Validated Terminal Review of the UNEP-GEF Project

‘Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program’

GEF ID 3405

2010 – 2022

UNEP Ecosystems Division

Validation date: June 2024

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This report has been prepared by an external consultant as part of a Terminal Review, which is a management-led process to assess performance at the project's operational completion. The UNEP Evaluation Office provides templates and tools to support the review process and provides a formal assessment of the quality of the Review report, which is provided within this report's annexed material. In addition, the Evaluation Office formally validates the report by ensuring that the performance judgments made are consistent with evidence presented in the Review report and in-line with the performance standards set out for independent evaluations. As such the project performance ratings presented in the Review report may be adjusted by the Evaluation Office. 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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Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program
GLF-2238-2716-4B77-SB-000780.70
03/24

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This Terminal Review was prepared for UNEP/GEF Biodiversity and Land Degradation unit by Ernesto Ocampo Edye.

The reviewer/s would like to express their gratitude to all persons met and who contributed to this review, as listed in Annex II - Key persons contacted / interviewed.

The reviewer would like to particularly thank the Project Team, the Task Manager, Mr. Robert Erath and Mrs. Gloritzel Frangakis, and past Task – Managers Tea García-Huidobro, Marianella Araya-Quesada and Thais Narciso for their contribution and collaboration throughout the review process, and Mr. Andrés Factos, from MAATE – the NEA – who has spent many dozens of hours answering the countless questions that this reviewer has asked throughout the development of this review, while in difficult times for his Country.

Sincere appreciation is also expressed to delegates from country stakeholders and Institutions (MAGAP, INIAP, AGROCALIDAD, IICA, USFQ, UDLA) that answered the many questions posed by the reviewer, committed their time to virtual and face to face long interviews, completed the questionnaires and took time to provide comments to the draft report.,

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

BRIEF EXTERNAL CONSULTANT(S) BIOGRAPHY

Dr. Ernesto Ocampo is an independent consultant that has more than 18 years of UN consultancy experience coordinating & managing Biosafety Projects in Latin America and the Caribbean, helping to implement worldwide capacity-building activities, managing the support of Biosafety Clearing House Regional Consultants to participating LAC countries, writing and publishing educational materials on CPB and BCH in 6 UN official languages (in the Biosafety Clearing House and BCH Virtual Environment), conducting several dozen courses and workshops at global (CBD COP-MOP), regional and national levels, developing National BCH applications and helping to design and evaluate BCH Capacity Building Projects.

ABOUT THE REVIEW

Joint Review: No

Report Language: English.

Review Type: Terminal Review

Brief Description: This report is a management-led Terminal Review of a UNEP/GEF project implemented between 2010 and 2022. The project's overall development goal was to assist Ecuador in having a workable and transparent national biosafety framework in place, fulfilling its obligations as a Party to the CP, and thus contributing to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology. 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 countries.

Key words: Biodiversity, Biosafety, Cartagena Protocol, Local Environmental Governance, Living Modified Organisms

Data collection period: July 2023 – February 2024

Field mission dates: 7 – 11 November 2023

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LIST OF ACRONYMS

AGROCALIDAD	Ecuadorian Agency for Quality Assurance of Agriculture
BCH	Biosafety Clearing House
Bioseg Unit	Biosafety Unit at the Ministry of Environment
CAE	Ecuadorian Customs Corporation
CAN	Andean Community of Nations
CBD	Convention on Biological Diversity
CBOs	Community based organizations (peasant organizations)
CEDENMA	Body which represents a large group of environmental NGOs
CIBE	Centre for Biotechnological Research of Ecuador
CNA	Competent National Authority
CPB	Cartagena Protocol in Biosafety
DNBANP	National Division of Biodiversity and Natural Protected Areas of MAE
FMO	Fund Manager officer
GEF	Global Environment Facility
GM	Genetically modified
IICA	Inter-American Institute for Cooperation on Agriculture
INEN	Ecuadorian Institute of Standardization
INIAP	National Institute of Agricultural Research
LMOs	Living Modified Organisms
M&E	Monitoring and Evaluation
MAE	Ministry of the Environment
MAATE	Ministry of the Environment, Water and Ecologic Transition
MAGAP	Ministry of Agriculture, Livestock, Aquaculture and Fisheries
MIPRO	Ministry of Industries and Productivity
MERCI	Ministry of Foreign Affairs
MSP	Ministry of Public Health
MTR	Mid-Term Review

NBC	National Biosafety Commission
NBF	National Biosafety Framework
NCC	National Coordination Committee
NEA	National Executing Agency
NGO	Non-Governmental Organizations
NPC	National Project Coordinator
OAE	Ecuadorian Accreditation Organization
PC	Project coordinator
PCR	Polymerase chain reaction
PPG	Project Preparation Grant
RA&M	Risk assessment and management
SAB	General State Annual Budget
SC	Steering Committee
SENACYT	National Secretariat on Science and Technology
SENAE	Ecuadorian Customs Corporation
SENESCYT	National Secretariat on Higher Education, Science, Technology and Innovation
SENPLADES	Secretariat of Planning and National Development
SOLCA	Laboratory of Generics of the Society Against Cancer
TM	Task Manager
TOC	Theory of Change
TORs	Terms of Reference
UNEP	United Nations Environment Programme

