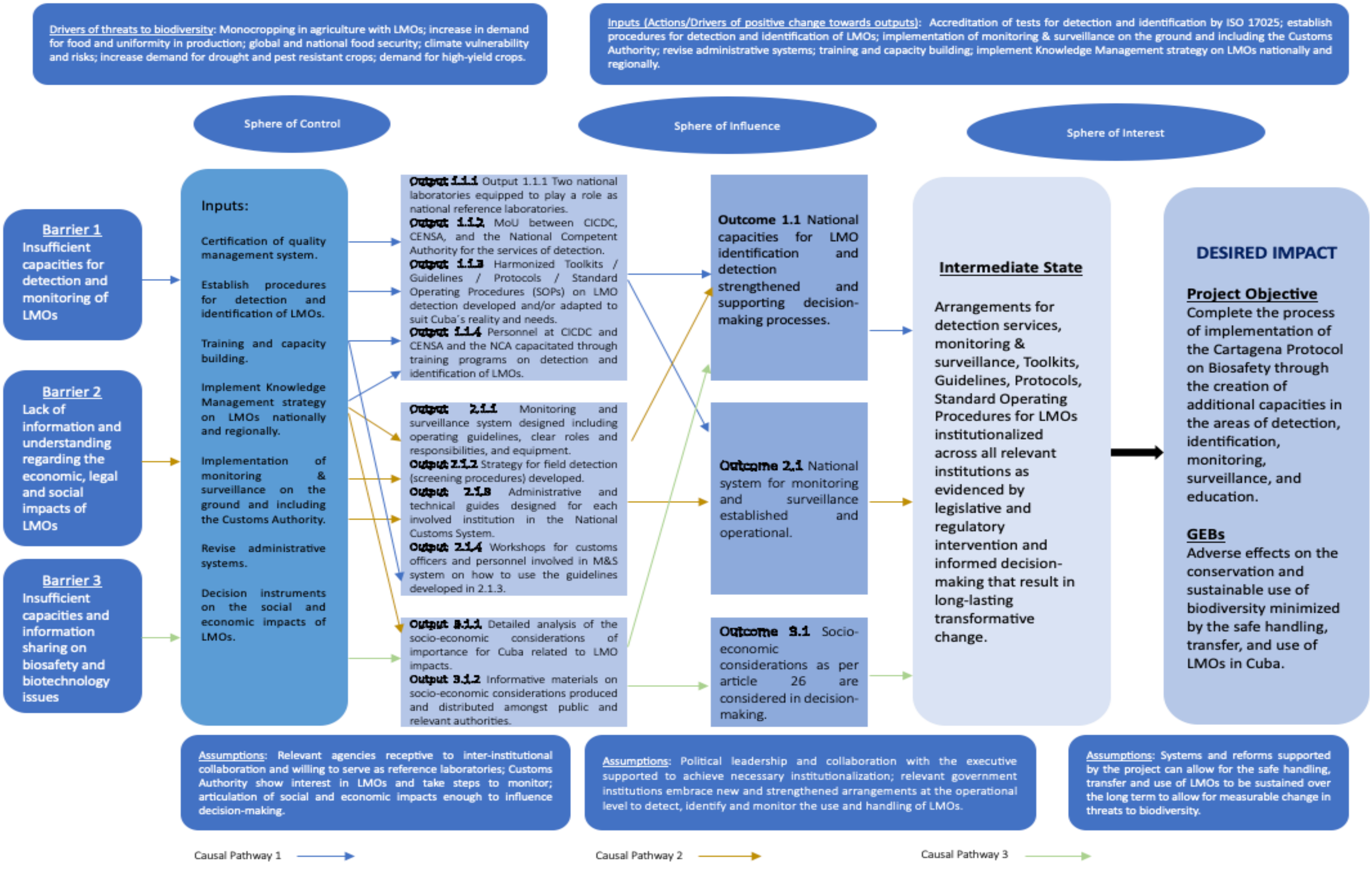
This causal pathway proposes that **if** the socio-economic impacts of LMOs are properly analysed and the results are packaged and tailored to the variety of audiences in the country through an assertive LMO awareness campaign, **then** the enabling environment for the inclusion of socio-economic impacts into LMO decision-making would be created, **because** there will no longer be a lack of a common position among the authorities on whether or not socio-economic conditions are important for LMO decision-making.

29. **Intermediate State:**

All three causal pathways converge on a common Intermediate State in which arrangements for detection services, monitoring & surveillance, Toolkits, Guidelines, Protocols, Standard Operating Procedures for LMOs must be institutionalized across all relevant institutions as evidenced by legislative and regulatory intervention and informed decision-making that result in long-lasting transformative change, before the Cartagena Protocol on Biosafety can effectively implemented in Cuba.

30. The causal pathways inferred from the Project Document, Logical Framework, progress reports and stakeholder inputs for moving from barriers to outputs to outcomes show strong coherence, resulting in a TOC that is likely to lead to desired impacts if all drivers of positive change are delivered and assumptions hold true to the end of the project. There are clear linkages between pathways which connect outputs and outcomes of different components, as well as precursor linkages between outcomes; for example, all causal pathways support Outcome 1.1 and causal pathway 1 supports both Outcomes 1.1 and 1.2.

## Figure 3. Reconstructed TOC Diagram



# IV. REVIEW FINDINGS

## A. Strategic Relevance

**Alignment to UNEP's UNEP Medium Term Strategy (MTS), Programme of Work (POW) and Strategic Priorities**

31. The project aligns with **UNEP's Subprogramme 3**: Healthy and productive ecosystems and Subprogramme 4: Environmental governance; **Expected Accomplishments**: (1) National capacities for Living Modified Organisms (LMOs) identification and detection strengthened and supporting decision-making processes, (2) National system for monitoring and surveillance established and operational, (3) Socio-economic considerations as per article 26 of the Cartagena Protocol on Biosafety are considered in decision-making; and with **Programme of Work** Outputs (1) Two national laboratories: Centre for Scientific Research for the Civil Defence and National Centre for Agricultural Health equipped to play a role as national reference laboratories, (2) Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment, and (3) Detailed analysis of the socio-economic considerations of importance for Cuba related to the impacts of LMOs.

**Alignment to Donor/GEF/Partners Strategic Priorities**

32. The project aligns with the Global Environment Facility's and United Nations Environment Programme's strategic programs, applicable at the time of project design. The project is consistent with the GEF-6 Biodiversity Focal Area (BD-2 Program 5), Outcome 5.1: adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (both women and men), and specifically focusing on transboundary movements.

**Relevance to Global, Regional, Sub-regional and National Priorities**

33. The 2022-2026 United Nations Multi-Country Sustainable Development Framework (UN MSDF) for the Caribbean region cites Outcome 6 'Caribbean countries manage natural resources and ecosystems strengthening their resilience and enhancing the resilience and prosperity of the people and communities that depend on them' which is relevant to the objectives under this project. The project is fully aligned with the Cartagena Protocol on Biosafety, and with Articles 11, 15,16, 17, 18, 19, 22, 23 and 26.

34. This project is consistent with the United Nations Sustainable Development Goal (SDG 2 – Zero Hunger), Target 2.5, By 2020, maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, and promote access to and fair and equitable sharing of benefits arising; Indicator 2.5.1- Number of plant and animal genetic resources for food and agriculture secured in either medium- or long-term conservation facilities, and Indicator 2.5.2 -

Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction.

35. The project is consistent with Cuba's National Biodiversity Strategy and Action Plan 2016-2020 (NBSAP), including Target 7 "Relevant measures to ensure the safe and peaceful use of biological agents and genetically modified organisms have been established" and Action F under Target 2 to "Develop and implement training programs on biosafety; Access, protection and management of genetic resources; protected areas; Management of invasive alien species; Endemic and / or threatened species; Priority ecosystems, climate change and economic valuation, in correspondence with the target groups". Reducing risks and threats to biodiversity, including through the identification, detection, and monitoring of LMOs, are identified as priority actions in both the National Environmental Strategy (EAN) and the Biodiversity Program for the next five years.

**Complementarity with Existing Interventions/Coherence**

36. The project complements the recently concluded UNEP/GEF Project 'Implementing National Biosafety Frameworks (NBF)' in the Caribbean (GEF Project ID: 2967), which sought to assist 12 Caribbean countries to establish systems and processes for compliance with the Cartagena Protocol on Biosafety. That project achieved the establishment of a regional platform for biosafety knowledge management, a regional network for the detection of genetically modified organisms, a Master of Science Program on Biosafety through the University of the West Indies, and technical guidelines, hands-on training, and expert advice.

| **Rating for Strategic Relevance:** | ***'Highly Satisfactory'*** |
|---|---|

### B. Quality of Project Design

37. In the project document the relevant UNEP sub-programme is identified, as well as the associated Expected Accomplishments and Programme of Work Outputs; linkages to GEF BD2 Program 5 are clearly articulated. Consistency with national priorities and complementarity and consistency with several regional policy level agreements and a relevant baseline are also included. The Project Results Framework clearly captures the intended logic of the project inclusive of associated outcome level indicators with clear results at the outcome level; the intended scope of the project is clearly captured and baseline information in relation to key performance indicators are included. Mid-Term and End-of-Project targets are identified for each indicator at the outcome level, while the Mid-Term targets in the Results Framework, supported by the annual activities identified in the work plan, are appropriate to track progress of outputs towards outcomes. Monitoring responsibilities for day-to-day project implementation is assigned to the Project Management Unit and the UNEP Task Manager. An M&E budget was included, and the project work plan follows a chronogram that is linked to the project's intervention logic.

38. Barriers are identified, solutions defined, and summary problem statement provided. Even though the Project Results Framework clearly captures the intended logic of the project inclusive of associated outcome level indicators with clear results at the outcome level,

there was no theory of change and logical pathways diagram; these were developed by this MTR. There is also a lack of clearly articulated logical pathways and the critical actors to be involved in each pathway in the project's TOC. There is a lack of articulation linking the Bali Strategic Plan to the project, even though at the activity level there have been South-South Cooperation between the project and Argentina and Mexico. No Stakeholder Engagement Plan and no Gender Action Plan were prepared for the project. The final score of Project Design based on the results of the Project Design Quality Assessment is 4.56.

| **Rating for Quality Design:** ***'Satisfactory'*** |
|---|

## C. Effectiveness

**Availability of Outputs**

39. This section provides a brief overview of the status of the project's outputs by component at the time of the MTR. The assessment below is based on mid-term targets defined in the Project Results Framework, validated against the results of project implementation to date as reported in the PIRs, as observed during the MTR, and with due consideration of inputs provided by the Project Team and stakeholders during interviews conducted as part of this MTR process. A summary of the project's performance at the output level for technical components is provided in Table 3.

**Component 1: Creation of the necessary capacities for identification and detection of Living Modified Organisms (LMOs).**

40. At the time of the MTR and based on assessment of performance at the output level, the overall delivery for this component has been estimated at **87.5%**. The project has done well at procuring and receiving all reagents, equipment and supplies necessary for the operation of the two reference laboratories, with these having now started active research activities on LMOs. A Procedures Manual that was subject to peer review was also developed and adopted for the operations of the laboratories in question. Likewise, the approval and incorporation of the laboratories into the quality management system of both entities, CENSA and CICDC, represents an important achievement. Two workshops were held that allowed for sharing of results with a group of key actors from different research centres specialized in the subject and to validate the proposals presented on the Procedures Manual. Collaboration agreements between ORSA and CENSA and with CICDC were signed and shared and accessible on the Anubis platform of UNEP. In terms of guidelines, toolkits and standard Operating Procedures, the project conducted a review of national and international regulations and a workshop on the subject where draft of protocols, techniques and procedures for the detection and identification of GMOs were presented, providing a baseline against which proposals prepared by specialists from both reference laboratories were approved in a meeting of the Biosafety Technical Standards Committee. Management procedures, the need for a timetable for the accreditation process and the specific topic of certification were also discussed in that meeting.


**Figure 4. Some of the equipment procured by the project for national laboratories working on LMO identification and detection.**

41. Progress has been made in the definitions of the detection limits established based on the training recently received in Mexico at the National Reference Centre for the Detection of Genetically Modified Organisms (CNRDOGM) of the Agri-food Health, Safety and Quality Service (SENASICA). The cohesion and exchange of knowledge of experts from the Quality Control Departments of CENSA and CICDC has been important in defining the limits for the qualitative tests to be accredited, a key output of this project. Although progress has been made in the validation of the protocols for qualitative tests for the detection and identification of two events, one in soybean and the other in GM corn, there are still reasonable doubts regarding the time proposed for the completion of this activity (December 2023). To date, two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 Standard. These were given by CGDC experts at the request of the project management unit, aimed at specialists from CENSA, CICDC, CENATOX and ORSA. A total of 29 students, mostly women, received the corresponding certificate. The project has organized and conducted specialists training in Mexico. The first two were organized for CENSA and CICDC technical specialists (1. Detection and identification Qualitative and quantitative methods in different matrices. 2. Validation of molecular assays). More recently, a mission was concluded where specialists from the quality area of both institutions and regulators were incorporated. The objective of this last training was the implementation of ISO/IEC 17025: 2017 in an accredited laboratory. The accreditation schedule for CENSA and CICDC has been adjusted, awaiting a review and inputs from quality experts from both institutions. One concern, to date, is whether it will be possible, working in an uninterrupted manner, to comply with the result of concluding the accreditation of the laboratories by the end of 2024.

**Component 2: Creation of the necessary capacities for monitoring and surveillance of Living Modified Organisms (LMOs).**

42. At the time of the MTR and based on assessment of performance at the output level, the overall delivery for this component has been estimated at **76%.** The project has delivered the Comparative Study of National and International Guidelines on M&S of LMOs and Adverse Effects. The Adverse Effects Monitoring and Surveillance System (SMV) was completed and presented to the National GMO Commission in June 2022, in addition to the procedures for sampling and detection in the field and at the borders. These were reviewed and discussed among experts from ORSA, CENATOX and the Plant Health Directorate of the Ministry of Agriculture. A practical field sampling exercise was carried out in the province of Pinar del Río, in an area where transgenic corn was released, which made it possible to evaluate the procedure and obtain lessons learned for future actions. The project sponsored a mission to Argentina in April of 2023, where specialists from ORSA and CENATOX received training on issues related to the entry, monitoring and field surveillance of regulated GMO trials, including regulations and conditions for importation and field controls of GMO seeds. The field sample-drawing and detection procedure and the procedure for taking samples in borders were completed, and the associated reports were uploaded to the Anubis Platform of UNEP.

**Figure 5. Training in Argentina to specialists from Cuban National Laboratories and the Office for the Regulation of Environmental security (March 2023).**

43. A training workshop for customs officers and personnel involved in the M&S system was conducted with the participation of Borders Authorities (Customs, Animal and Plant Health), the Ministry of Foreign Trade and Investment (MINCEX), CENATOX, CICDC, CENSA and ORSA. In addition, specialists from the Ministry of Agriculture's Plant Health Directorate provided theoretical training in sampling at borders for biosafety inspectors linked to the Project. The first workshop on field monitoring techniques was held over two days in November 2022 with the participation of different institutions related to the subject. The second workshop was scheduled to take place in October 2023, but was postponed to the first quarter of 2024 because the planned program for taking samples in the field could not be met, the results of which were to be presented at the second workshop. The causes of this non-compliance are related to the severe difficulties that have been occurring in the country with the availability of fuel, which is more severe in areas outside the capital. A Workshop to present the Monitoring and Surveillance System and the strategy for the implementation of the project has yet to be held. During the workshop, the results of the farmer surveys will be presented, as well as the procedures for field and border sampling and the strategy to be followed by the CNA will be discussed.

**Figure 6. Training to staff of Border Authorities (May 2022).**

**Component 3: Identification of socio-economic considerations of importance for Cuba arising from the impact of LMOs, as per article 26 of the CPB.**

44. At the time of the MTR and based on assessment of performance at the output level, the overall delivery for this component has been estimated at **65%.** The project has

conducted A study on International Regulations About SECs, with the corresponding report uploaded to the Anubis Platform of UNEP. The project also made substantial efforts to collaborate with the Cuban Academy of Sciences on the topic of SECs. The project has engaged the Directorate of Social and Humanistic Sciences of CITMA, ORSA in the territories, Social Science Councils of the territories (provinces), Universities, local governments, and communities where SEC studies will be carried out representing areas with a history of commercial-scale releases of genetically modified crops. Before the project's end, efforts will be made to evaluate the social and economic impacts of GM crops (maize and soy) recently released in Placetas, Villa Clara and Sanguily, municipality of Venezuela in Ciego de Avila province. Specifically, the initiative will determine the economic and consequently social effects on the communities associated with the areas that have incorporated the cultivation of transgenic crops in the municipality, and will diagnose the perception of producers, beneficiaries, and the population of the communities under study, on the socioeconomic effects resulting from the use of such crops.