PROJECT IDENTIFICATION TABLE

Table 1. Project Identification Table

UNEP PIMS ID:	GFL-2328-2716-4 B77 SB-000780.70 GFL-11207-14AC003 SB-000780.70.02		
DONOR (GEF/GCF etc) ID:	3405		
Implementing Partners			
Relevant SDG(s):	Ecuador UNDAF 2019-2022, Strategic Priority 2: Planet 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 Indicator 2.5.2 Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction.		
Sub-programme:	Ecosystem Management	Expected Accomplishment(s):	The main objective of the project is to help Ecuador to implement the national biosafety framework and implementation of the Cartagena Protocol on biosafety. Specific objectives of each project activity are: Component 1: Finalizing the policy and regulatory biosafety framework. Component 2: Putting in place a fully functional system for decision making and control of LMOs Component 3: Building human and institutional capacity for biosafety Component 4: Improving public awareness and participation in biosafety.
UNEP approval date:	22 November 2010	Programme of Work Output(s):	PoW 2018/2019 Subprogram 3 – Healthy & Productive Ecosystems
Expected start date:	16 December 2010	Actual start date:	4 March 2011 (original PCA) 4 July 2018 (2nd PCA)
Planned completion date:	15 December 2014 (original PCA) extended to April 2016 in 1st Amendment 30 April 2020 (2nd PCA) extended to 31 January 2022 in 1st Amendment	Actual operational completion date:	31 March 2022

Planned project budget at approval:	USD 1,738,245.00	Actual total expenditures reported as of 31 December 2021:	USD 3,883,035.54
Planned Environment Fund allocation:	USD 665,818.00	Actual Environment Fund expenditures reported as of 31 December 2021:	USD 639,518.54
Planned Extra-Budgetary Financing:		Secured Extra-Budgetary Financing:	
		Actual Extra-Budgetary Financing expenditures reported as of [date]:	
First disbursement:	March 2011	Planned date of financial closure:	31 January 2022
No. of formal project revisions:	1 (2nd PCA)	Date of last approved project revision:	4 July 2018
No. of Steering Committee meetings:	6[1]	Date of last/next Steering Committee meeting:	Last: April 2013 / Next:
Mid-term Review/ Evaluation *(planned date):*	January 2012	Mid-term Review/ Evaluation (actual date):	April 2013
Terminal Review *(planned date):*		Terminal Review (actual date):	March 2024
Coverage - Country(ies):	Ecuador	Coverage - Region(s):	Latin America
Dates of previous project phases:	Extensions: 1st Amendment to 1st PCA: April 2016 April 2016 - July 2018 - (Inactivity period) July 2018 – April 2020 (2nd PCA) 1st Amendment to 2nd PCA: April 2020 – January 2022	Status of future project phases:	

[1] Based on reported NSC meetings available in ANUBIS. No NSC meetings reported after 2013.

I. EXECUTIVE SUMMARY

Project background

1. Ecuador ratified the Cartagena Protocol on Biosafety (CP) in 2003 and is also a Party to the Convention on Biological Diversity (CBD). The Global Project on "Development of National Biosafety Frameworks" was implemented with funding from the Global Environment Facility (GEF) and support from the United Nations Environment Program (UNEP) to prepare countries for the entry into force of the CP by developing national regulations and designing a National Biosafety System. In Ecuador, the "Development of National Biosafety Framework" project was launched in June 2003 and concluded in June 2006, resulting in a proposal for a framework or system that includes National Biosafety Regulations for LMOs.
2. In 2008, Ecuador voted in favour of a new Constitution that limits the use of genetically modified organisms, including the import and cultivation of seeds and crops. While designing this Project, this declaration was interpreted as a need for a system or national biosafety framework to effectively meet the provisions of the Constitutional Principle.
3. With this background, Ecuador requested support from GEF through UNEP to finance the project to implement the National Biosafety Framework. The project aims to assist Ecuador in having a workable and transparent national biosafety framework in place, fulfilling its obligations as a Party to the CP, and thus contributing to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology.
4. This Project was designed from **2008**, with a PPG of USD 16000, disbursed in July 2008. The PIF was submitted in January 2008 and approved in July 2008. The project was approved by GEF on 10/05/2010 and by UNEP on November 2010. The formal start date was 15/12/2010, with a duration of 4 years (48 months). The midterm review was carried out in April 2013, when several project activities were already significantly delayed. In December 2014 the 1st amendment to the PCA was signed, setting a new completion date of December 2015. In 2016 the Project was closed, and the unspent funds had to be returned to UNEP ($ 201,543.81, approx. 30% of the total allocated GEF funds). On 4/07/2018 a new PCA agreement was signed with the participation of IICA, for developing the activities that had not been completed previously and the execution of the remaining funds (approximately one third of the original total), with a completion date of April 2020.The activities were resumed in early 2029. In 2020 an amendment to this 2nd PCA was signed, extending the execution of this 2nd phase until January **2022**.
5. The Project is a MSP with a total (original) budget of USD 1,767,004 integrated as follows:
   - GEF Financing: USD 681,818 (USD 16,000 for the PPG and USD 665,818 for the Project)
   - Country co-financing contribution: Total USD 1,085,186 (USD 12,759 for PPG, in-cash USD 720,000 and in-kind USD 352,427).
   - In the final report the country reported that the co-finance contribution had been increased from USD 1,072,427 to a total of USD 3,215,375.85
6. The project's objective was "to assist Ecuador in having a workable and transparent national biosafety framework in place, to fulfil its obligations as a Party to the Cartagena Protocol and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology". This would be accomplished through four technical components, and a fifth component covering project management, monitoring and evaluation:
   - Component 1: Finalizing the policy and regulatory biosafety framework.
   - Component 2: Putting in place a fully functional system for decision making and control of LMOs.
   - Component 3: Building human and institutional capacity for biosafety.
   - Component 4: Improving public awareness and participation in biosafety.