45. In February and May 2023, workshops were held to present the international biosafety project and the importance of these SEC studies in the communities of Placetas (Villa Clara) and Sanguily municipality of Venezuela (Ciego de Avila), respectively, with an important participation of local stakeholders. It should be noted that the results of the SEC studies are expected to differ among sites, since in Placetas the study population is a community of private producers and in Ciego de Avila, the study will be carried out among workers and population working in a state enterprise.

**Figure 7. Community Workshop in Placetas (February 2023)**

**Figure 8. Community Workshop in Venezuela (May 2023)**

**Component 4: Project Monitoring, Evaluation and Reporting.**

46. While there was a delay in the preparation of the first financial audit report due to Covid-19, to date three financial audits have been completed for the project. To date, 12 Quarterly Expenditure Reports have been completed; the expense report corresponding to period 3 of 2023 is not approved yet. PIRs corresponding to 2021, 2022 and 2023 were also developed and approved.

47. Due to Covid-19, the Inception Workshop was postponed until September 8-9, 2021, with the participation of key stakeholders, and co-chaired by the Cuban Deputy Minister of Science, Technology and Environment and the UNEP Task Manager. Five Steering Committee Meetings have been held to date, with the participation of the UNEP Task Manager. Recurring issues discussed in PSC meetings included the progress of imports according to the date of completion of the accreditation process of the laboratories, the delay in payments to suppliers linked to administrative issues associated with the payment services provided by UNDP Cuba on behalf of UNEP, the financial mechanisms for disbursements from Nairobi, and unique challenges faced by the country to access USD and other implications of the embargo in terms of importation of goods. Two Annual Workshop on Lessons Learned were held, in which the results obtained from 2020-2021 and 2022 were presented. The financial contribution provided by this project enabled Cuba's participation in the II Congress of the SOVE - Symposium on standards for the regulation of genetically modified insects (November 2022) held in La Plata, Argentina and recently (May) the Biosafety project was presented at the IV International Seminar on Agricultural Health (SISA), held in Cuba, within the Symposium on food safety and food security, addressing the topic of biosafety and its relation to food security in Cuba.

### Table 3. Summary Progress of Project Outputs at the MTR

| Outputs | Progress at MTR (%) | Summary Evidence of Progress at MTR |
|---|---|---|
| **Outcome 1.1: National capacities for LMO identification and detection strengthened and supporting decision-making processes.** | | |
| Output 1.1.1: Two national laboratories -- Centro de Investigaciones Científicas de la Defensa Civil (CICDC) and Centro Nacional de Sanidad Agropecuaria (CENSA) -equipped to play a role as national reference laboratories. (certified by normative NC ISO 9001:2015 and accredited by the NC ISO / IEC 17025:2000) | 93% | All reagents, equipment and supplies necessary for the operation of the two reference laboratories, with these having now started active research activities on LMOs.<br>Procedures Manual for the work of both laboratories.<br>Approval and incorporation of the laboratories into the quality management system of both CENSA and CICDC. |
| Output 1.1.2 MoU between CICDC, CENSA, and the National Competent Authority (the National Centre of Biological Safety) for the services of detection. | 100% | Collaboration agreements between ORSA and CENSA and with CICDC were signed and shared and accessible on the Anubis platform of UNEP. |
| Output 1.1.3 Harmonized Toolkits / Guidelines / Protocols / Standard Operating Procedures (SOPs) on LMO detection developed and/or adapted to suit Cuba´s reality and needs. | 96% | Review of national and international regulations and a workshop on Standard Operating Procedures, producing draft approved in a meeting of the Biosafety Technical Standards Committee. |
| Output 1.1.4. Thresholds for LMO detection officially established. | 66% | Detection limits established based on the training recently received in Mexico and the results of the tests carried out by the specialists of both laboratories. |
| Output 1.1.5 Personnel at CICDC and CENSA and the NCA capacitated through training programs on | 100% | Two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 |

| | | |
|---|---|---|
| detection and identification of LMOs. | | Standard. |
| Output 1.1.6 National Reference Laboratory certified by the NC ISO 9001: 2015 and accredited by the NC ISO / IEC 17025: 2017 | 70% | Specialists training in Mexico first for CENSA and CICDC specialists on detection and identification, qualitative and quantitative methods, and validation of molecular assays. The second training focused on the implementation of ISO/IEC 17025: 2017 in an accredited laboratory. |
| **Outcome: 2.1: National system for monitoring and surveillance established and operational.** | | |
| Output 2.1.1: Monitoring and surveillance system designed and operating (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment. | 60% | Comparative Study of National and International Guidelines on M&S of LMOs and Adverse Effects. The Adverse Effects Monitoring and Surveillance System (SMV) was completed. |
| Output 2.1.2 Strategy for field detection (screening procedures) developed. | 100% | Procedures for sampling and detection in the field was developed. |
| Output 2.1.3 Administrative and technical guides designed for each involved institution (Veterinary and Phytosanitary borders Officers (Ministry of Agriculture) and Customs Officers (General Customs of the Republic of Cuba) and inspector from CSB) in the National Customs System. | 100% | Procedures for the taking of samples at the borders were developed. |
| Output 2.1.4 Workshops for customs officers and personnel involved in M&S system on how to use the guidelines developed on 2.1.3. | 44% | Training workshop for customs officers and personnel involved in the M&S system was conducted with the participation of Borders Authorities. The second workshop is postponed due to challenges in implementing program for field sampling. A Workshop to present the Monitoring and Surveillance System and the strategy for the implementation of the project has yet to be held. |
| **Outcome 3.1: Socio-economic considerations as per article 26 are considered in decision-making.** | | |
| Output 3.1.1 Detailed analysis of the socio-economic considerations of importance for Cuba related to LMO impacts completed and guiding decision-making. | 100% | Study on International Regulations About SECs completed. |
| Output 3.1.2 Informative materials on socio-economic considerations produced and distributed amongst general public and relevant authorities. | 30% | The project made substantial efforts to collaborate with the Cuban Academy of Sciences on the topic of SECs, and has engaged key government entities, Universities, local governments, and communities where SEC studies will be carried out representing areas with a history of commercial-scale releases of genetically modified crops.<br>Workshops were held to present the international biosafety project in the communities of Placetas (Villa Clara) and Sanguily municipality of Venezuela (Ciego de Avila). |

### Achievement of Project Outcomes

48. Consistent with the discussion presented in the reconstructed ToC at Evaluation, this section seeks to determine the extent to which the anticipated outcomes of the project are likely to be achieved, thus contributing to the intermediate state identified in the TOC and

ultimately to the project's intended impact. The progress of the outputs discussed above, coupled to the discussion and logic of the TOC at Evaluation, form the substantive basis upon which this assessment of achievement of direct outcomes is based. This assessment also considers the fact that some outcomes may rely on the collective delivery of multiple outputs, and that some outputs contribute to the delivery of multiple outcomes and may be across project components. This concept was described in the outputs to impact analysis in the reconstructed TOC. Also, and based on the project's work plan, some outputs may not yet due for complete delivery at the MTR, and therefore should not be assessed as 'delayed' and/or negatively affecting the delivery of the relevant outcome or outcomes.

**Outcome 1.1: National capacities for LMO identification and detection strengthened and supporting decision-making processes.**

49. The output (1.1.1) for equipping reference laboratories with state-of-the-art equipment for LMO identification, and the most important for the delivery of the outcome and consequently, the project's Intermediate State, is 93% complete with approximately 15 months of technical project implementation remaining. The other two outputs critical to the achievement of Outcome 1.1 in terms of the institutionalization of LMO detection and identification (Output 1.1.2) and capacity building within key institutions (Output 1.1.5) are both 100% complete, establishing a solid path towards the project's Intermediate State, as defined in the TOC. The output addressing institutional tools and protocols to strengthen institutional governance in LMO detection and identification (Output 1.1.3) is 96% complete. The two remaining outputs are 66% (Output 1.1.4) and 70% (Output 1.1.6) complete, respectively, at the MTR. This component represents 55% of the project's budget, is 87.5% complete, and is the most important in terms of the project's overall objective. At the MTR, the drivers defined in the TOC for achieving the outcome are in place and the assumptions are holding true, especially in relation to inter-institutional collaboration for successful uptake and implementation of the national biosafety framework. This component and corresponding outcome are well on track for complete delivery by end of project.

**Outcome: 2.1: National system for monitoring and surveillance established and operational.**

50. Two of the four Outputs to deliver this outcome are 100% complete, relating to strategy for field detection of LMOs (Output 2.1.2) and administrative and technical guides designed for each involved institution (Output 2.1.3). However, even though the Adverse Effects Monitoring and Surveillance System (SMV) has been developed (Output 2.1.1), there is still work to be done for its actual implementation. Output 2.1.4 addressing capacity building for customs officers and personnel involved in the M&S system on how to use the guidelines developed is only partially complete (44%) due to technical and administrative implementation challenges and will thus require further attention during the time remaining in the project, since the complete delivery of Output 2.1.1. is dependent on Output 2.1.4 being fully delivered. Mid-term targets for this outcome are partially delivered. The condition of the assumptions and drivers applicable to Outcome 2.1 are partially favourable but can be improved with technical and administrative adjustments among all institutions concerned.

**Outcome 3.1: Socio-economic considerations as per article 26 are considered in decision-making.**

51. The project has fully delivered Output 3.1.1 (100%) in the form of a Study on International Regulations About SECs, in response to the need for a detailed analysis of the socio-economic considerations of importance for Cuba related to LMO impacts to guide decision-making. This MTR could not identify any evidence that the mentioned study is being applied to the decision-making process. In terms of the remaining Output 3.1.2 on informative materials on socio-economic considerations produced and distributed amongst the public and relevant authorities, some progress has been made in terms of information workshops in stakeholder communities and in the form of informative materials on the project's objective and scope that have been produced and disseminated. However, there is still work to be done to achieve the full scope of the output in relation to assessing and quantifying in the field the socioeconomic impacts of LMOs on communities. Output 3.1.2 is estimated to have been delivered at 30%. The condition of the assumptions and drivers applicable to Outcome 3.1 are partially favourable but can be improved with technical and administrative adjustments by Project Management.

**Achievement of Likelihood of Impact**

52. Assessment of likelihood of Impact was conducted using the tool provided by the Evaluation Office of UN Environment Programme as updated on July 29th, 2021. At the MTR, the likelihood of impact is **'Likely'.** As indicated in the Likelihood of Impact Assessment Results in Table 4, drivers to support transition from Outputs to Project Outcomes are partially in place; most assumptions for the change process from Outputs to Project Outcomes seem to hold. Even though the outcomes to achieve Intermediate States have not been fully achieved, Likelihood of Impact is affected by the fact that consistent with the project's design, planned outcomes including the principal one for achieving the project's Intermediate State is not programmed to be fully achieved until the end of the project, even though it has been substantially delivered at the MTR. The equipping of reference laboratories, the establishment of tools and protocols for LMO detection, identification and sampling, establishment of the Adverse Effects Monitoring and Surveillance System, and capacity building to personnel of key laboratories place the project on a robust path towards full achievement of the intermediate state defined in the TOC and in the achievement of the intended impact.

| **Rating for Effectiveness:** | **'Highly *Satisfactory*'** |
|---|---|

## A. Financial Management

**Adherence to UNEP's Financial Policies and Procedures**

53. As evidenced from a review of Quarterly Expenditure Reports (QER) and Report of Independent Auditors, there were no material shortcomings in Audit Reports, thus there have been no audit recommendations nor the need for management response, suggesting adherence to UNEP's Financial Policies and Procedures. However, based on a review of documents in Anubis, time transpired between the submission of a QER and receiving the

approval from UNEP for said report can be lengthy at times, suggesting the need for clarifications and revisions to reports before approvals are granted.

### Table 4. Likelihood of Impact Assessment Results

A GUIDE FOR THE RATING LIKELIHOOD OF IMPACT

Reset Form

| | Select Response | | Likelihood of impact | | | | | | Likelihood of impact | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | HU | U | MU | ML | L | HL | HU | U | MU | ML | L | HL |
| Drivers to support transition from Outputs to Project Outcomes are ... | Partially in place | | Not in place | Partially in place | Partially in place | In place | In place | In place | | 1 | 1 | | | |
| Assumptions for the change process from Outputs to Project Outcomes ... | Partially hold | | Do not hold | Partially hold | Partially hold | Hold | Hold | Hold | | 1 | 1 | | | |
| Proportion of Project Outcomes fully or partially achieved? | All | | None | Some | Some | Some | Some | All | | | | | | 1 |
| Which Project Outcomes? (the most important to attain intermediate states / impact or others) | | Answer not required | n/a | Others | Others | Most important | Most important | n/a | | | | | | 1 |
| Level of Project Outcome achievement? | Partial | | n/a | Partial | Full | Partial | Full | Full | | 1 | | 1 | | |
| Drivers to support transition from Project Outcome(s) to Intermediate States are ... | Partially in place | | n/a | Not in place | Not in place | Partially in place | Partially in place | In place | | | | 1 | 1 | |
| Assumptions for the change process from Project Outcomes to Intermediate States ... | Partially hold | | n/a | Do not hold | Do not hold | Partially hold | Hold | Hold | | | | 1 | | |
| Proportion of Intermediate States achieved? | Some | | n/a | n/a | None | None | Some | All | | | | | 1 | |
| Level of Intermediate State achievement? | Partial | | n/a | n/a | n/a | n/a | Partial | Full | | | | | 1 | |
| Drivers to support transition from Intermediate States to Impact are ... | Partially in place | | n/a | Not in place | Not in place | Not in place | Partially | In place | | | | | 1 | |
| Assumptions for the change process from Intermediate States to Impact ... | Partially hold | | n/a | Do not hold | Do not hold | Do not hold | Partially | Hold | | | | | 1 | |
| | | | | | | | | | 0 | 3 | 2 | 3 | 5 | 2 |

OVERALL RATING

LIKELY

## Completeness of Financial Information

54. The project's financial information at the time of the MTR was complete for the most part, and included Quarterly Expenditure Reports, Half Yearly Reports, Annual Project Implementation Reports, and Annual Audit Reports. An exception to the completeness of reporting is project budget information by component and co-financing data by source, as

evidenced in Tables 5 and 6 below. While the MTR is required to report budget and expenditure by project component, expenditures are recorded and reported according to cost centres of Anubis, not according to project components. There is no standardized formula for estimating co-financing. The PCA signed between Cuba and UNEP refers to a Co-finance Report Template in Annex 14, but this MTR saw no evidence of that reporting. Based on information available in Anubis, UNEP has made six (6) Cash Advances to UNDP on behalf of the project, totalling **US$1,131,901.22** or **61.97%** of the total GEF Funding of US$1,826,484. As per information provided by the Project Executing Agency, real budget execution at the time of the MTR is US$642,455.37 or **35.12%** of the total GEF Budget. This budget execution suggests a difference of US$489,445.85 (when compared to total cash advance) is available at UNDP for project payments; however, the Project Executing Agency has expressed concern over long overdue payments to suppliers and the threat of lawsuit received by the project from a supplier for non-payment of equipment procured by the project for the reference laboratories being supported by the project. The Project Executing Agency has suggested that limits on payments (maximum of US$200,000) as per UNEP policy and guidelines are partially responsible for the payment delays, and emphasized that, due to the nature of the equipment procured by the project, the value of some contracts may exceed the US$200,000 limit imposed by UNEP. It must be highlighted, however, that a possible solution to resolve the issues of access to USD and other consequences of the embargo against Cuba that have resulted in this cumbersome arrangement for project disbursements, is the consideration that UNDP be engaged as Fund Management Agency. It is believed this would simplify some of the bureaucracy involved in procurement and financial management and would result in much more efficient project management processes. This idea, however, may require endorsement by the Cuban government (and possibly the GEF), and agreement from UNDP Cuba.

**Communication Between Finance and Project Management Staff**

55. The Project Manager's level of awareness of the project's financial status is limited to UNEP Budget Lines as appears in ANUBIS. Communications between the Fund Management Office is satisfactory as evidenced by the approval of financial and audit reports and consecutive disbursements. However, the Project Executing Agency has registered its displeasure with not able to receive summary information from UNDP on payments made on behalf of the project and to be able to see real balances of the project fund available at UNDP at any given time. The Project Executing Agency eventually sees reports of UNDP activities and payments on behalf of the project, once these have been provided to UNEP by UNDP. There is also no mechanism in place at UNDP to confirm whether a payment made by the project has been received by a payee unless there is a complaint from the payee that the funds have not arrived.

| **Rating for Financial Management:** ***'Satisfactory'*** |
|---|

## Table 5. Expenditure by Component

| Component/sub-component/output<br><br>All figures as USD | Estimated cost at design | Actual Cost/ expenditure | Expenditure ratio (actual/planned) |
|---|---|---|---|
| Component 1 | | NA | NA |
| Component 2 | | NA | NA |
| Component 3 | | NA | NA |
| Component 4 | | NA | NA |
| Project Management Cost | | NA | NA |
| **Total** | **US$1,826,484** | **US$642,455.37** | **35.12%** |

## Table 6: Co-financing Table

| Co-financing (Type/Source) | UN Environment 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 | |
| ORSA | | | 1,308,031 | NA | | | 1,308,031 | NA | NA |
| CICDC | | | 130,500 | NA | | | 130,500 | NA | NA |
| CENSA | | | 459,412 | NA | | | 459,412 | NA | NA |
| CENATOX | | | 22,500 | NA | | | 22,500 | NA | NA |
| **Totals** | | | **1,920,443** | NA | | | **1,920,443** | NA | NA |

## Table 7: Financial Management Table

| NON-GEF AND GEF PROJECTS | | | |
|---|---|---|---|
| **Financial management components:** | | **Rating** | **Evidence/ Comments** |
| **1. Adherence to UNEP's policies and procedures:** | | **S** | |
| Any evidence that indicates shortcomings in the project's adherence to UNEP or donor policies, procedures, or rules | | No | No material shortcomings in Audit Reports. |
| **2. Completeness of project financial information:** | | | |
| Provision of key documents to the reviewer (based on the responses to A-H below) | | MS | |
| A. | Co-financing and Project Cost's tables at design (by budget lines) | Yes | No breakdown of budgets by project components. |
| B. | Revisions to the budget | Yes | |
| C. | All relevant project legal agreements (e.g., SSFA, PCA, ICA) | Yes | |

| | | | |
|---|---|---|---|
| D. | Proof of fund transfers | Yes | |
| E. | Proof of co-financing (cash and in-kind) | No | The PSA refers to a Co-finance Report Template in Annex 14; this MTR saw no evidence of this being done. |
| F. | A summary report on the project's expenditures during the life of the project (by budget lines, project components and/or annual level) | Yes | Annual budget revisions serve for this purpose. |
| G. | Copies of any completed audits and management responses *(where applicable)* | Yes | |
| H. | Any other financial information that was required for this project (list): | N/A | |
| **3. Communication between finance and project management staff** | | **S** | |
| Project Manager and/or Task Manager's level of awareness of the project's financial status. | | MS | Expenditure by project component or by outcome not readily available. |
| Fund Management Officer's knowledge of project progress/status when disbursements are done. | | S | |
| Level of addressing and resolving financial management issues among Fund Management Officer and Project Manager/Task Manager. | | MS | While understandable, there are clearly challenges in using UNDP as an intermediary for payment purposes. |
| Contact/communication between by Fund Management Officer, Project Manager/Task Manager during the preparation of financial and progress reports. | | S | |
| Project Manager, Task Manager and Fund Management Officer responsiveness to financial requests during the review process | | S | |
| **Overall rating** | | **S** | |

### B. Efficiency

56. The project undergone an almost 2-year delay due to institutional reforms within the Project Executing Agency, coupled to challenges posed by COVID-19, when the project finally got underway in the first half of 2020. The impacts of COVID-19 demanded an efficient project management approach to keep the project on track as best as possible during the first 18 months of implementation. The project employed strict health guidelines as mandated by the Cuban Government and carried on project implementation activities to the extent possible under the circumstances, and focused primarily on inception, planning, and coordination activities. Notwithstanding these challenges, in addition to some staff turnover early in project implementation, the project has done well in delivering substantially on the most important outcomes for project success, even though the country faces unique challenges in terms of access to USD and complications in effecting payment via UNDP to international suppliers. While it can be argued that progress to date could have been done through more efficient procurement and financial management interventions, the decision to move to an alternative arrangement between UNEP, Government of Cuba, and UNDP, does not rest with the Project Management Unit and would require high-level political intervention, and possibly high-level consultations with the GEF. The project has also efficiently used regional resources for capacity building (Mexico and Argentina) and events where the project success stories can be presented.

| | |
|---|---|
| **Rating for Efficiency:** | **'Moderately *Satisfactory*'** |

### C. Monitoring and Reporting

**Monitoring Design and Budgeting**

57. Costed Monitoring & Evaluation Plan was developed for the project and is being followed accordingly and at the MTR the budget seems appropriate. The M&E plan is supported by the Reporting Requirements developed during project design which outlines planning and reporting requirements in support of M&E according to a predetermined timeline during project implementation. While most outcome indicators in the Project Results Framework are appropriate, these are not disaggregated by relevant stakeholder groups including gender and minority/disadvantaged groups and gender sensitive indicators are not available.

**Monitoring of Project Implementation**

58. Project monitoring is conducted on a continuous basis by a Project Coordinator based in ORSA and by the Project Steering Committee which meets to review project progress at least twice per year. UNEP conducts monitoring both remotely and on the ground by the GEF Task Manager and the Programme Management Assistant. The project has now seen its third UNEP Task Manager due to internal restructuring at UNEP. Quarterly Expenditure Reports, Half Yearly Reports, Project Implementation Reports, and independent Audit Reports are generally prepared and submitted to UNEP. Project Implementation Reports provide details of progress and challenges and serve as a powerful monitoring tool. Half Yearly Reports help to identify or anticipate early challenges which may be corrected immediately and not wait until a PIR is prepared at the end of the project year. This MTR and the Terminal Evaluation also form part of the project's monitoring framework.

**Project Reporting**

59. Better quality control and agreement of level of completion of outputs and achievement of outcomes as reported in PIRs can benefit from closer scrutiny of those reports by the PSC before they are submitted to UNEP. There is no established guideline for what constitutes 10%, 20%, 30% progress, etc. As has already been indicated above, better reporting of co-financing by source and expenditure by project component and/or outcome will substantially improve reporting. This MTR did not find any significant deficiencies in reporting besides those already mentioned.

| | |
|---|---|
| **Rating for Monitoring and Reporting:** | **'*Satisfactory*'** |

### D. Sustainability

**Socio-political Sustainability**

60. Currently, political support seems optimum at the national level for project success. Biosafety and commitment to the Cartagena Protocol are clearly embedded in multiple pieces of national policy in Cuba, demonstrating political commitment for long term

implementation of biosafety protocols. The quantification of the socio-economic impacts of LMOs in a Cuban context being developed by this project will provide the baseline required to further strengthened biosafety considerations in national decision-making, including in national food and security decisions.

**Financial Sustainability**

61. All entities involved in biosafety implementation are state entities, and thus any sustained activities to upscale or replicate project outcomes will be financed from state budget. The provision of biosafety products and services is also a possibility, as some of the entities involved in the project have been and continue to be involved in the production of biopharmaceutical products for global commercialization, and thus have the business dimension required to develop, price, and market biosafety products and services.

**Institutional Sustainability**

62. The recent institutional reforms at CITMA and ORSA in terms of mandate better position the country for the development of the biosafety industry. The key institutions involved in biosafety all now have strengthened capacity for the detection, identification, monitoring, and management of LMOs. These institutions have additionally, been working on biosafety since the country adopted the Cartagena Protocol and have now established a cadre of biosafety professionals that are deeply enshrined in the country's institutional framework for biosafety development.

| **Rating for Sustainability:** | ***'Highly Likely'*** |
|---|---|

## E. Factors Affecting Performance and Cross-Cutting Issues

**Preparation and Readiness**

63. Project preparation is deemed to be satisfactory; however, the drivers, assumptions, causal pathways, and intermediate state of the TOC were not developed. However, the project design was built on previous GEF-UNEP funded initiatives on biosafety which provided a robust baseline for project development, leading to a high level of achievement, guided by personnel with extensive institutional memory, having been engaged in the previous initiatives.

**Quality of Project Management and Supervision**

64. Considering the challenges caused by the COVID 19 pandemic, the project has shown creativity and adaptive management in its approach to get implementation on track. The Project Coordinator and Project Team displayed a high level of competence and commitment in efforts to deliver project activities and engage project stakeholders, in the development and submission of required project reports. UNEP's supervision has been appropriate as evidenced by the UNEP's participation in the PSC, field visits, and other evidence of feedback and support accessible in PIRs and on Anubis. The PSC, as a project supervision body provides an opportunity to elevate supervision and buy-in at a higher level within government, that would be crucial for political and financial sustainability, considering

the importance of biosafety as part of Cuba's National Security Policy and its importance to the country's GDP. This, however, requires initiative on the part of the Project Executing Agency and the PSC itself.

**Stakeholders Participation and Cooperation**

65. The project has been successful in engaging the primary stakeholders, these being mainly specialized institutions and centres in the country that are associated with the topic of biosafety. The most senior people of the four key institutions involved are members of the PSC; this has proven to be of strategic benefit to the project as the process to achieve inter-institutional collaboration was successfully achieved through institutional agreements and MOUs, leading to the approval and incorporation of the two reference laboratories into the quality management system of entities (CENSA and CICDC), being the primary laboratories supported by the project. While there have been community engagements in Placetas and Venezuela, formal partnerships with the Private Sector and critical Non-government Organizations are not available. A Stakeholder Engagement Plan was not prepared for the project.

**Responsiveness to Human Rights and Gender Equality**

66. The project designed identified that "the project will be mainly undertaken from specialized institutions/centres in Havana, and therefore will have limited opportunities to engage women and/or men in field-level work as other projects more related to agriculture or management of resources typically do". Even though no gender analysis was conducted, the project document includes measures to ensure women benefit from project interventions and includes some gender-sensitive indicators in the Project Results Framework, though not to the level required by GEF and UNEP policies. No Gender Action Plan or Gender Marker were prepared for the project. Of note is the fact that two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 Standard in which a total of 29 students, mostly women, received the corresponding certificate. The integrated approach to human/natural systems was not defined in the project document.

**Environmental and Social Safeguards**

67. The project is being implemented within the framework of the Policy for the Use of Genetically Modified Organisms in Cuban Agriculture which fully embraces environmental and social safeguards. Decree Law 4/2020 implements this policy with the creation of a National Commission composed of several authorities and chaired by the head of the Ministry of Science, Technology, and the Environment, with the aim of harmonizing the decision-making process for the safe and orderly use of GMOs in the country's agricultural development programs. To strengthen the decision-making process, capacities have been created and strengthened in two national laboratories, and a system for surveillance and monitoring adverse effects has been designed with capacity for its implementation currently being created by this project. The National Commission is already taking charge of decision-making processes about the safe and orderly use of GMOs in the country's agricultural programs.

**Country Ownership and Driven-ness**

68. At the MTR there is certainly country ownership as evidenced by the level of representation on the PSC and by the commitment and success of the Project Executing Agency in engaging all relevant institutions in project ownership and inter-institutional collaboration. In addition to CENSA, ORSA, CENATOX, and CICDC, the project has been successful in engaging the Customs Authorities and the National Centre for Agriculture, especially in aspects relating to field detection, monitoring, and surveillance of LMOs. The project is driven by national policies relevant to biosafety and the government's commitment to the Cartagena Protocol, while benefitting from high levels of technical capacity resident within the four key national institutions involved.

**Communication and Public Awareness**

69. While the project's 'Knowledge Management' approach was only briefly described in one section of the Project Document, there are two project components dedicated to learning, communications, and outreach. There are appropriate strategies defined and implemented for communication and dissemination of results and lesson sharing, with gender-sensitive approaches where feasible, and designed to respond to the needs of different types of audiences. Workshops were held to present the international biosafety project and the importance of SEC studies in the communities of Placetas (Villa Clara) and Sanguily municipality of Venezuela (Ciego de Avila) in addition to numerous training workshops, and informative and communications materials were produced and disseminated on the project's objectives, activities, and results. South-South knowledge exchange has occurred between technical specialists of Cuba and technical biosafety specialists in Mexico and Argentina. The project has also supported Cuba's participation in the II Congress of the SOVE - Symposium on standards for the regulation of genetically modified insects held in La Plata, Argentina, and the project's participation in the IV International Seminar on Agricultural Health (SISA), held in Cuba. This MTR did not come across evidence of a structured communication strategy for the project and there is no dedicated project website or link, however, project activities are disseminated via the institutional page of ORSA CITMA on Facebook and X (previously Twitter).

| |
|---|
| **Rating for Factors Affecting Performance and Cross Cutting Issues:**<br><br>***'Satisfactory'*** |

# V. CONCLUSIONS AND RECOMMENDATIONS

## A. Conclusions

70. The project "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" seeks to further complete the process of implementation of the Cartagena Protocol on Biosafety through the creation of additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms and the socio-economic considerations of importance for Cuba related to them. At the MTR, the project has done well at procuring and receiving all reagents, equipment and supplies necessary for the operation of the two reference laboratories, a Procedures Manual for the operations of the laboratories in question, and the approval and incorporation of the laboratories into the quality management system of CENSA and CICDC. Collaboration agreements between ORSA and CENSA and with CICDC were signed, protocols, techniques and procedures for the detection and identification of GMOs were approved by the Biosafety Technical Standards Committee. Limits for the qualitative tests to be accredited have been defined after training was received from SENASICA in Mexico, two national training have been conducted on the requirements of the NC ISO / IEC 17025: 2017 Standard, while international training was received on the implementation of this standard. In terms of capacity for LMO detection and identification, the project is well on its way to fully deliver the defined targets by the project's end.

71. The project also developed the Adverse Effects Monitoring and Surveillance System (SMV) which was approved by the National GMO Commission, in addition to the procedures for LMO sampling and detection in the field and at the borders. The project sponsored a mission to Argentina where specialists from ORSA and CENATOX received training on the entry, monitoring, and field surveillance of regulated GMO trials, including regulations and conditions for importation and field controls of GMO seeds. The field sample-drawing and detection procedure and the procedure for taking samples in borders were also completed. The project has delivered training to Customs Officers and other personnel involved in the M&S system, the Ministry of Agriculture's Plant Health Directorate provided theoretical training in sampling at borders for biosafety inspectors, and a workshop on field monitoring techniques has been conducted. The project has conducted a Study on International Regulations About Socio-Economic Considerations of LMO Use and has made substantial efforts to engage institutions across government on SECs of LMOs. The project has also invested in the development of Knowledge Management products which have been shared and disseminated across national institutions and has also presented the project's objectives and results in both national and international fora.

72. Notwithstanding the many successes described above, there are project implementation issues to be addressed. The timeline for the validation of the protocols for qualitative tests to detect and identify LMO events may need to be revisited due to technical delays. Also, the timeline for the accreditation of the laboratories in CENSA and CICDC is unclear and must be clarified. Field samplings have been hampered by a lack of fuel and questions the level of priority the project has in the broader scheme of things in the country. A Workshop to present the Monitoring and Surveillance System is yet to be held and efforts should be made by the project before the project ends to evaluate the impacts of GMO crops (Maize and Soy) recently released in Placetas, Villa Clara and Sanguily, municipality of

Venezuela in Ciego de Avila province, as a practical demonstration of the capacity acquired with the support of the project. The project is deficient in its reporting of project budget by component or outcomes and in the reporting of co-financing by source. While most outcome indicators in the Project Results Framework are appropriate, these are not disaggregated by relevant stakeholder groups including gender and minority/disadvantaged groups and only some gender sensitive indicators available, even though women are majority participants in all project events. While the project has made steps to engage institutional stakeholders, formal engagement and partnerships with the Private Sector and Non-government Organizations are not available. There are clear inconveniences all around in terms of the tri-partite arrangements for project payments in USD between UNEP, the Government of Cuba, and UNDP Cuba resulting in a cumbersome and inefficient system of payments to suppliers outside of Cuba.

73. The project's performance at the mid-term in response to the GEF-6 Core Indicator Targets, stakeholder engagement, gender responsiveness, safeguards, and Knowledge Management are summarized below in Table 8.