This Review

7. In line with the UNEP Evaluation Policy, the UNEP Programme Manual and the Guidelines for GEF Agencies in Conducting Terminal Evaluations, this TR has been carried out using a set of 9 commonly applied review criteria which include: (1) Strategic Relevance , (2) Quality of Project Design, (3) Nature of External Context, (4) Effectiveness (incl. availability of outputs; achievement of outcomes and likelihood of impact), (5) Financial Management, (6) Efficiency, (7) Monitoring and Reporting, (8) Sustainability and (9) Factors Affecting Project Performance and Cross-Cutting Issues (see Annex III – Review Framework /Matrix for more details on each review criterion).
8. Most review criteria are rated on a six-point scale as follows: Highly Satisfactory (HS); Satisfactory (S); Moderately Satisfactory (MS); Moderately Unsatisfactory (MU); Unsatisfactory (U); Highly Unsatisfactory (HU). Sustainability and Likelihood of Impact are rated from Highly Likely (HL) down to Highly Unlikely (HU) and Nature of External Context is rated from Highly Favourable (HF) to Highly Unfavourable (HU). The ratings against each criterion are 'weighted' to derive the Overall Project Performance Rating. The greatest weight is placed on the achievement of outcomes, followed by dimensions of sustainability.
9. The Review has two primary purposes:
   - to provide evidence of results to meet accountability requirements, and
   - to promote operational improvement, learning and knowledge sharing through results and lessons learned among UNEP, Ministry of Environment and Water of Ecuador and Inter-American Institute for Cooperation on Agriculture (IICA).
10.
11. Summary response to key strategic review questions:
12. Q1: *"To what extent has the project achieved an effective application of the Cartagena Protocol on Biosafety, implemented the national biosafety regulatory framework and developed national capacities to properly handle LMO to safeguard biodiversity?"*. Most technical capacities related to detection of LMOSs, Risk Assessment and Management have been achieved. However, the national biosafety regulatory framework has not yet materialised, and the project has only partially achieved an application of the Cartagena Protocol in the country.
13. Q2: *"What impact has been achieved by actors engaged in the project moving on and deploying their knowledge in novel areas? How were the lessons learned used in applying agile and adaptive management of the project?"*. Some actors involved in the Project (MAATE, AGROCALIDAD, MAGAP) have used the accumulated experience to continue working on novel biotechnology and biosafety related areas, particularly Synthetic Biology.
14. *Q3: "What changes were made to adapt to the effects of COVID-19 and how might any changes affect the project's performance?."* The majority of the last phase of the Project was developed during the COVID-19 pandemic. Several planned activities were modified to be developed using on-line channels (virtual workshops and meetings). This allowed the Project to be concluded.
15. Q4: *"How effectively has the project addressed MTR recommendations?"* The MTR was developed in April 2013, and the project extended to the end of 2021. Most recommendations related to delays were not effectively addressed.

Key findings

16. The Project was highly relevant to national and international priorities. Its objectives and strategies were aligned with policies and plans of GEF, UNEP and national 2008 Constitution mandates and public agencies roles and strategical plans. It was also aligned with existing regional agreements. The Project was designed satisfactorily with a comprehensive detail of outcomes, outputs and indicators grouped around the 4 main Project Components and based on the previous UNEP-GEF Project "Development of National Biosafety Frameworks". Several assumptions, drivers and risks were identified in the Project design, that did not hold during the Project implementation, and became strong barriers to completely achieving the intended impact and outcomes (mainly , Art. 401 of the 2008 Constitution, that declares Ecuador being a country "free of transgenics" and prohibiting the

introduction of LMOs in the country except for "special cases as authorized by the Assembly and the Government"). The nature of the external context for the project has been mostly unfavourable, particularly for the development of high-level regulations and harmonized inter-institutional procedures that required a supporting political will.

17. An important part of the planned outputs were delivered by the project, particularly those related to technical aspects of LMOs detection, Risk Assessment and Risk Management. Manuals, guidelines, and procedures were developed with high quality and updated according to latest trends during the 2nd phase. Many hundreds of technicians and decision – makers from CNAs and other biosafety – related institutions were thoroughly trained. Laboratories for analysis and detection were identified, their installations updated for the specific task, and their personnel trained. However, due to the lack of real cases (e.g. applications to introduce LMOs in the country, for any of the CP addressed ends), this technical capacity is not being exercised in the field, and the same happens with the required administrative procedures and workflows.
18. Most required high-level norms have been developed (e.g. Plan of action for 10 years, biosafety policies and regulations, the National Environmental Code, and its Rulebook). Permanent inter-institutional coordination mechanisms were not yet formally installed by the end of the Project, although informal channels between the involved institutions do exist.
19. Some actors (mainly MAATE and partially MAGAP) engaged in the project are currently having an impact in addressing the issues arising from new biotechnologies (e.g., Synthetic Biology), building on-top of the knowledge and expertise developed during the Project.
20. The functioning of the National Biosafety Commission has been irregular during the entire lifespan of the Project. This also affected the Project Management, as (stated in the Prodoc) the Project National Steering Committee was the NBC itself.
21. Not all the CNAs and other Institutions have permanently included management and administrative costs of a national system of security of biotechnology. Only MAATE, AGROCALIDAD and MAGAP have stable positions dedicated (partially) to LMOs related biosafety tasks.
22. Public awareness and participation component development suffered also from the lack of political support and the general perception against LMOs.
23. The National Biosafety Portal, or National BCH website, is the main channel for deploying several of the intended outputs regarding Public Awareness and Participation (e.g. a national system for public participation, publication of national up-to-date biosafety information, virtual libraries of Risk Assessment, databases of experts, institutions and projects, and other technical information). At the time of this review, this Portal is not operative (the reviewer found it not operative at least since June 2023), with the consequences that all these outputs / products are not available for the general public. The reviewer communicated this finding to the NEA delegate in several opportunities during the development of this review. There is a shortage of technical human resources to update and maintain information on the National BCH. No LMOs decision-making consultation has taken place (no decision has been made) and there is no space available currently in the MAATE website for such consultations.
24. The public opinion survey developed during the 2nd Phase of the Project with IICA Collaboration in 2020 in its final conclusions briefly compared its results to the baseline Project data that had been taken from a 2008 survey, concluding that an improvement of the public perception about biotechnology can be observed, and that "there has not been a significant improvement in scientific knowledge dissemination in Ecuador"

25. Regarding Project Efficiency: the Project was delayed several times and its implementation ended up extending from 4 to almost 12 years. Despite delays, most of the planned activities were implemented under an adapted budget. Administrative and financial management had an increment of cost, due to extended amount of audits, UNDP service charges, funds transfer operations. UNEP resources had to be allocated (Task Manager, Fund Manager, Administrative Assistance and other related staff and services) for 12 years management instead of 4. At the same time, the management, administrative and technical resources mobilized by the Government and Stakeholder Institutions did have to be significantly increased during implementation.