**Table 8. Project Performance in Response to Strategic Review Questions**

| Strategic Question | Project Performance at the Mid-Term |
|---|---|
| What is the performance at the project's mid-point against Core Indicator Targets? | This project was designed to address the two replenishment targets of GEF-6 Corporate Result 6: *Enhance capacity of countries to implement MEAs (multilateral environmental agreements) and mainstream into national and sub-national policy, planning financial and legal frameworks.*<br><br>Consistent with the replenishment targets of GEF-6 Corporate Result 6, the project has strengthened national capacities for LMO detection, identification, monitoring, and surveillance, and has developed the baseline data needed to inform decision-making relating to the socio-economic impacts of LMOs in Cuba, as defined in Article 26 of the Cartagena Protocol. |
| What has been the progress, challenges, and outcomes regarding engagement of stakeholders in the project/program? | A Stakeholder Engagement Plan (SEP) was not developed for the project, as such, the project's approach has been to target stakeholders in accordance with those identified in the Project Document, as well as new ones that present opportunities for partnerships that may be useful in supporting project objectives and sustainability of project outcomes. As this is a GEF-6 project, a SEP was not a requirement at the time of design. |
| What has been the progress, challenges, and outcomes regarding gender-responsive measures and any intermediate gender result areas? | Even though no gender analysis was conducted, the project document includes measures to ensure women benefit from project interventions and includes some gender-sensitive indicators in the Project Results Framework, though not to the level required by GEF and UNEP policies. No Gender Action Plan or Gender Marker were prepared for the project. Of note is the fact that two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 Standard in which a total of 29 students, mostly women, received the |

| | |
|---|---|
| | corresponding certificate. Generally, women are majority participants in project events. |
| What has been the experience at the project's mid-point against the Safeguards Plan submitted at CEO Approval? | The safeguards risk identified at CEO Approval has not changed. The project is being implemented within the framework of the Policy for the Use of Genetically Modified Organisms in Cuban Agriculture which fully embraces environmental and social safeguards. To strengthen LMO decision-making process, capacities have been created and strengthened in two national laboratories, and a system for surveillance and monitoring adverse effects has been designed with capacity for its implementation currently being created by this project. |
| What has been the progress, challenges, and outcomes regarding the implementation of the project's Knowledge Management (KM) Approach, including: Knowledge and Learning Deliverables | There are appropriate strategies defined and implemented for communication and dissemination of results and lesson sharing, with gender-sensitive approaches where feasible, and designed to respond to the needs of different types of audiences. This MTR did not come across evidence of a structured communication strategy for the project implemented via mainstream media or social media, and there is no dedicated project website or link. |

74. The Reconstructed TOC confirms that the project is following a robust theory of change with appropriately formulated outputs, direct outcomes, intermediate state, and long-term results. The outcome indicators are verifiable and appropriate for recording progress towards the achievement of the development objectives. Assessment of the drivers, assumptions for the change processes, delivery of the most significant outcomes, and the proportion of intermediate state achieved at the MTR all suggest that the likelihood of impact is **'Likely'.** A Summary Assessment and Rating is presented in Table 9. The success of the project thus far has benefitted from a high level of technical and administrative capacity in the Project Management Unit and in ORSA, complemented by a competent set of specialists in CENSA, CICDC and CENATOX that are fully committed to the project's objectives and desirous of the project's success. Even with all the complexities involved, the project could not have procured and received all the equipment and supplies for the reference laboratories without the support of UNDP Cuba.

**Table 9. Summary Assessment and Rating**

| Criterion | Summary Assessment | Rating |
|---|---|---|
| **A. Strategic Relevance** | | **HS** |
| *1. Alignment to UNEP's MTS, POW and strategic priorities* | The project aligns with **UNEP's Subprogramme 3**: Healthy and productive ecosystems and **Subprogramme 4**: Environmental governance. | HS |
| *2. Alignment to Donor/Partner strategic priorities* | The project is consistent with the GEF-6 Biodiversity Focal Area (BD-2 Program 5), Outcome 5.1: adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (both women and men), and specifically focusing on transboundary movements. | HS |

| Criterion | Summary Assessment | Rating |
|---|---|---|
| *3. Relevance to regional, sub-regional and national environmental priorities* | The 2022-2026 United Nations Multi-Country Sustainable Development Framework (UN MSDF) for the Caribbean region cites Outcome 6 'Caribbean countries manage natural resources and ecosystems strengthening their resilience and enhancing the resilience and prosperity of the people and communities that depend on them' which is relevant to the objectives under this project. The project is fully aligned with the Cartagena Protocol on Biosafety, and with Articles 11, 15,16, 17, 18, 19, 22, 23 and 26. Consistent with SDG Goal 2: Zero Hunger, Target 2.5. | HS |
| *4. Complementarity with relevant existing interventions* | Consistent with Cuba's National Biodiversity Strategy and Action Plan 2016-2020 and with the National Environmental Strategy. The project complements the recently concluded UNEP/GEF Project 'Completion and Strengthening of the Cuban National Biosafety Framework for the Effective Implementation of the Cartagena Protocol (GEF ID:3643)' and the UNEP/GEF Project 'Implementing National Biosafety Frameworks (NBF)' in the Caribbean (GEF Project ID: 2967). | HS |
| **B. Quality of Project Design** | Barriers are identified, solutions defined, and summary problem statement provided. Even though the Project Results Framework clearly captures the intended logic of the project inclusive of associated outcome level indicators with clear results at the outcome level, there was no theory of change and logical pathways diagram. There is also a lack of clearly articulated logical pathways and the critical actors to be involved in each pathway in the project's TOC. No Stakeholder Engagement Plan and no Gender Action Plan were prepared for the project. | **S** |
| **C. Effectiveness** | | **HS** |
| *1. Availability of outputs* | Of the 12 outputs of the project, at the mid-term 5 were 100% delivered, 1 was 96% delivered, 1 was 93% delivered, 2 were over 50% delivered and 1 under 50% delivered, with an overall average delivery of the three technical components at 76.2%. | HS |
| *2. Achievement of project outcomes* | The output (1.1.1) for equipping reference laboratories with state-of-the-art equipment for LMO identification, and the most important for the delivery of the outcome and consequently, the project's Intermediate State, is 93% complete with approximately 15 months of technical project implementation remaining. The other two outputs critical to the achievement of Outcome 1.1 are both 100% complete, establishing a solid path towards the project's Intermediate State. Two of the four Outputs to deliver Outcome 2.1 are 100% complete, however, the other two outputs are only 60% and 44% delivered. the complete delivery of Output 2.1.1. is dependent on Output 2.1.4 being fully delivered. The project has fully delivered Output 3.1.1 (100%) and Output 3.1.2 is estimated to have been delivered at 30%, in support of Outcome 3.1. | HS |
| *3. Likelihood of impact* | Drivers to support transition from Outputs to Project Outcomes are partially in place; most assumptions for the change process from Outputs to Project Outcomes seem to hold. Even though the outcomes to achieve Intermediate States have not been fully achieved, Likelihood of Impact is affected by the fact that consistent with the project's design, planned outcomes including the principal one for achieving the project's Intermediate State is not programmed to be fully achieved until the end of the project, even though it has been substantially delivered at the MTR. | L |
| **D. Financial Management** | | **S** |
| *1.Adherence to UNEP's policies and procedures* | As evidenced from a review of Quarterly Expenditure Reports (QER) and Report of Independent Auditors, there were no material shortcomings in Audit Reports, thus there have been no audit recommendations nor the need for management response, suggesting adherence to UNEP's Financial Policies and Procedures. However, based on a review of documents in Anubis, time transpired between the submission of a QER and receiving the approval from UNEP for said report can be lengthy at times, suggesting the need for clarifications and revisions to reports before approvals are granted | S |

| Criterion | Summary Assessment | Rating |
|---|---|---|
| *2.Completeness of project financial information* | The project's financial information at the time of the MTR was complete for the most part, and included Quarterly Expenditure Reports, Half Yearly Reports, Annual Project Implementation Reports, and Annual Audit Reports. An exception to the completeness of reporting is project budget information by component and co-financing data by source. | S |
| *3.Communication between finance and project management staff* | Communications between the Fund Management Office is satisfactory as evidenced by the approval of financial and audit reports and consecutive disbursements. However, the Project Executing Agency has registered its displeasure with not able to receive summary information from UNDP on payments made on behalf of the project and to be able to see real balances of the project fund available at UNDP at any given time. There is also no mechanism in place at UNDP to confirm whether a payment made by the project has been received by a payee unless there is a complaint from the payee that the funds have not arrived. | S |
| **E. Efficiency** | The project undergone an almost 2-year delay due to institutional reforms within the Project Executing Agency, coupled to challenges posed by COVID-19. The project employed strict health guidelines as mandated by the Cuban Government and carried on project implementation activities to the extent possible under the circumstances. Notwithstanding these challenges, in addition to some staff turnover early in project implementation, the project has done well in delivering substantially on the most important outcomes for project success, even though the country faces unique challenges in terms of access to USD and complications in effecting payment via UNDP to international suppliers. | **S** |
| **F. Monitoring and Reporting** | | **S** |
| *1. Monitoring design and budgeting* | The M&E plan is supported by the Reporting Requirements developed during project design which outlines planning and reporting requirements in support of M&E according to a predetermined timeline during project implementation. While most outcome indicators in the Project Results Framework are appropriate, these are not disaggregated by relevant stakeholder groups including gender and minority/disadvantaged groups and gender sensitive indicators are not available. | S |
| *2. Monitoring of project implementation* | Project monitoring is conducted on a continuous basis by a Project Coordinator based in ORSA and by the Project Steering Committee which meets to review project progress at least twice per year. UNEP conducts monitoring both remotely and on the ground by the GEF Task Manager and the Programme Management Assistant. | S |
| *3.Project reporting* | Better quality control and agreement of level of completion of outputs and achievement of outcomes as reported in PIRs can benefit from closer scrutiny of those reports by the PSC before they are submitted to UNEP. There is no established guideline for what constitutes 10%, 20%, 30% progress, etc. Better reporting of co-financing by source and expenditure by project component and/or outcome will substantially improve reporting. | MS |
| **G. Sustainability** | | **HL** |
| *1. Socio-political sustainability* | Currently, political support seems optimum at the national level for project success. Biosafety and commitment to the Cartagena Protocol are clearly embedded in multiple pieces of national policy in Cuba, demonstrating political commitment for long term implementation of biosafety protocols. The quantification of the socio-economic impacts of LMOs in a Cuban context being developed by this project will provide the baseline required to further strengthened biosafety considerations in national decision-making, including in national food and security decisions. | HL |
| *2. Financial sustainability* | All entities involved in biosafety implementation are state entities, and thus any sustained activities to upscale or replicate project outcomes will be financed from state budget. The provision of biosafety products and services is also a possibility, as some of the entities involved in the project have been and continue to be involved in the production of biopharmaceutical products for global commercialization, and thus have | HL |

| Criterion | Summary Assessment | Rating |
|---|---|---|
| | the business dimension required to develop, price, and market biosafety products and services. | |
| *3. Institutional sustainability* | The recent institutional reforms at CITMA and ORSA in terms of mandate better position the country for the development of the biosafety industry. The key institutions involved in biosafety all now have strengthened capacity for the detection, identification, monitoring, and management of LMOs. These institutions have additionally, been working on biosafety since the country adopted the Cartagena Protocol and have now established a cadre of biosafety professionals that are deeply enshrined in the country's institutional framework for biosafety development. | HL |
| **H. Factors Affecting Performance and Cross-Cutting Issues** | | **S** |
| *1. Preparation and readiness* | Project preparation is deemed to be satisfactory; however, the drivers, assumptions, causal pathways, and intermediate state of the TOC were not developed. However, the project design was built on previous GEF-UNEP funded initiatives on biosafety which provided a robust baseline for project development, leading to a high level of achievement, guided by personnel with extensive institutional memory, having been engaged in the previous initiatives. | S |
| *2. Quality of project management and supervision* | Considering the challenges caused by the COVID 19 pandemic, the project has shown creativity and adaptive management in its approach to get implementation on track. The Project Coordinator and Project Team displayed a high level of competence and commitment in efforts to deliver project activities and engage project stakeholders, in the development and submission of required project reports. | S |
| *2.1 UNEP/Implementing Agency:* | UNEP's supervision has been appropriate as evidenced by the UNEP's participation in the PSC, field visits, and other evidence of feedback and support accessible in PIRs and on Anubis. | S |
| *2.2 Partners/Executing Agency:* | The Executing Agency has done well and has shown great competence in project delivery. The PSC, as a project supervision body provides an opportunity to elevate supervision and buy-in at a higher level within government, that would be crucial for political and financial sustainability, considering the importance of biosafety as part of Cuba's National Security Policy and its importance to the country's GDP. This, however, requires initiative on the part of the Project Executing Agency and the PSC itself. | S |
| *3. Stakeholders participation and cooperation* | The project has been successful in engaging the primary stakeholders, these being mainly specialized institutions and centres in the country that are associated with the topic of biosafety. The most senior people of the four key institutions involved are members of the PSC; this has proven to be of strategic benefit to the project as the process to achieve inter-institutional collaboration was successfully achieved. Formal partnerships with the Private Sector and Non-government Organizations are not available. A Stakeholder Engagement Plan was not prepared for the project. | S |
| *4. Responsiveness to human rights and gender equality* | Even though no gender analysis was conducted, the project document includes measures to ensure women benefit from project interventions and includes some gender-sensitive indicators in the Project Results Framework. Of note is the fact that two national training activities have been developed on the requirements of the NC ISO / IEC 17025: 2017 Standard in which a total of 29 students, mostly women, received the corresponding certificate. The integrated approach to human/natural systems was not defined in the project document. | MS |
| *5. Environmental, social and economic safeguards* | The project is being implemented within the framework of the Policy for the Use of Genetically Modified Organisms in Cuban Agriculture which fully embraces environmental and social safeguards. Decree Law 4/2020 implements this policy with the creation of a National Commission composed of several authorities and chaired by the head of the Ministry of Science, Technology and the Environment, with the aim of harmonizing the | S |

| Criterion | Summary Assessment | Rating |
|---|---|---|
| | decision-making process for the safe and orderly use of GMOs in the country's agricultural development programs. | |
| *6. Country ownership and driven-ness* | At the MTR there is certainly country ownership as evidenced by the level of representation on the PSC and by the commitment and success of the Project Executing Agency in engaging all relevant institutions in project ownership and inter-institutional collaboration. The project is driven by national policies relevant to biosafety and the government's commitment to the Cartagena Protocol, while benefitting from high levels of technical capacity resident within the four key national institutions involved. | S |
| *7. Communication and public awareness* | There are appropriate strategies defined and implemented for communication and dissemination of results and lesson sharing, with gender-sensitive approaches where feasible, and designed to respond to the needs of different types of audiences. Workshops were held to present the project and the importance of SEC studies in rural communities, in addition to numerous training workshops, and informative and communications materials. South-South knowledge exchange has occurred between technical specialists of Cuba and technical biosafety specialists in Mexico and Argentina. This MTR did not come across evidence of a structured communication strategy for the project implemented via mainstream media or social media, and there is no dedicated project website or link. | S |
| **Overall Project Rating** | | **S** |

## B. Lessons learned.

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| **Lesson Learned #1:** | **Institutional Memory and Resident Capacity Proven to be Crucial Assets for Project Success.** |
| **Context/comment:** | The fact that the persons involved in this project at the level of the Project Steering Committee have been involved in the execution of the previous biosafety projects in the country at very senior levels in their respective institutions, has made it relatively easy to obtain support for project activities, as all parties see the project as providing incremental value not just in technical support, but also opportunity for increased knowledge and capacity, while building on processes initiated in previous projects. |

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| **Lesson Learned #2:** | **Working only with State Institutions Demands a Different Approach to Stakeholder Participation and Ownership.** |
| **Context/comment:** | Since this project worked primarily with four state institutions, stakeholder participation and ownership were determined by institutional mandate, where participation is not optional, and the project is not required to invest in convincing stakeholders of the potential benefits to be able to garner support and stakeholder buy-in. The lack of participation by private sector, non-government organizations, and civil society challenges the spirit of both the Global Environment Facility and United Nations Environment Programme's Stakeholder Engagement Policies from definition to implementation, and evaluation of compliance with social safeguards. |

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| **Lesson Learned #3:** | **Project Execution Efficiency within a Cuban Context may Require a Relook at Project Implementation Policies.** |
| **Context/comment:** | The cumbersome situation faced by this project in terms of the tri-partite arrangements between the Government of Cuba, the United Nations Environment Programme, and the United Nations Development Programme should not be repeated. While the project has been exceptional in terms of technical delivery, it has suffered from extreme inefficiencies in terms of procurement and international payments. Project execution efficiency must be given priority above all other considerations when defining project execution arrangements, even if it means that the role of UNDP must be redefined. |

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| **Lesson Learned #4:** | **Project Results can Consolidate Cuba's Strategic Positioning as a Leader in Capacity Building for LMO Detection, Identification and Management in the Central America and Caribbean Region.** |
| **Context/comment:** | The last biosafety project implemented in Cuba established a baseline to strategically position the country to lead in LMO detection and identification and complemented the already established progress in the pharmaceutical industry. This current project has provided the additional push needed to consolidate the country's LMO capacity with tremendous potential for the provision of LMO related services and products. This is acritical element for the sustainability and upscaling of project's outcomes beyond Cuba. |

## C. Recommendations

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| **Recommendation #1:** | **Define the timeline for the validation of protocols for qualitative tests and for the accreditation of the two reference laboratories.** |
| **Challenge/problem to be addressed by the recommendation:** | These two elements are critical for the project to fully deliver the planned outcomes and achieve the desired impacts, especially as it relates to international recognition and the ability to export LMO related goods and services. |
| **Priority Level:** | High (critical) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit |
| **Proposed implementation timeframe:** | Immediately |

75. Cross-reference(s) to rationale and supporting discussions:
- Section V.A paragraph 72.

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| **Recommendation #2:** | **Address the availability of fuel for project purposes at the highest** |

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| | **political level.** |
| **Challenge/problem to be addressed by the recommendation:** | As per the Project Cooperation Agreement, Cuba has acquired an international commitment for the successful implementation of the project, and as such all facilities must be provided for this to happen. Access to fuel is not an exception and this a basic but recurrent operational necessity. |
| **Priority Level:** | High (critical) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit and UNEP |
| **Proposed implementation timeframe:** | Within 12 months of the MTR Report. |

76. Cross-reference(s) to rationale and supporting discussions:
    - Section V. paragraph 72.

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| **Recommendation #3:** | **Implement practical demonstrations of the capacity acquired with the support of the project.** |
| **Challenge/problem to be addressed by the recommendation:** | Efforts should be made by the project before the project ends to evaluate the impacts of GMO crops (Maize and Soy) recently released in Placetas, Villa Clara and Sanguily, municipality of Venezuela in Ciego de Avila province, as a practical demonstration of the capacity acquired with the support of the project. This is important for international recognition and the ability to export LMO related goods and services. |
| **Priority Level:** | Medium (important) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit |
| **Proposed implementation timeframe:** | Within 4 months of the MTR Report. |

77. Cross-reference(s) to rationale and supporting discussions:
    - Section V. paragraph 72.

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| **Recommendation #4:** | **Explore the feasibility and convenience of redefining the role of UNDP for the remainder of project implementation.** |
| **Challenge/problem to be addressed by the recommendation:** | To improve the project's performance rating in the Terminal Evaluation it will be helpful to improve project efficiency as it relates to procurement and international payments. It is also necessary to improve access by the Project Management Unit to details of payments made on its behalf in a timely manner. This MTR notes however, that most of the international procurement has been conducted for the |

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| | reference laboratories, and as such the quantum of international payments to be made may be much less for the remainder of the project, and as such, project principals may want to consider the convenience and added value of this recommendation at this stage of project implementation. |
| **Priority Level:** | High (critical) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit and UNEP |
| **Proposed implementation timeframe:** | Immediately |

78. Cross-reference(s) to rationale and supporting discussions:
    - Section V. paragraph 72.

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| **Recommendation #5:** | **Report project budget by component and co-financing by source.** |
| **Challenge/problem to be addressed by the recommendation:** | To comply with requirements of United Nations Environment Programme Evaluation Office and the requirements of the Project Cooperation Agreement (Annex 14). |
| **Priority Level:** | High (critical) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit |
| **Proposed implementation timeframe:** | Immediately. |

79. Cross-reference(s) to rationale and supporting discussions:
    - Section V. paragraph 72

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| **Recommendation #6:** | **Explore elevating the level of representation on the Project Steering Committee** |
| **Challenge/problem to be addressed by the recommendation:** | The PSC, as a project supervision body provides an opportunity to elevate supervision and buy-in at a higher level within government, that would be crucial for political and financial sustainability, considering the importance of biosafety as part of Cuba's National Security Policy and its importance to the country's GDP. |
| **Priority Level:** | Medium (important) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit and Project Steering Committee |

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| **Proposed implementation timeframe:** | Immediately |

80. Cross-reference(s) to rationale and supporting discussions:
    - Section V. paragraph 72

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| **Recommendation #7:** | **Strengthen safeguards compliance, human rights, and gender dimensions.** |
| **Challenge/problem to be addressed by the recommendation:** | While it is understood that when this GEF-6 project was designed a SEP and a GAP were not required documents, the project, however, has not implemented any structured approach to ensure gender mainstreaming or the monitoring of compliance with safeguards. It is recommended that protocols for mainstreaming gender and safeguards be incorporated into the daily decision-making processes, activities, and events of the project. |
| **Priority Level:** | Medium (important) |
| **Type of Recommendation** | Partner |
| **Responsibility:** | Project Management Unit |
| **Proposed implementation timeframe:** | Within 3 months of the MTR Report. |

## ANNEX I. PEOPLE CONSULTED DURING THE REVIEW

**Table 10: People consulted during the Review.**

| Project Stakeholder | Title/Post | Institution |
|---|---|---|
| Dianet Hernández Sainz | Head of Biodiversity and Biosafety Department | Office of Environmental Regulation and Security |
| Tanya Romay Fernández | Project Coordinator | Office of Environmental Regulation and Security |
| Yanet Valdés Collado | Logistics Assistant | Office of Environmental Regulation and Security |
| Yodaimys Bacallao Salcedo | Head of Project Component 1 | Office of Environmental Regulation and Security |
| Marta Dubed Echevarría | General Sub-Director | Scientific Investigations Centre for Civil Defence |
| Madeline Blanco de Armas | Head of Molecular Biology Laboratory | Scientific Investigations Centre for Civil Defence |
| Otto Cruz Ruiz | Scientific Sub-Director | Scientific Investigations Centre for Civil Defence |
| María Teresa Pérez Guevara | Quality Department Sub-Director | Scientific Investigations Centre for Civil Defence |
| Nivian Montes de Oca Martínez | Director General | National Centre for Agricultural Health |
| María Karla Castro Montes de Oca | Head of Molecular Biology Laboratory | National Centre for Agricultural Health |
| Yanet Rodríguez Perdomo | Representative of the Institution | National Centre for Agricultural Health |
| Aliuska Leal Venta | Director General | National Centre for Toxicology |
| Odette Beiro Castro. | Head of Department for Toxicology Bioassays | National Centre for Toxicology |
| Yordanka Domínguez Linares | Principal Specialist | National Centre for Toxicology |
| Pedro Ruiz Hernandez | Principal Specialist – International Projects | Directorate for International Relations - CITMA |
| Alejandro Cabello Gutiérrez | Commercial Sub-Director | Scientific and Technical Import & Export Company |
| María Miranda Vaquero | Director General | National Accreditation Office of |

| | | |
|---|---|---|
| | | the Republic of Cuba |
| **UNEP** | | |
| Robert Erath | Task Manager | UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division<br><br>UNEP Regional Office for Latin America and the Caribbean |
| Gloritzel Frangakis Cano | Programme Management Assistant | UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division<br><br>UNEP Regional Office for Latin America and the Caribbean |
| Thais Narciso | Past Task Manager | UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division<br><br>UNEP Regional Office for Latin America and the Caribbean |
| Tea Garcia-Huidobro | Past Task Manager | UNEP's GEF Biodiversity and Land Degradation Unit, Ecosystems Division<br><br>UNEP Regional Office for Latin America and the Caribbean |
| Rachel Kagiri | Fund Management Officer | Ecosystems Division, UNEP |
| Solomon Kinuthia | Finance Assistant | Ecosystems Division, UNEP |
| **UNDP** | | |
| Gengis Cok | Finance Assistant | Finance Unit, UNDP |

# ANNEX II. KEY DOCUMENTS CONSULTED

**Project planning and reporting documents**

- GEF Project Information Form
- UNEP Project Review Committee comments and checklist
- GEF Secretariat Review Sheet and Agency Response
- UNEP Environmental and Social Safeguards Screening report
- GEF CEO Endorsement Request Document
- GEF Project Budget
- UNEP Project Budget
- Project Co-financing Budget
- Project Cooperation Agreement between UNEP and ORSA
- Project Implementation Review, June 2021
- Project Implementation Review, June 2022
- Project Implementation Review, June 2023
- Auditor's Report for Period 3 April to 31 December 2020
- Auditor's Report for Period 1 January to 31 December 2021
- Auditor's Report for Period 1 January to 31 December 2022
- Project Work Plan 2022
- Project Work Plan 2023
- Estudio comparativo de lineamientos nacionales e internacionales sobre monitoreo y vigilancia de OGMs.
- Procedimiento de Muestreo y detección en Muestras de Campo.

**Project outputs – Overall**

- Reagents, equipment, and supplies for LMO detection laboratories procured and received.
- Procedures Manual for detection laboratories developed and adopted.
- Incorporation of detection laboratories in quality management system of CENSA and CICDC
- Interinstitutional Collaboration Agreements signed (ORSA, CENSA, and CIDC).
- Technical workshops to review protocols, techniques, and procedures for LMO detection and identification.
- Two national training activities developed on the requirements of the NC ISO / IEC 17025: 2017 Standard.
- At least three foreign training conducted (Mexico and Argentina).
- Field sample-drawing and detection procedure developed.
- Sampling procedures at border points developed.
- Analysis of the socio-economic considerations of importance for Cuba related to LMO impacts completed.

**Previous reviews/evaluations of GEF Funded Projects**

- Mid-Term Review Report: Advancing Conservation in the Eastern Caribbean (GEF Project ID: 9860), 2023
- Mid-Term Review Report: The Path to 2020 – Antigua and Barbuda, (GEF Project ID: 9402/UNEP Project ID: 01405), 2022
- Mid-Term Review Report: Strengthening Access and Benefit Sharing (ABS) in The Bahamas, (GEF Project ID: 5744/UNEP Project ID: 01262), 2021
- Mid-Term Review Report: Effective Implementation of the Access and Benefit sharing and Traditional Knowledge Regime in Peru in accordance with the Nagoya Protocol, (GEF Project ID: 8025/UNEP Project ID: 01345), 2021
- Mid-Term Review Report: Sustainable Pathways – Protected Areas and Renewable Energy in Antigua and Barbuda (GFL/5060-2711-4E04), UNEP/GEF, 2018
- Mid-Term Review Report: Advancing the Nagoya Protocol in Countries of the Caribbean Region, (GFL/5060-2711-4E67), UNEP/GEF, 2017

**Reference documents**

- UNEP Evaluation Office MTR Tools Package including Guidance on the preparation of the MTR Inception Report and Guidance on the preparation of the MTR Main Report
- UNEP Evaluation Policy, Revised October 2022
- UNEP Evaluation Manual, Revised June 2022
- Biennial Programme of Work 2018-2019
- UNEP Medium-Term Strategy 2018-2021
- Bali Strategic Plan for Technology and Capacity Building
- GEF-6 Biodiversity Strategy
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity
- Theory of Change Primer – GEF STAP
- Guidelines on the GEF Project and Program Cycle Policy (2020 Update)
- GEF ROTI Handbook, August 2005, OPS4 – Progress Towards Impact

## ANNEX III. BRIEF CV OF THE REVIEWER

| | |
|---|---|
| **Name** | Noel Devany Jacobs Sr |
| **Profession** | Project Development and M&E Specialist<br>Institutional Development & Management Consultants Limited |
| **Nationality** | Belizean |
| **Country experience** | **Africa:** Kenya, Madagascar<br><br>**Americas:** Argentina, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guyana, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru, Suriname, Uruguay<br><br>**Caribbean:** Antigua & Barbuda, Barbados, Belize, Cuba, Dominica, Dominican Republic, Grenada, Jamaica, St. Kitts & Nevis, St. Vincent & the Grenadines, Saint Lucia, Trinidad & Tobago<br><br>**Asia:** Indonesia |
| **Education** | Master's degree in marine biology (1996), National Polytechnic Institute (CINVESTAV), Merida, Yucatan, Mexico<br><br>Bachelor's Degree in Aquaculture Engineering (1992), Technical Institute of the Sea, Guaymas, Sonora, Mexico<br><br>March 2017 – The Strategy Consultant; Chartered Management Institute (CMI)/Institute of Consulting (IC)/Advanced Management Skills (AMS); London, England, United Kingdom.<br><br>March 2017 – The Lean Operations Consultant; Chartered Management Institute (CMI)/Institute of Consulting (IC)/Advanced Management Skills (AMS); London, England, United Kingdom.<br><br>March 2017 – The Professional Consultant; Chartered Management Institute (CMI)/Institute of Consulting (IC)/Advanced Management Skills (AMS), London, England, United Kingdom.<br><br>May 2012 – Advanced Level Organizational Development Certified Consultant Program (ODCC); Institute of Organization Development (IOD), Fort Lauderdale, Florida, U.S.A.<br><br>March 2009 - Practitioner's Program in the Critical Components of Effective Governance; BoardSource, Arlington, Virginia, U.S.A.<br><br>June 2007 – Certified Fund-Raising Manager (CFRM); Centre on Philanthropy, Indiana University, Indianapolis, U.S.A.<br><br>November 2003 – Certificate in Negotiation and Decision-Making Strategies; Columbia University Graduate School of Business, New York, U.S.A<br><br>June 2002 - Leaders in Development: Managing Political & Economic Reform; John F. Kennedy School of Government, Harvard University, Cambridge, Massachusetts, U.S.A. |

**Short biography**

Mr. Jacobs has 19 years of experience working as an International Development Consultant in project design, management, and evaluation primarily in biodiversity, climate change, marine resources, protected areas, land degradation, sustainable tourism, Blue Economy, and policy development. He has successfully designed many GEF projects and has conducted numerous Mid-Term Evaluations of GEF and non-GEF projects. He also has extensive experience as an Institutional Development Consultant, focusing on Institutional Assessments, Organizational Re-structuring, Development of Organizational Policies, Strategic Plans, and Operational Guidelines and Manuals for Organizations and Projects. Mr. Jacobs has worked extensively as a consultant in more than 30 countries in a multitude of sectors including Tourism, Marine Fisheries, Coastal Zone Management, Environment, Climate Change, Aviation, Cultural Heritage, Health, among others. His analytical skills and ability to effectively apply the multi-sector approach in planning and policy development has proven to be a tremendous asset in the delivery of services to a wide diversity of clients primarily in Latin America and the Caribbean.