26. Regarding Sustainability: Biosafety Unit in MAATE is recognized as a reference, sustained technical authority in the field of Biosafety in the country. However, the lack of enough assigned personnel may pose a high risk on the capacity to operate, manage, and coordinate a National Biosafety System. The involvement of other institutions has decayed over the years, and the inter-sectorial coordination is yet to be formalized and functional. When developing this review and interacting with several actors from different Institutions, the reviewer perceived an important lack of interest in the subject of LMOs biosafety, a consequence of more than 15 years of the Constitutional restrictions being in place in the country. The political and public negative perception of LMOs status, with the hard restrictions mandated in the 2008 Constitution regarding LMOs, results in a very strong barrier against further development of a national integrated and operational biosafety system to address LMOs decision – making.

27. The Intended Impact, "Incremented level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and focusing, in particular, on transboundary movements", has been limited: there exist now in Ecuador the technical human resources and procedures to deal with specific aspects of LMO transboundary movement, but no harmonized legislation and inter-institutional procedures are formally in place.

28. Adaptive management has been applied to complete the Project in a particularly adverse context, creating a partnership with IICA in 2018 and, later, especially during COVID-19 pandemic the last 2 years of the project.

Conclusions

29. Based on the findings from this review, the project demonstrates performance at the **MS** level (a table of ratings against all review criteria is found in the Conclusions section, below). The project has demonstrated strong performance in technical capacity building (trained several hundreds of people in all the required biosafety subject topics, created capacity for LMOs detection in national laboratories, addressed the complex issue of national LMO surveillance, risk assessment and risk management). Areas that would benefit/would have benefited from further attention are final political and high-level approval of the harmonized drafted laws and regulations related to a functional, operative system for managing LMOs transboundary movements (as stated in CP), and an improvement of mechanisms for public awareness on biosafety and biotechnology, along with an operational system for public participation and feedback on decisions taken about LMOs.

30. The Project was effective to produce several technical outputs and to create human and laboratories capacities to manage the technical aspects of LMOs related decision – making.

31. High level norms have been approved during the years, but the lack of political support and the barriers imposed by the 2008 Constitution have in fact prevented the instalment and operation of a functional LMOs decision – making inter-institutional administrative system, despite the existence of all technical capacities needed.

32. The analysed barriers also played a role against the Project efficiency: spanning through several government periods and political changes, the Project suffered from many changes in authorities, NPC, and national resources allocation.

33. The Project has been an important mechanism for maintaining the issue of LMOs transboundary movements in the country agenda, and currently there exists in Ecuador a consolidated Biosafety Unit in the Ministry of Environment, with a lot of experience and very valuable national and international relationships, that permits Ecuador to continue working with novel biotechnologies and the regulation of their products.

34. The delays in Project duration caused significant increments of costs for the Government and committed national stakeholders and other institutions (Project management, administration, infrastructure). For UNEP-GEF, extending from the initial planned 4 years to a total duration of about 12 years implied important increment in management and administrative costs.

Table 1 Summary of Project Ratings

Criterion	Rating	EOU Validated Rating
A. Strategic Relevance	**HS**	**HS**
B. Quality of Project Design	**S**	**S**
C. Nature of External Context	**U**	**MU**
D. Effectiveness	**MS**	**MS**
E. Financial Management	**S**	**S**
F. Efficiency	**MU**	**U**
G. Monitoring and Reporting	**MS**	**MS**
H. Sustainability	**MU**	**U**
I. Factors Affecting Performance and Cross-Cutting Issues[2]	**MS**	**MS**
Overall Project Rating	**MS**	**MU**

Lessons Learned

35. Lesson 1: The Project has faced a very challenging context, with strong barriers to achieve some of the outcomes, derived from the current national legislation and adverse public perception of LMOs and lack of high-level support. In all the interviews and conferences maintained by the reviewer, the dedication and professionalism of the NEA appointed officers and particularly the NPC and biosafety officer has been commended. However, due to the previously mentioned barriers, many regulations and harmonized norms that were drafted as Project outputs did not count with the required high-level political authorities' support. The lack of governmental decision to approve proposed regulations and implement the system acted as a barrier to achieve some high-order Project outcomes.

36. Lesson 2: The development of all technical outputs and products has been effective and of high quality, and the training activities reached many hundreds of biosafety involved professionals.

37. Lesson 3: The collaboration of IICA in several stages of the Project was key for the successful development of many outputs.

38. Lesson 4: An important result of the Project has been the formal and sustainable creation and operation of the Biosafety Unit inside MAATE, not only for this Project management but for other issues related to Biosafety in general. Particularly, this Unit is now working on new biotechnology matters (Synthetic Biology) that need to be addressed at a national level.

39. Lesson 5: Although the Project included a Component specifically addressing Public Awareness, its outcomes have not been enough to overcome the existing general resistance to address and legislate specific norms to deal with LMOs related biosafety decision – making. When the Project was designed using the methodology of logic framework, the risk inherent to the existing pathway that is evident in the RToC from Public Awareness (particularly focused on political awareness and buy-in) to the intermediate state *"System for decision making and control of LMOs is fully functional", was* not sufficiently valued. During Project implementation this issue proved to be critical.