### **Key specialties and capabilities cover**:

- Design of International Development Projects
- Evaluations and reviews of International Development Projects
- Institutional Assessments
- Organizational Governance
- Strategic Planning
- Policy Development

### Selected assignments and experiences

- GEF-7 Project Document: Energy Efficiency for the Transition to Carbon Neutral Cities in Colombia (ongoing)
- GEF-7 Project Document: Enhancing Political Will for Sustainable Protected Areas Financing
- GEF-7 Project Document: Promoting sustainability in the agave-mezcal value chain through restoration and integrated management of biocultural landscapes in Oaxaca, Mexico
- GEF-7 Project Document: Implementing Alliance for Zero Extinction (AZE) Site Conservation and Preventing Global Extinctions
- GEF-7 Project Document: Mainstreaming biodiversity conservation in the tourism sector of the protected areas and strategic ecosystems of San Andres, Old Providence, and Santa Catalina islands.
- GEF-7 Project Document: Promoting National Blue Economy Priorities Through Marine Spatial Planning in the Caribbean Large Marine Ecosystem
- GEF-7 Project Document: UAVs/Drones for Equitable Climate Change Adaptation: Participatory Risk Management through Landslide and Debris Flow Monitoring in Mocoa, Colombia
- GEF-7 Project Document: Conservation of wildcats and prey species through public-private partnerships and human-jaguar conflict management in Panama.
- GEF-6 Project Document: Improving Environmental Management through Sustainable Land Management in St. Kitts and Nevis
- GEF-6 Project Document: Ecosystem-based biodiversity friendly cattle production framework for the Darien Region of Panama
- GEF-6 Project Document: 'Transformation of the Panela (sugar cane) Sub-Sector in Colombia Through Nationally Appropriate Mitigation Actions (NAMA) to the Impacts of Climate Change'
- GEF-5 Project Document: Andes Adaptation to the Impacts of Climate Change on Water Resources (AICCA)'
- M&E Specialist: Development of an Institutional Monitoring & Evaluation Framework for the Protected Areas Conservation Trust (PACT) with Alignment to the National Protected Areas System (NPAS)
- M&E Specialist: Design of a Monitoring & Evaluation System for the Portfolio of GEF Projects in the Development Bank of Latin America

### Independent reviews/evaluations:

- Mid-Term Review of the Project "Advancing Conservation in the Eastern Caribbean" (UNEP/GEF)
- Mid-Term Review of the Project "Path to 2020 – Antigua & Barbuda" (UNEP/GEF)
- Mid-Term Review of the Project "Strengthening access and benefit sharing (ABS) in the Bahamas" (UNEP/GEF)
- Mid-Term Review of the Project "Effective Implementation of the Access and Benefit Sharing and Traditional Knowledge Regime in Peru in accordance with the Nagoya Protocol" (UNEP/GEF)
- Mid-Term Evaluation of the Project "Sustainable Pathways -- Protected Areas and Renewable Energy" (UNEP/GEF).
- Mid-Term Evaluation of the project "Management and Protection of Key Biodiversity Areas (KBA)" (World Bank/GEF)
- Mid-Term Evaluation of the Project "Marine Conservation and Climate Adaptation Project (MCCAP)" (World Bank/Adaptation Fund)
- Mid-Term Evaluation of Project "Advancing the Nagoya Protocol in Countries of the Caribbean Region" (UNEP/GEF)
- Final Evaluation of Project "Making Tourism Benefit Communities Adjacent to Archaeological Sites" (MTBCAAS)" (European Union)
- Mid-Term Evaluation of Project "Making Tourism Benefit Communities Adjacent to Archaeological Sites" (MTBCAAS)" (European Union)

## ANNEX IV. REVIEW TORS

### TERMS OF REFERENCE

### Mid-Term Review of the UNEP/GEF project

### "Creation of additional biosafety capacities that lead to a full implementation of the Cartagena Protocol on Biosafety in Cuba" and "GEF ID 9860".

- **Section 1: PROJECT BACKGROUND AND OVERVIEW**

## D. Project General Information

**Table 1. Project summary**

| | | | |
|---|---|---|---|
| **UNEP Sub-programme:** | Programme of Work 2021-2022<br><br>Subprogramme 3: Healthy and productive ecosystems<br><br>Subprogramme 4: Environmental governance | **UNEP Division/Branch:** | Ecosystems Division, GEF Biodiversity and Land Degradation Unit, Biodiversity and Land Branch. |
| **Expected Accomplishment(s):** | National capacities for LMO identification and detection strengthened and supporting decision-making processes.<br><br>National system for monitoring and surveillance established and operational.<br><br>Socio-economic considerations as per article 26 are taken into account in decision-making. | **Programme of Work Output(s):** | Two national laboratories: Centre for Scientific Research for the Civil Defence (CICDC)<br><br>and National Centre for Agricultural Health equipped to play a role as national reference laboratories. (accredited by the NC ISO / IEC 17025:2000)<br><br>Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment. |

| | | | |
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| | | | Detailed analysis of the socio-economic considerations of importance for Cuba related to LMO impacts completed. |
| **SDG(s) and indicator(s)** | SDG 2 – Zero Hunger<br><br>Target 2.5 By 2020, maintain the genetic diversity of seeds, cultivated plants, and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, and promote access to and fair and equitable sharing of benefits arising.<br><br>Indicator 2.5.1 Number of plant and animal genetic resources for food and agriculture secured in either medium- or long-term conservation facilities.<br><br>Indicator 2.5.2 Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction. | | |
| **GEF Core Indicator Targets** (identify these for projects approved prior to GEF-7) | | | |
| **Dates of previous project phases:** | | **Status of future project phases:** | |

**FROM THE PROJECT 'SPIR REPORT (use latest version):**

| | |
|---|---|
| **Project Title:** | Creation of additional Biosafety Capacities that lead to a Full Implementation of the Cartagena Protocol on Biosafety in Cuba. |

| | |
|---|---|
| **Executing Agency:** | Office of Environmental Regulation and Security (ORSA) of the Ministry of Science, Technology and Environment. |

| | |
|---|---|
| **Project partners:** | CICDC: Centre for Scientific Research for the Civil Defence (CICDC)<br><br>CENSA: National Centre for Agricultural Health<br><br>CENATOX: National Toxicology Centre |

| | |
|---|---|
| | UNDP Cuba<br><br>EMIDICT: Specialized Importer, Exporter and Distributor for Science and Technology (company in charge of equipment imports) |

| | |
|---|---|
| **Geographical Scope:** | National |

| | |
|---|---|
| **Participating Countries:** | Cuba |

| | | | |
|---|---|---|---|
| **GEF project ID:** | 9860 | **IMIS number*[1]:** | GFL-11207-14AC0003-SB-014367 |
| **Focal Area(s):** | Biodiversity | **GEF OP #:** | |
| **GEF Strategic Priority/Objective:** | BD-2 Program 5 | **GEF approval date*:** | 17 July 2017 |
| **UNEP approval date:** | 24 March 2020 | **Date of first disbursement*:** | 8 June 2020 |
| **Actual start date[2]:** | 3 April 2020 | **Planned duration:** | 60 months |
| **Intended completion date*:** | 31 March 2025 | **Actual or Expected completion date:** | N/A |
| **Project Type:** | Medium-sized Project (MSP) | **GEF Allocation*:** | USD 1,826,484 |
| **PPG GEF cost*:** | - | **PPG co-financing*:** | - |
| **Expected MSP/FSP Co-financing*:** | USD 1,920,443 | **Total Cost*:** | USD 3,746,927 |
| **Mid-term Review/eval. (planned date):** | January 2023 | **Terminal Evaluation (planned date):** | N/A |
| **Mid-term Review/eval. (actual date):** | N/A | **No. of revisions*:** | 3 |

[1] Fields with an * sign (in yellow) should be filled by the Fund Management Officer

[2] Only if different from first disbursement date, e.g., in cases were a long time elapsed between first disbursement and recruitment of project manager.

| | | | |
|---|---|---|---|
| **Date of last Steering Committee meeting:** | 4 May 2022 | **Date of last Revision*:** | 17 May 2022 |
| **Disbursement as of 31 December 2022*:** | USD 891,449.33 | **Date of planned financial closure*:** | 30 April 2026 |
| **Date of planned completion[3]*:** | 31 March 2025 | **Actual expenditures reported as of 30 December 2022[4]:** | USD 644,980.62 |
| **Total co-financing realized as of 31 December 2022** | USD 556,487.74 | **Actual expenditures entered in IMIS as of 31 December 2022*:** | N/A |
| **Leveraged financing:[5]** | | | |

## E. Project Rationale

The use of Genetically Modified Organisms (GMO) has been controversial over the years since they have the potential to contribute to human wellbeing in fields like agriculture, bioremediation, and climate change, amongst others. However, their safe use is imperative to minimize possible risks to the environment and human health.

Based on this, the Cartagena Protocol on Biosafety calls for international standards on the use of GMOs under a precautionary principle. Cuba along with other countries in the region has made significant efforts towards having a functional biosafety system. Nonetheless, the complexity of such enterprise requires additional efforts to allow the country to take advantage of use of GMOs as well as to minimize the possible negative effects that they could have. The former UNEP-GEF projects had a vast impact on the country´s ability to do this, and on the capacities of the national biosafety authority (Office of Environmental Regulation and Security, ORSA) to fulfil its role, but there are still prevailing needs that should be addressed in order to guarantee a more smooth and coherent operation of the system. Some of these needs relates to local capacity for GMO monitoring, surveillance, and detection; issues that were not addressed during the former implementation project. Similarly, issues related to Liability and Redress (L&R) and Socio-Economic Considerations (SEC) have not been addressed and are of great importance for the country considering its unique situation related to trade, and the possibility of upcoming changes in this respect, as well as the recent ratification of the Supplementary Protocol on Liability and Redress, in alignment with CBD COP-MOP decision VIII/11.

[3] If there was a "Completion Revision" please use the date of the revision.

[4] Information to be provided by Executing Agency/Project Manager

[5] See above note on co-financing

Based on the former, the global environmental problem that the current initiative will try to address is the unsafe use of GMOs and the associated consequences that this could have to the environment and human health.

**F. Project Results Framework**

Project objective: To further complete the process of implementation of the Cartagena Protocol on Biosafety (CPB) through the creation of additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms (GMOs) and the socio-economic considerations of importance for Cuba related to them.

**Component 1: Creation of the necessary capacities for identification and detection of Living Modified Organisms (LMOs).**

**Outputs for component 1:**

1.1.1 Two national laboratories -- Centre for Scientific Research for the Civil Defence (CICDC) and National Centre for Agricultural Health (CENSA) - equipped to play a role as national reference laboratories. (accredited by the NC ISO / IEC 17025:2000)

1.1.2 MoU between CICDC, CENSA, and the National Competent Authority (the National Centre of Biological Safety) for the services of detection.

1.1.3 Harmonized Toolkits / Guidelines / Protocols / Standard Operating Procedures (SOPs) on LMO detection developed and/or adapted to suit Cuba´s reality and needs.

1.1.4 Personnel at CICDC and CENSA and the NCA capacitated through training programs on detection and identification of GMOs.

**Outputs for component 2:**

2.1.1 Monitoring and surveillance system designed (building on early developments of the project implementation) including operating guidelines, clear roles and responsibilities, and equipment.

2.1.2 Strategy for field detection (screening procedures) developed.

2.1.3 Administrative and technical guides designed for each involved institution (Veterinary and Phytosanitary borders Officers (Ministry of Agriculture) and Customs Officers (General Customs of the Republic of Cuba) and inspector from ORSA) in the National Customs System.

2.1.4 Workshops for customs officers and personnel involved in M&S system on how to use the guidelines developed on 2.1.3.

Component 3: Identification of socio-economic considerations of importance for Cuba arising from the impact of GMOs, as per article 26 of the CPB.

**Outputs for component 3:**

3.1.1 Detailed analysis of the socio-economic considerations of importance for Cuba related to GMO impacts completed.

3.1.2 Informative materials on socio-economic considerations produced and distributed amongst general public and relevant authorities.

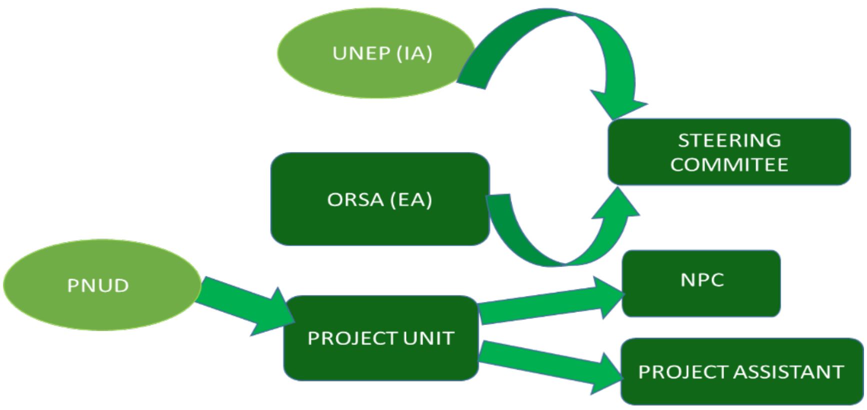
**G. Executing Arrangements**

Project design consider the participation of key stakeholders. In the case of biosafety, at least four institutions play an important role in the achievement of objectives and the implementation of the Cartagena Protocol; each of these four institutions has been identified in the development of the national biosafety framework. The Office of Environmental Regulation and Security (ORSA) of the Ministry of Science, Technology and Environment (CITMA) is the competent authority for Biosecurity in Cuba and the national authority for the Cartagena Protocol. ORSA is responsible for and coordinates the process of decision making on GMOs, including consultations with authorities of other agencies, and it establishes legal and technical standards for biosafety. The designated laboratories, namely the Center for Scientific Research for the Civil Defense (CICDC) and the National Centre for Agricultural Health (CENSA), are responsible for the identification and detection of the GMOs, and the National Centre for Toxicology (CENATOX) carries on eco-toxicological studies for the evaluation of adverse impacts from GMOs, under the guidance and oversight of the ORSA. The National Accreditation Office of the Republic of Cuba (ONARC) directly affect the accreditation of laboratories.

The table below summarizes the participants in the project and their responsibilities.

| Institution | Responsibilities |
|---|---|
| The Office of Environmental Regulation and Security (ORSA) of the Ministry of Science, Technology and Environment (CITMA) | According to its mandate, the ORSA coordinate and implement the main components of the project. There is a project work group, and it is the main coordinator of the project activities, maintaining close links with other institutions. The ORSA has been the lead executing agency of former UNEP-GEF projects and therefore has the necessary experience to undertake this job. |
| Centre for Scientific Research for the Civil Defence (CICDC)and the National Centre for Agricultural Health (CENSA) | For activities related to the identification and detection of GMOs on behalf of the National Competent Authority. A representative of each laboratory participates on the Project Steering Committee. The labs work on the development of protocols and other technical documents needed to make appropriate determinations regarding GMOs. |
| National Centre for Toxicology (CENATOX) | CENATOX undertake eco-toxicological studies for the evaluation of adverse impacts into the environment from GMOs. This activity represents the essential base for the monitoring and surveillance system and will allow for the quick detection of adverse effects from GMOs so that adequate response measures can be adopted. |
| National Accreditation Authority of the Republic of Cuba (ONARC) | ONARC play a leading role in the process of accreditation of designated laboratories. This institution also coordinates the process of accreditation of professional skills related to biosafety. |
| United Nations Environment Programme (UNEP) | UN Environment is the Implementing Agency of the project and provide technical support to the ORSA. As an implementing agency, UN Environment administer the funding sent to the Executing Agency (ORSA), participate as a member of the Steering Committee, and undertake monitoring activities of the project. UN Environment act through its Regional Office for Latin America and the Caribbean located in Panama. |

| | |
|---|---|
| The United Nations Development Programme (UNDP) | UNDP Cuba participate in the operational-financial processes for payment of suppliers (UNEP-UNDP Cuba-ORSA) and facilitate other payments, for example, vatic for capacitation's were liquidity is necessary to be done. The contracting for the Mid-Term Review of the consultant/foreign firm will be done through UNDP, based on the proposal of an expert previously selected by ORSA and UNEP, indicating to the executing agency the procedures required for such purposes. |




## H. Project Cost and Financing

| Sources of Co-financing | Name of Co-financier | Type of Co-financing | Amount ($) |
|---|---|---|---|
| Recipient Government | National Centre of Biological Safety (CSB) | Grants | 1,308,031 |
| Recipient Government | Centro de Investigaciones Científicas de la Defensa Civil (CICDC) | Grants | 130,500 |
| Recipient Government | Centro Nacional de Sanidad Agropecuaria (CENSA) | Grants | 459,412 |
| Recipient Government | Centro Nacional de Toxicología (CENATOX) | Grants | 22,500 |
| **Total Co-financing** | | | **1,920,443** |

| GEF Agency | Trust Fund | Country/ Regional/Global | Focal Area | Programming of Funds | (in $) | | |
|---|---|---|---|---|---|---|---|
| | | | | | GEF Project Financing | Agency | Total |

| | | | | | (a) | Fee [a] (b) | (c)=a+b |
|---|---|---|---|---|---|---|---|
| UNEP | GEF TF | Cuba | Biodiversity | | 1,826,484 | 173,516 | 2,000,000 |
| **Total Grant Resources** | | | | | 1,826,484 | 173,516 | 2,000,000 |

## I. Implementation Issues

The project has experienced different risks in terms of implementation and actions have been taken to solve them:

- The project was approved in July 2017; however, the first activities were carried out in April 2020, due to changes in the structure of the Ministry of Science, Technology and Environment that impacted the internal of ORSA. The CSB (signatory of the project) ceased to exist to be structured in a Department of Biodiversity and Biosafety, belonging to the Directorate of Environmental Control, assuming new roles, including biodiversity issues. This led to the exodus of some key specialists and, consequently, the restructuring of the project's coordinating group. Even before the signing of the PCA, a strategy for implementation was designed through conciliation meetings between the participating entities and the project team with the assistance of a consultant, to identify the current national context, review the approved documents and propose relevant modifications for the start-up. In this regard, it was proposed to UNEP to make an initial adjustment to the budget, and the procurement appendix was reviewed, making proposals for the purchase of equipment according to the needs of the moment and the capacities to be created in the laboratories.

- Worsening of the epidemiological situation in the world and Cuba with the COVID-19 Pandemic. A health and biosafety Protocol focused on the transmission of respiratory infections was prepared for the management of meetings and workshops. Vaccination of the entire project team and other related entities was carried out for the incorporation to meetings and workshops. An exhaustive search of places for the development of the events was made, guaranteeing sufficient space and safe conditions, certified through national and international sanitary protocols, limiting the number of participants when necessary.

- Cuba has been restructuring its economic model, with changes in the international monetary system, taxes, banking regulations, etc. For that reason, the project has identified and developed proactive management for all activities that require external services and identify suppliers, address the difficulties for the implementation of the project with the Coordinating Group and institutional authorities. In addition, the project uses UNDP as a third party for procurement to ensure that project funds are kept in USD and are thus less vulnerable to change in Cuban economy.

- Fluctuations in the personnel during the project implementation entailing changes in the coordinator and other important support staff. A national document was created with an update of the new personnel, which was approved by the International Affairs Office. To mitigate this risk, the project will link several people on key tasks. Moreover, minutes and reports of all the activities implemented will be made to maintain the historical memory of the project and ensure that new members can have a solid foundation in order to continue the implementation.

- Delay in acquiring necessary inputs (goods and services) for project activities that depend on an import process. However, we have performed trend analysis of the current prices of the goods and services to define priorities if needed, meetings with the EMIDICT Management to address the issues. The project carries out import procedures well in advance in order to procure goods and services in a timely manner; it also maintains regular contacts with importing companies and negotiate support from UNDP for direct payments in USD.

- ## Section 2. OBJECTIVE AND SCOPE OF THE MID-TERM REVIEW

## J. Objective of the Review

In line with the UNEP Evaluation Policy[1] and the UNEP Programme Manual[2], the Mid-Term Review is undertaken approximately half-way through project implementation to analyse whether the project is on-track, what problems or challenges the project is encountering, and what corrective actions are required. The MTR will assess project performance to date (in terms of relevance, effectiveness, and efficiency), and determine the likelihood of the project achieving its intended outcomes and supporting their sustainability.

## K. Key Review Principles

Mid-Term Review findings and judgements will be based on **sound evidence and analysis**, clearly documented in the Review Report. Information will be triangulated (i.e. verified from different sources) as far as possible, and when verification is not possible, the single source will be mentioned (whilst anonymity is still protected). Analysis leading to evaluative judgements should always be clearly spelled out.

As this Review is being undertaken at the mid-point of project implementation, particular attention will be given to identifying implementation challenges and risks to achieving the expected project objectives and sustainability, which will support potential course correction. Possible questions to be considered include:

- Does the TOC properly reflect the project's intended change process?
- Is the stakeholder analysis still appropriate and adequate to support the project's ambitions?
- Are results statements in keeping with both UNEP and GEF definitions (e.g. outcomes are expressed as the uptake or use of outputs)
- Are roles and responsibilities commonly understood and playing out effectively?
- Is there an effective monitoring mechanism for the project's implementation (this is separate from, and supports, reporting in the annual PIR)?
- Is the rate of expenditure appropriate for the mid-point?
- Have plans for inclusivity (human rights, gender considerations, disability inclusion etc.) been implemented as planned, or does more need to be done?
- Are safeguard identification and mitigation plans being monitored and steps taken to minimize negative effects?
- Is there an exit strategy in place and are the elements needed for the project's benefits to be sustained after the project end, being incorporated in the project implementation?
- Have recommendations from previous performance assessments (where they exist) been appropriately addressed?
- (Where relevant) What changes were made to adapt to the effects of COVID-19 and how might any changes affect the project's performance?

A Mid-Term Review is a *formative assessment*, which requires that the consultants go beyond the assessment of "*what*" the project performance is and make a serious effort to provide a deeper understanding of "*why*" the performance is as it is. (i.e. what is contributing to the achievement of the project's results). This should provide the basis for the lessons that can be drawn from the project at the mid-point and the recommendations that support adaptive management for the remainder of the project.

**Attribution, Contribution and Credible Association:** To *attribute* any outcomes and impacts to a project intervention, one needs to consider the difference between what has happened with, and what would have happened without, the project (i.e. take account of changes over time and between contexts in order to isolate the effects of an intervention). This requires appropriate baseline data and the identification of a relevant counterfactual, both of which are frequently not available for

[1]https://www.unenvironment.org/about-un-environment/evaluation-office/policies-and-strategies

[2]https://wecollaborate.unep.org

evaluations. Establishing the *contribution* made by a project in a complex change process relies heavily on prior intentionality (e.g. approved project design documentation, logical framework) and the articulation of causality (e.g. narrative and/or illustration of the Theory of Change). Robust evidence that a project was delivered as designed and that the expected causal pathways developed supports claims of contribution and this is strengthened where an alternative theory of change can be excluded. A *credible association* between the implementation of a project and observed positive effects can be made where a strong causal narrative, although not explicitly articulated, can be inferred by the chronological sequence of events, active involvement of key actors and engagement in critical processes.

A key aim of the Mid-Term Review is to encourage reflection and learning by UNEP staff, the Executing Agency and key project stakeholders. The Review Consultant should consider how reflection and learning can be promoted, both through the review process and in the communication of review findings and key lessons. Clear and concise writing is required on all review deliverables. There may be several intended audiences, each with different interests and needs regarding the report. The Task Manager will plan with the Review Consultant which audiences to target and the easiest and most effective way to communicate the key review findings and lessons to them. This may include some or all of the following: a webinar, conference calls with relevant stakeholders, the preparation of a review brief or interactive presentation. Draft and final versions of the Main Review Report will be shared with key stakeholders by the Task Manager and a copy of the final version will be submitted to the UNEP Evaluation Office, who will provide an assessment of the quality of the Review Report based on a standard UNEP template.

## L. Key Strategic Questions.

In addition to the evaluation criteria outlined in Section 10 below, the Review will address the **strategic questions** listed below. These are questions of interest to UNEP and to which the project is believed to be able to make a substantive contribution. Also included are five questions that are required when reporting in the GEF Portal and these must be addressed in the MTR.

Q1: To what extent is the project following a robust theory of change with appropriately formulated outputs, direct outcomes, intermediate states, and long-term results? What revisions are required to ensure that the intervention can be effectively evaluated at the end of its cycle? This includes consideration of whether the outcome indicators are verifiable and appropriate for recording progress towards the achievement of the development objectives.

Q2: How sustainable and replicable are efforts to create additional capacities in the areas of identification, detection, monitoring, and surveillance of Living Modified Organisms (GMOs)?

Q3: To what extent are socioeconomic considerations of importance to Cuba related to the Cartagena Protocol on Biosafety being tackled by this project and how perennial are efforts in this regard being undertaken by the project?

Address the questions required for the GEF Portal in the appropriate parts of the report and provide a **summary of the findings in the Conclusions section of the report**:

a) Under Monitoring and Reporting/Monitoring of Project Implementation:
What is the performance at the project's mid-point against Core Indicator Targets? *(For projects approved prior to GEF-7, these indicators will be identified retrospectively and comments on performance provided)*.
b) Under Factors Affecting Performance/Stakeholder Participation and Cooperation:
What has been the progress, challenges, and outcomes regarding engagement of stakeholders in the project/program? *(This should be based on the description included in the Stakeholder Engagement Plan or equivalent documentation submitted at CEO Endorsement/Approval)*
c) Under Factors Affecting Performance/Responsiveness to Human Rights and Gender Equality:
What has been the progress, challenges, and outcomes regarding gender-responsive measures and any intermediate gender result areas? *(This should be based on the documentation at CEO Endorsement/Approval, including gender-sensitive indicators contained in the project results framework or gender action plan or equivalent)*
d) Under Factors Affecting Performance/Environmental and Social Safeguards:

What has been the experience at the project's mid-point against the Safeguards Plan submitted at CEO Approval? The risk classifications reported in the latest PIR report should be verified and any measures taken to address identified risks assessed. *(Any supporting documents gathered by the Consultant during this review should be shared with the Task Manager for uploading in the GEF Portal)*

e) Under Factors Affecting Performance/Communication and Public Awareness:

What has been the progress, challenges, and outcomes regarding the implementation of the project's Knowledge Management Approach, including: Knowledge and Learning Deliverables (e.g. website/platform development); Knowledge Products/Events; Communication Strategy; Lessons Learned and Good Practice; Adaptive Management Actions. *(This should be based on the documentation approved at CEO Endorsement/Approval)*

## M. Evaluation Criteria

All evaluation criteria will be rated on a six-point scale. Sections A-G below, outline the scope of the criteria and a link to a table for recording the ratings is provided in Annex 1. A weightings table will be provided in excel format (see notes in Annex 1) to support the determination of an overall project rating.

### *A. Strategic Relevance*

The Review will assess the extent to which the activity is suited to the priorities and policies of the target group, recipient, and donor. The Review will include an assessment of 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, as well as each country's UNDAF. Under strategic relevance an assessment of the complementarity of the project with other interventions addressing the needs of the same target groups will be made. This criterion comprises four elements:

**i. *Alignment to the UNEP Medium Term Strategy[3] (MTS), Programme of Work (POW) and Strategic Priorities***

The Review should assess the project's alignment with the MTS and POW under which the project was approved and include, in its narrative, reflections on the scale and scope of any contributions made to the planned results reflected in the relevant MTS and POW. UNEP strategic priorities include the Bali Strategic Plan for Technology Support and Capacity Building[4] (BSP) and South-South Cooperation (S-SC). The BSP relates to the capacity of governments to comply with international agreements and obligations at the national level; promote, facilitate and finance environmentally sound technologies and to strengthen frameworks for developing coherent international environmental policies. S-SC is regarded as the exchange of resources, technology, and knowledge between developing countries.

**ii. *Alignment to Donor/Partner Strategic Priorities***

Donor strategic priorities will vary across interventions. The Review will assess the extent to which the project is suited to, or responding to, donor priorities. In some cases, alignment with donor priorities may be a fundamental part of project design and grant approval processes while in others, for example, instances of 'softly earmarked' funding, such alignment may be more of an assumption that should be assessed.

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

[3] UN Environment's Medium-Term Strategy (MTS) is a document that guides UN Environment's programme planning over a four-year period. It identifies UN Environment's thematic priorities, known as Sub-programmes (SP), and sets out the desired outcomes, known as Expected Accomplishments (EAs), of the Sub-programmes. https://www.unenvironment.org/about-un-environment/evaluation-office/our-evaluation-approach/un-environment-documents

[4] http://www.unep.fr/ozonaction/about/bsp.htm

The Review will assess the alignment of the project with global priorities such as the SDGs and 2030 Agenda. The extent to which the intervention is suited, or responding to, the stated environmental concerns and needs of the countries, sub-regions, or regions where it is being implemented will be considered. Examples may include UN Development Assistance Frameworks (UNDAF) or, national or sub-national development plans, poverty reduction strategies or Nationally Appropriate Mitigation Action (NAMA) plans or regional agreements etc. Within this section consideration will be given to whether the needs of all beneficiary groups are being met and reflects the current policy priority to leave no-one behind.

**iv. *Complementarity with Existing Interventions/Coherence*[5]**

An assessment will be made of how well the project, either at design stage or during the project inception or mobilization[6], took account of ongoing and planned initiatives (under the same sub-programme, other UNEP -programmes, or being implemented by other agencies within the same country, sector or institution) that address similar needs of the same target groups. The Review will consider if the project team, in collaboration with Regional Offices and Sub-Programme Coordinators, made efforts to ensure their own intervention was complementary to other interventions, optimized any synergies and avoided duplication of effort. Examples may include work within UNDAFs or One UN programming. Linkages with other interventions should be described and instances where UNEP's comparative advantage has been particularly well applied should be highlighted.

### *B. Effectiveness*

The Review will assess effectiveness across three dimensions: delivery of outputs, achievement of project outcomes and, where appropriate and feasible, likelihood of impact. At the mid-point more emphasis is placed on performance at the output and outcome levels, but observations about likelihood of impact may be helpful for course correction or adjusting the emphasis of the project's efforts.

***i. Availability of Outputs*[7]**

The Review will assess the project's success in producing the programmed outputs and achieving targets and milestones as per the project design document (ProDoc). Any *formal* modifications/revisions made during project implementation will be considered part of the project design. Where the project outputs are inappropriately or inaccurately stated in the ProDoc, a table should be provided showing the original formulation and the amended version for transparency. The delivery of outputs will be assessed in terms of both quantity and quality, and the assessment will consider their usefulness and the timeliness of their provision. It is noted that emphasis is placed on the performance of those outputs that are most important to achieve outcomes. The Review will briefly explain the reasons behind the success or shortcomings of the project in delivering its programmed outputs and meeting expected quality standards.

***ii. Achievement of Project Outcomes*[8]**

The achievement of project outcomes is assessed as performance against the project outcomes defined in the Project Results Framework[9]. These are outcomes that are intended to be achieved by

[5]This sub-category is consistent with the new criterion of 'Coherence' introduced by the OECD-DAC in 2019.

[6]A project's inception or mobilization period is understood as the time between project approval and first disbursement. Complementarity during project implementation is considered under Efficiency, see below.

[7]Outputs are the availability (for intended beneficiaries/users) of new products and services and/or gains in knowledge, abilities, and awareness of individuals or within institutions (UNEP, 2019)

[8]Outcomes are the use (i.e. uptake, adoption, application) of an output by intended beneficiaries, observed as changes in institutions or behavior, attitude or condition (UNEP, 2019)

[9]UNEP staff are currently required to submit a Theory of Change with all submitted project designs. The level of 'reconstruction' needed during an evaluation will depend on the quality of this initial TOC, the time that has lapsed between project design and

the end of the project timeframe and within the project's resource envelope. Emphasis is placed on the achievement of project outcomes that are most important for attaining intermediate states. As with outputs, a table can be used where substantive amendments to the formulation of project outcomes is necessary to make them consistent with UNEP guidelines. Where possible, the review should report evidence of attribution, contribution or credible association between UNEP's intervention and the project outcomes.

***iii. Likelihood of Impact***

Based on the articulation of longer-term effects as defined in the project objective or stated intentions, the Review will, where possible, assess the likelihood of the intended, positive impacts becoming a reality.

The Review will also consider the likelihood that the intervention may lead, or contribute, to unintended negative effects (e.g. will vulnerable groups such as those living with disabilities and/or women and children, be disproportionally affected by the project?). Some of these potential negative effects may have been identified in the project design as risks or as part of the analysis of Environmental, Social and Economic Safeguards[10]. The Review will consider the extent to which the project is playing a catalytic role or is promoting longer-term scaling up and/or replication[11].

### *C. Financial Management*

Under financial management the Mid-Term Review will assess a) whether the rate of spend is consistent with the project's length of implementation to-date, the agreed workplan and the delivery of outputs and b) whether financial reporting and/or auditing requirements are being met consistently and to adequate standards by all parties. This includes an assessment of whether UNEP's financial management policies and the GEF's fiduciary standards are being met. Any financial management issues that are affecting the timely delivery of the project or the quality of its performance will be highlighted.

### *D. Efficiency*

The Review will assess the *cost-effectiveness and timeliness* of project execution. Focusing on the translation of inputs into outputs, cost-effectiveness is the extent to which an intervention has achieved, or is expected to achieve, its results at the lowest possible cost. Timeliness refers to whether planned activities were delivered according to expected timeframes as well as whether events were sequenced efficiently. The Review will describe any cost or time-saving measures put in place to maximize results within the secured budget and agreed project timeframe and consider whether the project is being implemented in the most efficient way compared to alternative interventions or approaches. The Review will also assess ways in which potential project extensions can be avoided through stronger project management.

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implementation (which may be related to securing and disbursing funds) and the level of any changes made to the project design. In the case of projects pre-dating 2013 the intervention logic is often represented in a logical framework and a TOC will need to be constructed in the inception stage of the evaluation.