Recommendations

40. Recommendation 1 (to NEA, Government): As the Project has already finished and some final outcomes not fully achieved, the most important immediate recommendation is to continue working for the approval of the complete set of harmonized intersectoral regulations and make the National

[2] While ratings are required for each of these factors individually, they should be discussed within the Main Review Report as cross-cutting issues as they relate to other criteria. Note that catalytic role, replication and scaling up are expected to be discussed under Effectiveness if they are a relevant part of the TOC.

Biosafety System operational (complying with the CP), by approving and installing the necessary administrative procedures and coordination among the involved CNAs and other related Institutions.

41. Recommendation 2 (to NEA, Government): Closely linked to the previous recommendation is one of promptly addressing the budget needs to be able to operate this system, considering human resources and infrastructure (including logistics for detection laboratories).
42. Recommendation 3 (to NEA, Government): As the country faces (and has been demonstrated) the illegal introduction and planting of LMOs, it is imperative to put in place regulations, procedures and measures to be taken to address this reality.
43. Recommendation 4 (to NEA, Government): To promote the research on LMOs in the country, revise and approve the required regulations that address the introduction of LMOs for research (contained use as specified in the CP). Drafts have been produced by the Project.
44. Recommendation 5 (to NEA, Government): Continue fostering the regular functioning of the recently approved National Biosafety Committee, not only to address LMOs related decisions but also to have installed an expert inter – agencies able to address next generation technologies (e.g. products derived from Synthetic Biology).

Validation

The report has been subject to an independent validation exercise performed by UNEP's Evaluation Office. The performance ratings for the 'Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program' (GEF ID 3405), set out in the Conclusions and Recommendations section, have been adjusted as a result. The overall project performance is validated at the 'Moderately Unsatisfactory' level. Moreover, the Evaluation Office has found the overall quality of the report to be 'Moderately Satisfactory' (see Annex XII).

45. In line with the UNEP Evaluation Policy[3] and the UNEP Programme Manual[4], the Terminal Review (TR) is undertaken at operational completion of the project to assess project performance (in terms of relevance, effectiveness and efficiency), and determine outcomes and impacts (actual and potential) stemming from the project, including their sustainability. The Review has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote operational improvement, learning and knowledge sharing through results and lessons learned among UNEP and Ministry of Environment and Water of Ecuador, Inter-American Institute for Cooperation on Agriculture (IICA). Therefore, the Review will identify lessons of operational relevance for future project formulation and implementation, especially for future phases of the project, where applicable.

46. Ecuador ratified the Cartagena Protocol on Biosafety (CP) in 2003 and is also a Party to the Convention on Biological Diversity (CBD). The Global Project on "Development of National Biosafety Frameworks" was implemented with funding from the Global Environment Facility (GEF) and support from the United Nations Environment Program (UNEP) to prepare countries for the entry into force of the CP by developing national regulations and designing a National Biosafety System. In Ecuador, the "Development of National Biosafety Framework" project was launched in June 2003 and concluded in June 2006, resulting in a proposal for a framework or system that includes National Biosafety Regulations for LMOs.

47. In 2008, Ecuador voted in favour of a new Constitution that limits the use of genetically modified organisms, including the import and cultivation of seeds and crops. However, this declaration needs to be translated into a system or national biosafety framework to effectively meet the provisions of the Constitutional Principle.

48. With this background, Ecuador requested support from GEF through UNEP to finance the project to implement the National Biosafety Framework. The project aims to assist Ecuador in having a workable and transparent national biosafety framework in place, fulfilling its obligations as a Party to the CP, and thus contributing to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology.

49. The Project was designed from **2008**, with a PPG of USD 16000, disbursed in July 2008. The PIF was submitted in January 2008 and approved in July 2008. The project was approved by GEF on 10/05/2010 and by UNEP on November 2010. The formal start date was 15/12/2010, with a duration of 4 years (48 months) and a total approved GEF funds of USD 665,818. The Midterm evaluation was carried out in April 2013, when several project activities were already significantly delayed. In December 2014 the 1st amendment to the PCA was signed, setting a new completion date of December 2015. In 2016 the Project was closed, and the unspent funds had to be returned to UNEP ($ 201,543.81, approx. 30% of the total allocated GEF funds). On 4/07/2018 a new PCA agreement was signed with the participation of IICA, for developing the activities that had not been completed previously and the execution of the remaining funds (approximately one third of the original total), with a completion date of April 2020.The activities were resumed in early 2029. In 2020 an amendment to this 2nd PCA was signed, extending the execution of this 2nd phase until January **2022**.

50. The original Project design was aligned with GEF's Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1) approved in December 2006, and was in line with the Focal Area Strategies and Strategic Programming for GEF-4 (Doc GEF/C.31/10) approved in July 2007. It responded directly to Biodiversity Strategic Objective 3: To safeguard biodiversity - Strategic Programme 6 Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. It is also fully aligned with the key elements emphasized in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol: (i) The need to develop a functional political, legal and

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

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

regulatory biosafety framework.(ii) The need to strengthen technical and institutional capacity in biosafety, and establish a system for handling requests, carrying out risk assessments, decision-making on LMOs, communicating decisions, monitoring and enforcement. (iii) The need for awareness raising activities, education on biosafety, access to information and public participation on decision-making for LMOs.

51. The main entities involved in the project execution were:

- Ministry of Environment, Water and Ecologic Transition
- Inter-American Institute for Cooperation on Agriculture (IICA)
- SENESCYT: Secretariat of Higher Education, Science, Technology and Innovation
- MAGAP: Ministry of Agriculture and Livestock
- AGROCALIDAD: Agency for Phytosanitary Control,
- INIAP: National Institute of Agricultural Research,
- MIPRO: Ministry of Production, International Trade, Investment and Fishing,
- MSP: Ministry of Public Health
- SENAE: customs
- MRECI: Ministry of Foreign Affairs
- SENPLADES: Secretariat of Planning
- IICA: Inter-American Institute for Cooperation on Agriculture

II. REVIEW METHODS

A. Review process and criteria

52. This review adopted a participatory approach, consulting with project team members, partners and beneficiaries at several stages throughout the process. Central to the review was the analysis (and reconstruction) of the project's Theory of Change. Consultations were held during the review inception phase to arrive at a nuanced understanding of how the project intended to drive change and what contributing conditions ('assumptions' and 'drivers') would need to be in place to support such change. The (reconstructed) Theory of Change, supported by a graphic representation and narrative discussion of the causal pathways, was discussed further with respondents during the data collection phase, and refined as appropriate. The final iteration of the Theory of Change is presented in this final review report and has been used throughout the review process.

53. Below is a schematic representation of the Terminal Review process and the various stages entailed, as prescribed by the UNEP Evaluation Office.

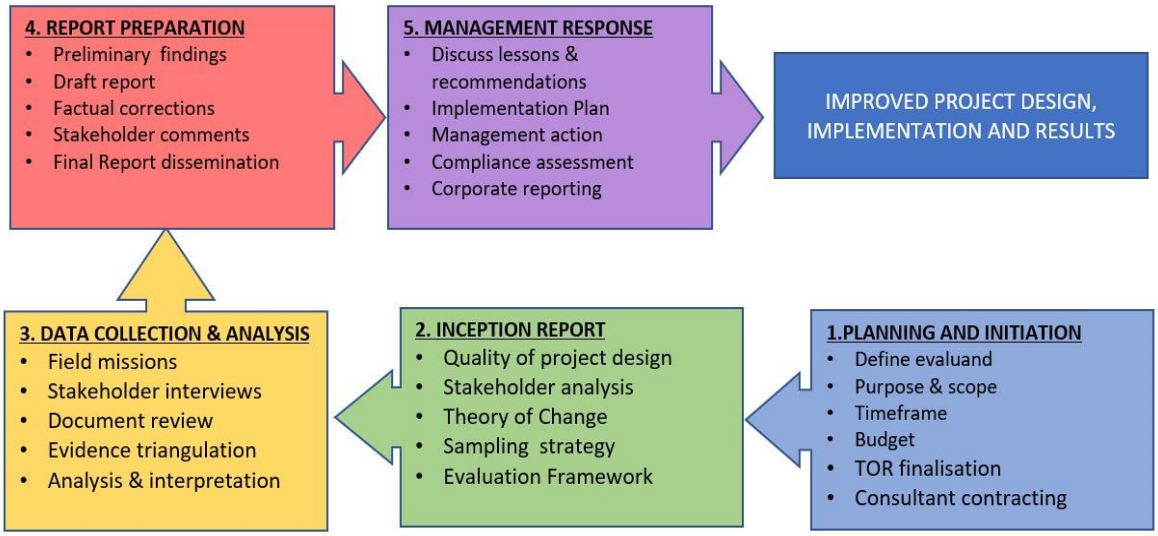

Figure 1 UNEP Review Process

54. This Terminal Review consisted of an in-depth participatory assessment of the project's design, management, performance (relevance, effectiveness and efficiency), outcomes and impacts (actual and potential), and sustainability. As required in UNEP Reviews, the project will be evaluated against nine criteria: (1) Strategic Relevance, (2) Quality of Project Design, (3) Nature of External Context, (4) Effectiveness (incl. availability of outputs; achievement of outcomes and likelihood of impact), (5) Financial Management, (6) Efficiency, (7) Monitoring and Reporting, (8) Sustainability and (9) Factors Affecting Project Performance and Cross-Cutting Issues. For each criterion, the UNEP Evaluation Office has developed a ratings matrix containing detailed descriptions of the main elements required to be demonstrated at each level (from 'Highly Satisfactory' to 'Highly Unsatisfactory').

55. In addition to these criteria, the review TORs establishes a series of Strategic Questions that are of interest to UNEP and to which the project is believed to be able to make a substantive contribution:

- Q1: To what extent has the project achieved an effective application of the Cartagena Protocol on Biosafety, implemented the national biosafety regulatory framework and developed national capacities to properly handle LMO to safeguard biodiversity?
- Q2: What impact has been achieved by actors engaged in the project moving on and deploying their knowledge in novel areas? How were the lessons learned used in applying agile and adaptive management of the project?
- Q3: What changes were made to adapt to the effects of COVID-19 and how might any changes affect the project's performance?
- Q4: How effectively has the project addressed MTR recommendations?

B. Data collection and sampling

56. Desktop studies of project documents, verbal and written communications (both in-person and virtually) with project stakeholders, and a country visit between November 8 and 11, 2023 were all part of the data-gathering process. Due to the long extension of this project (2010-2020) a very large amount of documents, products, periodic project reports, budget and audit reports, have been created and reported in ANUBIS and made available to this reviewer. The desktop study and triangulation of this information started in early August 2023 and extended through March 2024.
57. The project team from the government NPC (MAE-MAATE), UNEP staff (current Task-Manager and 3 other past – Task Manager that had been in charge of this Project during their respective times, and the Administrative Assistant that has been working for the Project since it started), representatives from other partner institutions (government agencies and State companies), especially members of the NSC, and direct project beneficiaries (e.g., industry, academy, farmers, civil society representatives) were the main stakeholders scheduled for interviews for primary data collection.
58. Stakeholders were consulted using semi-structured interviews (on-site or virtual) and additional more detailed questionnaires.
59. Interviews and questionnaires were based on the questions detailed in Annex III – Review Framework classified according to the different stakeholder roles. On-line detailed questionnaires were developed and distributed, as detailed in Annex III-b – data collection tools. An initial guide was sent to stakeholder representatives with whom a face-to-face interview was scheduled during the on-site mission, asking them to prepare information around the following high–level lines (in Spanish language):