[10]Further information on Environmental, Social and Economic Safeguards (ESES) can be found at http://wedocs.unep.org/handle/20.500.11822/8718http://www.unep.org/about/eses/

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

### *E. Monitoring and Reporting*

The Review will assess monitoring and reporting across two sub-categories: monitoring of project implementation, and project reporting.

*i. Monitoring of Project Implementation*

Each project should be supported by a sound monitoring plan that is designed to track progress against SMART[12]results towards the achievement of the project's outputs and outcomes, including at a level disaggregated by gender, marginalisation, or vulnerability, including those living with disabilities. The Review will assess the use and quality of the monitoring plan. In particular, the evaluation will assess the relevance and appropriateness of the project indicators as well as the methods used for tracking progress against them as part of conscious results-based management. This assessment will include consideration of whether the project gathered relevant and good quality baseline data that is accurately and appropriately documented. TheReview will assess whether the monitoring system is operational and facilitates the timely tracking of results and progress towards project milestones and targets throughout the project implementation period. It will also consider the quality of the information generated by the monitoring system during project implementation and how it was used to adapt and improve project execution, achievement of outcomes and ensure sustainability. The Review should confirm that funds allocated for monitoring are being used to support this activity.

The performance at the project's mid-point against Core Indicator Targets should be reviewed. For projects approved prior to GEF-7, these indicators will be identified retrospectively and comments on performance provided.

*ii. Project Reporting*

Projects funded by GEF have requirements with regard to verifying documentation and reporting (i.e. the Project Implementation Reviews, Tracking Tool, and CEO Endorsement template[13]), which will be made available by the Task Manager. The Review will assess the extent to which both UNEP and GEF reporting commitments have been fulfilled. Where corrective action is indicated in the annual Project Implementation Review reports (e.g. as an identified risk), the Review Consultant will record whether this action has been taken.

### *F. Sustainability*

Sustainability[14] is understood as the probability of the benefits associated with the project outcomes being maintained and developed after the close of the intervention. The Review will identify and

[12]SMART refers to results that are specific, measurable, achievable, relevant and time oriented. Indicators help to make results measurable.

[13]The Consultant(s) should verify that the annual Project Implementation Reviews have been submitted, that the Tracking Tool is being kept up-to-date and that in the CEO Endorsement template Table A and Section E have been completed.

[14]As used here, 'sustainability' means the long-term maintenance of outcomes and consequent impacts, whether environmental or not. This is distinct from the concept of sustainability in the terms 'environmental sustainability' or 'sustainable development', which imply 'not living beyond our means' or 'not diminishing global environmental benefits' (GEF STAP Paper, 2019, Achieving More Enduring Outcomes from GEF Investment)

assess the key conditions or factors that are likely to undermine or contribute to the persistence of benefits at the outcome level. Some factors of sustainability may be embedded in the project design and implementation approaches while others may be contextual circumstances or conditions that evolve over the life of the intervention. Where applicable an assessment of bio-physical factors that may affect the sustainability of project outcomes may also be included.

The Review will ascertain that the project has put in place an appropriate exit strategy and measures to mitigate risks to sustainability. The Review Consultant will consider a) the level of ownership, interest and commitment among government and other stakeholders to take the project achievements forwards, b) the extent to which project outcomes are dependent on future funding for the benefits they bring to be sustained and c) the extent to which the sustainability of project outcomes is dependent on issues relating to institutional frameworks and governance. It will consider whether institutional achievements such as governance structures and processes, policies, sub-regional agreements, legal and accountability frameworks etc. are robust enough to continue delivering the benefits associated with the project outcomes after project closure.

### *I. Factors Affecting Project Performance and Cross-Cutting Issues*

*These factors are rated in the ratings table but can be discussed as cross-cutting themes as appropriate under the other evaluation criteria, above. Where the issues have not been addressed under other evaluation criteria, the consultant(s) will provide summary sections under the following headings)*

*i. Preparation and Readiness*

This criterion focuses on the inception or mobilisation stage of the project. The Review will assess whether appropriate measures were taken to either address weaknesses in the project design or respond to changes that took place between project approval, the securing of funds and project mobilisation. In particular the Review will consider the nature and quality of engagement with stakeholder groups by the project team, the confirmation of partner capacity and development of partnership agreements as well as initial staffing and financing arrangements.

*ii. Quality of Project Implementation and Execution*

Specifically, for GEF funded projects, this factor refers separately to the performance of the Executing Agency and the technical backstopping and supervision provided by UNEP, as the Implementing Agency.

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

*iii. Stakeholder Participation and Cooperation*

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

The progress, challenges, and outcomes regarding engagement of stakeholders in the project/program should be reviewed. This should be based on the description included in the Stakeholder Engagement Plan or equivalent documentation submitted at CEO Endorsement/Approval.

*iv. Responsiveness to Human Rights and Gender Equity*

The Review will ascertain to what extent the project has applied the UN Common Understanding on the human rights-based approach (HRBA) and the UN Declaration on the Rights of Indigenous People. Within this human rights context the Review will assess to what extent the intervention adheres to UNEP's Policy and Strategy for Gender Equality and the Environment[15].

The report should present the extent to which the intervention, following an adequate gender analysis at design stage, has implemented the identified actions and/or applied adaptive management to ensure that Gender Equity and Human Rights are adequately considered. In particular, the Review will consider to what extent to which *project design, the implementation that underpins effectiveness and monitoring* have taken into consideration: (i) possible gender inequalities in access to, and the control over, natural resources; (ii) specific vulnerabilities of disadvantaged groups (especially women, youth and children and those living with disabilities) to environmental degradation or disasters; (iii) the role of women in mitigating or adapting to environmental changes and engaging in environmental protection and rehabilitation.

The progress, challenges, and outcomes regarding gender-responsive measures and any intermediate gender result areas should be reviewed. This should be based on the documentation at CEO Endorsement/Approval, including gender-sensitive indicators contained in the project results framework or gender action plan or equivalent.

*v. Environmental and Social Safeguards*

UNEP projects address environmental and social safeguards primarily through the process of environmental and social screening, risk assessment and management (avoidance or mitigation) of potential environmental and social risks and impacts associated with project and programme activities. The evaluation will confirm whether UNEP requirements[16] were met to: screen proposed projects for any safeguarding issues; conduct sound environmental and social risk assessments; identify and avoid, or where avoidance is not possible, mitigate, environmental, social, and economic risks; apply appropriate environmental and social measures to minimize any potential risks and harm to intended beneficiaries and report on the implementation of safeguard management measures taken.

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[15]The Evaluation Office notes that Gender Equality was first introduced in the UNEP Project Review Committee Checklist in 2010 and, therefore, provides a criterion rating on gender for projects approved from 2010 onwards. Equally, it is noted that policy documents, operational guidelines and other capacity building efforts have only been developed since then and have evolved over time. https://wedocs.unep.org/bitstream/handle/20.500.11822/7655/-Gender_equality_and_the_environment_Policy_and_strategy-2015Gender_equality_and_the_environment_policy_and_strategy.pdf.pdf?sequence=3&isAllowed=y

[16]For the review of project concepts and proposals, the Safeguard Risk Identification Form (SRIF) was introduced in 2019 and replaced the Environmental, Social and Economic Review note (ESERN), which had been in place since 2016. In GEF projects safeguards have been considered in project designs since 2011.

The evaluation will also consider the extent to which the management of the project is minimising UNEP's environmental footprint.

The Safeguards Plan submitted at CEO Approval should be reviewed, the risk classifications verified, and any measures taken to address identified risks assessed. Any supporting documents gathered by the Consultant should be shared with the Task Manager.

*vi. Country Ownership and Driven-ness*

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

*vii. Communication and Public Awareness*

The Review will assess the effectiveness of a) communication of learning and experience sharing between project partners and interested groups arising from the project during its life and b) public awareness activities that were undertaken during the implementation of the project to influence attitudes or shape behaviour among wider communities and civil society at large. The Review should consider whether existing communication channels and networks were used effectively, including meeting the differentiated needs of gender or marginalised groups, and whether any feedback channels were established. Where knowledge sharing platforms have been established under a project the Review will comment on the sustainability of the communication channel under either socio-political, institutional, or financial sustainability, as appropriate.

The progress, challenges and outcomes regarding the implementation of the project's Knowledge Management Approach, including Knowledge and Learning Deliverables (e.g. website/platform development); Knowledge Products/Events; Communication Strategy; Lessons Learned and Good Practice; Adaptive Management Actions should be reviewed. This should be based on the documentation approved at CEO Endorsement/Approval.

## Section 3. REVIEW APPROACH, METHODS AND DELIVERABLES

The Mid-Term Review will use a participatory approach whereby key stakeholders are kept informed and consulted throughout the review process. Both quantitative and qualitative evaluation methods will be used as appropriate to determine project achievements against the expected outputs, outcomes, and impacts. It is highly recommended that the Review Consultant maintains close communication with the project team and promotes information exchange throughout the review implementation phase in order to increase their (and other stakeholder) ownership of the review findings.

Where applicable, the Review Consultant should provide a geo-referenced map that demarcates the area covered by the project and, where possible, provide geo-reference photographs of key intervention sites (e.g. sites of habitat rehabilitation and protection, pollution treatment infrastructure, etc.)

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

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

Relevant background documentation, inter alia: relevant policies, laws and regulations: Legislation to support the implementation of the main obligations under the Cartagena Protocol is already in place in Cuba, headed by Decree Law No. 190 and associated technical and procedural regulations covering the technical biosafety requirements for facilities with biohazard in general and the procedures of the regulatory authority to undertake control functions through two main mechanisms: permits and inspections. Decision-making processes and risk assessment and management are fully covered in the existing legal framework, and further supported by technical documents such as a Guide for Risk Assessment and the adoption of UNE-CWA 15793: 2008 and UNE-CWA 16393: 2014 management systems on Biosafety as standards for Cuba. Recently, DL4/2020 has been put into force, creating the National Commission on GMOs that implements the Policy for the use of GMOs in Cuban agriculture, including a normative package that updates the regulations for the national authorities involved in the decision-making process in GMO-related activities.

Project Document and Appendices

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, reports from Lessons Learnt Workshops, reports from Steering Committee Meetings, Inception Workshop report, meeting minutes, relevant correspondence and including the Project Implementation Reviews and Tracking Tool etc.

Evaluations/Reviews of similar projects.

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

- Head of ORSA
- Head of CITMA
- Project Manager (PM) and project Manager Unit team members.
- UNEP Task Manager ™ and team members.
- UNEP Fund Management Officer (FMO).
- UNDP Program Manager.
- UNDP Finance Assistant.
- Representatives from key institutions that compose the biosafety regime in Cuba: CICDC: CENSA, CENATOX, ONARC
- Steering Committee Members
- Representatives from civil society and specialist groups (such as focal groups for socioeconomic considerations work, women's, farmers, and trade associations etc).

(c) **Field visits:** Matanzas (Colón), Villa Clara (Placetas), Ciego de Ávila (Venezuela).

(d) **Other data collection tools**: If needed, to be decided by the Review Consultant at the inception phase

## N. Review Deliverables and Review Procedures

1. The Review Consultant will prepare:

- **Inception Report:** (see Annex 3 for guidance on structure and content) containing confirmation of the results framework and Theory of Change of the project, project stakeholder analysis, review framework and a tentative review schedule.
- **Preliminary Findings Note:** typically, in the form of a PowerPoint presentation, the sharing of preliminary findings is intended to support the participation of the project team, act as a means to ensure all information sources have been accessed and provide an opportunity to verify emerging findings.

- **Draft and Final Review Reports:** (see Annex 4 for guidance on structure and content) containing an Executive Summary that can act as a stand-alone document; detailed analysis of the review findings organised by evaluation criteria and supported with evidence; lessons learned and recommendations and an annotated ratings table.

**Review of the draft review report**. The Review Consultant will submit a draft report to the Task Manager and revise the draft in response to their comments and suggestions. Once a draft of adequate quality has been peer-reviewed and accepted, the Task Manager will share the cleared draft report with key project stakeholders for their review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions as well as providing feedback on the proposed recommendations and lessons. Any comments or responses to draft reports will be sent to the Task Manager for consolidation. The Task Manager will provide all comments to the Review Consultant for consideration in preparing the final report, along with guidance on areas of contradiction or issues requiring an institutional response.

At the end of the review process and based on the findings in the Review Report, the Task Manager will prepare a **Recommendations Implementation Plan** in the format of a table, to be completed and updated at regular intervals, and circulate **Lessons Learned**.

## O. The Review Consultant

The Review Consultant who will work under the overall responsibility of the Project Manager Tanya Romay Fernández of the Environmental and Safety Regulatory Office (ORSA) in consultation with the Task Manager Thais Narciso and Programme Assistant Gloritzel Frangakis and the Fund Management Officer, Rachel Kagiri. The consultant will liaise with the Task Manager and the Project Manager on any procedural and methodological matters related to the Review. It is, however, the consultants' individual responsibility to arrange for their travel, visa, obtain documentary evidence, plan meetings with stakeholders (with assistance from the ORSA), organize online surveys, and any other logistical matters related to the assignment. The Project Team, supported by the Task Manager will, where possible, provide logistical support (introductions, meetings etc.) allowing the Review Consultant to conduct the Review as efficiently and independently as possible.

The Review Consultant will be hired over a period of 4months [May 2023 to September 2023 ] and should have the following: a university degree in environmental sciences, international development or other relevant political or social sciences area is required and an advanced degree in the same areas is desirable;  a minimum of 5 years of technical / evaluation experience is required, preferably including evaluating large, regional or global programs and using a Theory of Change approach; and a good/broad understanding of biosafety issues is desired. English and French are the working languages of the United Nations Secretariat. For this consultancy, fluency in oral and written English is a requirement and proficiency in Spanish is desirable. Working knowledge of the UN system and specifically the work of UNEP is an added advantage. The work will be home-based at least one mission to Cuba.

The Review Consultant will be responsible, in close consultation with the Task Manager and project Manager, for overall management of the review and timely delivery of its outputs, described above in Section 11 Evaluation Deliverables, above. The Review Consultant will ensure that all evaluation criteria and questions are adequately covered.

## P. Schedule of the Review

The table below presents the tentative schedule for the Review.

**Table 3. Tentative schedule for the Review**

| Milestone | Indicative Timeframe |
|---|---|
| Inception Report | 1.06.2023 |
| Review Mission | 1.07.2023 |

| | |
|---|---|
| Telephone interviews, surveys etc. | 1.07.2023 |
| PowerPoint/presentation on preliminary findings and recommendations | 31.07.2023 |
| Draft Report to Task Manager and Project Manager | 4.09.2023 |
| Draft Report shared with the wider group of stakeholders | 15.09.2023 |
| Final Main Review Report | |
| Final Main Review Report shared with all respondents | 30.09.2023 |

## Q. Contractual Arrangements

The Review Consultant will be selected and recruited by the Environmental and Safety Regulatory Office (ORSA) under a service Contract for approval by the Government of Cuba through the Ministry of Science, Technology and Environment on a "fees only" basis (see below). By signing the service contract with the ORSA, the consultant certifies that they have not been associated with the design and implementation of the project in any way which may jeopardize their independence and impartiality towards project achievements and project partner performance. In addition, they will not have any future interests (within six months after completion of the contract) with the project's executing or implementing units. All consultants are required to sign the Code of Conduct Agreement Form.

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

Schedule of Payment for the Consultant:

| **Deliverable** | **Percentage Payment** |
|---|---|
| Approved Inception Report *(as per annex document 3)* | 30% |
| Approved Draft Main Evaluation Report *(as per annex document 4)* | 30% |
| Approved Final Main Evaluation Report | 40% |

Fees only contracts:

The consultant may be provided with access to UNEP's Anubis information management system) and if such access is granted, the consultants agree not to disclose information from that system to third parties beyond information required for, and included in, the Review report.

In case the consultant is not able to provide the deliverables in accordance with these guidelines, and in line with the expected quality standards by the Project Manager in consultation with the Task Manager, payment may be withheld at the discretion of the Director of the ORSA until the consultants have improved the deliverables to meet the ORSA and UNEP's quality standards.

If the consultant(s) fail to submit a satisfactory final product to the Project Manager and Task Manager in a timely manner, i.e. before the end date of their contract, ORSA reserves the right to employ additional human resources to finalize the report, and to reduce the consultants' fees by an amount equal to the additional costs borne by the ORSA to bring the report up to standard or completion.