- *¿En qué medida los objetivos del Proyecto se han alcanzado?*
- *¿Cuáles han sido los productos y efectos del Proyecto, en particular los que se han instalado en forma permanente y sostenible?*
- *¿Cuáles han sido las limitaciones más relevantes para obtener los resultados esperados del Proyecto (organizacionales, administrativas, políticas, sociales, etc.)?*
- *¿Cuáles han sido otros productos, actividades o beneficios derivados de las actividades del Proyecto, que no se hubieran previsto originalmente y se encuentren hoy funcionales?*
- *¿Cuáles han sido las lecciones aprendidas, que puedan ser tenidas en cuenta para otros Proyectos?*

60. Project documentation such as reports, work plans, meeting minutes, and other outputs play a crucial role as an information source for this review. Annex III-b – data collection tools

An initial guide was sent to stakeholder representatives with whom a face-to-face interview was held during the on-site mission, asking them to prepare information around the following high–level lines (in Spanish language):

- *¿En qué medida los objetivos del Proyecto se han alcanzado?*
- *¿Cuáles han sido los productos y efectos del Proyecto, en particular los que se han instalado en forma permanente y sostenible?*
- *¿Cuáles han sido las limitaciones más relevantes para obtener los resultados esperados del Proyecto (organizacionales, administrativas, políticas, sociales, etc.)?*
- *¿Cuáles han sido otros productos, actividades o beneficios derivados de las actividades del Proyecto, que no se hubieran previsto originalmente y se encuentren hoy funcionales?*
- *¿Cuáles han sido las lecciones aprendidas, que puedan ser tenidas en cuenta para otros Proyectos?*

Surveys and questionnaires were sent to the interviewed and other emergent actors, based on the following developed question bank. Each questionnaire was customized according to stakeholder / actor role. All questions were translated to Spanish for constructing the web questionnaires. The questionnaires are available at:

NPC – IICA: https://forms.gle/fgwPHFEypVZt2XZh6

Academy and Laboratories: https://forms.gle/w9t6C9DpDk6sdK4i6

Industry: https://forms.gle/4vGGxWuaQsSB4s2y7

Ecuador Ministries: https://forms.gle/KAZxksFf9KPH2nGY6

Civil Society, NGOs, Public Awareness and Participation: https://forms.gle/NTAkVDDqwWUXPW199

QUESTION BANK FOR INTERVIEWS AND QUESTIONNAIRES

EVALUATION QUESTIONS	Civil Society / Consumers / NGOs	Academy	Industry Sector	Govt Stkholders: Ministries,	Govt - NPC - IICA	UNEP GEF Task Manager	HIGHLY SUCCESSFUL	MODERATEL SUCCESSFUL	MODERATELY UNSUCCESSFUL	DEFICIENT
A. STRATEGIC RELEVANCE										
1. To what extent were project objectives and implementation strategies consistent with: (a) UNE's mandate and policies at the time? (b) Regional, Sub-regional and National Environmental Priorities, (c) UN Environment Medium Term Strategy (MTS) and Programme of Work (POW), and (d) GEF Strategic Priorities ?						X				
2. Why did UNEP choose this project? How was UNEP role defined?						X				
3. Were the objectives and implementation strategies complementary with relevant existing interventions from the project partners and /or other stakeholders?					X	X				
B. QUALITY OF PROJECT DESIGN										
see section 3 and Annex B										
C. NATURE OF EXTERNAL CONTEXT										
4. Did the (political, environmental, social, institutional) context change during project implementation and how did the project adapt to this?										
D. EFFECTIVENESS										
i. Availability of Outputs										
5. How successful was the project in delivering its Outputs both in quantity and quality, as well as their usefulness and timeliness?	X	X	X	X	X	X				
6. To what extent did project Outputs contribute to achieving expected Outcomes and Intermediate States? (i.e., do causal pathways have a sound technical logic?)	X	X	X	X	X	X				

7. To what extent is there a sense of ownership over project Outputs and results?	X	X	X	X	X	X				
8. Were UNEP tools or methodologies (a) used or upscaled? or (b) developed that could be used in other Projects (within or beyond UNE)?					X	X				
9. Were key stakeholders (including project beneficiaries) appropriately involved in producing the programmed outputs?	X	X	X	X	X	X				
10. Did the project face any technical or political constraints in generating its Outputs? If yes, please explain. Were these identified, communicated and overcome opportunely? (i.e. before affecting the project)	X	X	X	X	X	X				
ii. Achievement of Project Outcomes										
11. How successful was the project in Finalizing the Policy and Regulatory Biosafety Framework (Biosafety policy and regulations formally approved, sustainably funded and their application initiated; Management of LMOs improved through permanent coordination mechanisms and structures)	X	X	X	X	X	X				
12. How successful was the project in Putting in place a fully functional system for decision making and control of LMOs?	X	X	X	X	X	X				
13. How successful was the project in Building human and institutional capacity for biosafety? (describe how many people have finalized biosafety - related graduate and post-graduate formation, specific training workshops on Risk Assessment, Risk Management, LMOs detection, other biosafety closely related capacity building efforts due to or influenced by the Project; describe how the technical infrastructure has evolved and (if) operative - e.g. detection labs-)	X	X	X	X	X	X				
14. How successful was the project in Improving public awareness and participation in biosafety? Describe institutional websites or portals (e.g., Ecuador Biosafety Portal, biosafety - related institutions websites, general Government websites) that currently address biosafety information and issues. Describe established and operational systems for public participation in LMOs decision making.	X	X	X	X	X	X				
15. To what extent can achieved Outcomes be directly attributed to project actions?	X	X	X	X	X	X				

16. Did the assumptions hold/were drivers positively influenced (as included in the ToC)	X	X	X	X	X	X				
iii. Likelihood of Impact										
17. To what degree the project is likely to create long-term impact (established policies, regulations, processes and resources both public and private to effectively and co-ordinately manage biosafety in the country)	X	X	X	X	X					
18. To what extent has the project helped to promote institutional changes, changes in behaviour or perception, policy changes, and new opportunities? Were these changes or new decisions prompted by increased scientific evidence/knowledge or capacity?	X	X	X	X	X					
19. Has the Project participant Institutions addressed other related lines beyond the original scope of work? If yes, please specify	X	X	X	X	X					
20. Did the assumptions hold / were drivers positively influenced in the transition from outcomes to impact? (as included in the RF and TOC)	X	X	X	X	X					
21. Have desired outcomes and impacts occurred amongst all stakeholder groups (and if not, why this might be).	X	X	X	X	X					
22. Did the project result in any unplanned positive effects? Did it lead to any unintended negative effects? If yes, please explain	X	X	X	X	X	X				
23. Are there any particular innovations and best practices coming from the project? Were there any gaps or potentials in innovation not realized?	X	X	X	X	X	X				
E. FINANCIAL MANAGEMENT										
24. Was financial information and communication between financial and project management staff complete and transparent?					X	X				
25. Were GEF financial resources disbursed by UNEP in a timely manner? If not, what were the obstacles faced? (financial, administrative, managerial)					X	X				

26. Were administrative processes (procurements, cooperation agreements, etc.) conducted efficiently and in a timely manner by MATE and/or IICA-Country Office?					X	X				
27. Were co-financing commitments met as programmed and made available in a timely manner?					X	X				
28. Were communications with the UNEP Fund Management Officer (in Nairobi) fluid and timely? Was the FMO involved in adaptive management decisions?					X	X				
29. Did any irregularities arise in procurements, use of financial resources and human resource management? If yes, describe these irregularities, together with any measures taken to correct/prevent them.					X	X				
F. EFFICIENCY										
30. How was the operational execution vs. original planning (budget wise)? Was the project implemented cost effective? (were the results achieved at the lowest possible cost					X	X				
31. How was the operational execution vs. original planning (time wise)?					X	X				
32. If present, what have been the main reasons for delay/changes in implementation? Have these affected project execution, costs and effectiveness?	X	X	X	X	X	X				
33. Was adaptive management applied adequately? Were any cost- or timesaving measures put in place in attempting to bring the project as far as possible in achieving its results within its secured budget and time?					X	X				
34. Did the project build adequately (create complementariness) on existing institutions, lessons of other initiatives, data sources, partnerships with third parties and ongoing projects?	X	X	X	X	X	X				
G. MONITORING AND REPORTING										
i. Monitoring Design and Budgeting										
35. To what extent was the project M&E plan viable, Outcome-based and included SMART indicators?					X	X				

36. Were M&E responsibilities clearly defined across project teams? Did the project include an M&E budget? Were project stakeholders involved in monitoring?					X	X				
ii. Monitoring of Project Implementation										
37. Was the M&E system operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period?					X	X				
38. How did project teams monitor the participation of disaggregated groups (gendered, marginalised or vulnerable groups, including those with disabilities) in project activities?					X	X				
39. Did monitoring lead to adaptive management and contribute to resolving implementation problems?					X	X				
iii. Project Reporting										
40. Were the required progress, expenditure and terminal reports prepared satisfactorily by the national project team and submitted on time? Were all reporting requirements met?						X				
H. SUSTAINABILITY										
i. Socio-political sustainability										
41. In the absence of external support from UNEP and GEF, is there sufficient government and stakeholder commitment to continue using, enforcing and improving the developed NBF to guide management decisions?	X	X	X	X	X	X				
42. How likely are the government and other stakeholders to continue with individual capacity development efforts for implementing NBF activities?	X	X	X	X	X	X				
43. What are the key factors that contributed to the sustainability of project results and impacts?	X	X	X	X	X	X				
ii. Financial sustainability										

44. To what extent is the continuity of project results and their impact dependent on continued financial support?	X	X	X	X	X	X				
45. What is the likelihood that adequate financial resources will be or will become available to continue implementation the programs, plans, agreements, monitoring systems etc. prepared and agreed upon under the project?	X	X	X	X	X	X				
iii. Institutional sustainability										
46. How likely are the plans, programmes, structures, capacities or collaborations strengthened by the project (either at the site or national level) to remain in place over time for continued support to NBF efforts?	X	X	X	X	X	X				
47. How likely are the government and other stakeholders to continue with institutional capacity development efforts for NBF?	X	X	X	X	X	X				
48. Are there complementary frameworks, mechanisms or processes that already exist that could contribute to the sustainability of NBF efforts?	X	X	X	X	X	X				
I. FACTORS AFFECTING PROJECT PERFORMANCE										
i. Preparation and Readiness										
49. Was the project ready for implementation reasonably soon after project approval? Were appropriate measures 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?					X	X				
ii. Quality of Project Management and Supervision										
50. How effective and efficient was project management by MATE and IICA? How well did they adapt to changes during the project lifetime?						X				
51. To what extent did the National Steering Committee (NSC) provide guidance and oversight, and contribute to effective project implementation?	X	X	X	X	X	X				
52. To what extent did the project team respond to the guidance/recommendations provided by: (a) the National Sterring Committee (NSC)? (b) the UNEP GEF Task Manager?	X	X	X	X		X				

53. Did the project face any operational or institutional constraints that influenced its implementation? If yes, please explain. Were these identified, communicated and overcome opportunely?	X	X	X	X	X	X				
54. How effective and efficient was UNE's project supervision as GEF Agency? (includes monitoring, reporting, risk management, and participation in Steering Committee meetings)					X					
55. Did UNEP provide technical support? If so, what kind? Was it timely and effective?					X					
iii. Stakeholder Participation and Cooperation										
56. To what extent did the project achieve effective stakeholder participation and/or collaboration?	X	X	X	X	X	X				
57. To what extent were stakeholders (local or national) involved in: (a) project design; (b) the sharing of lessons learnt from the project; or (c) the sharing of expertise and technical knowledge, or the pooling of resources?	X	X	X	X	X	X				
iv. Responsiveness to Human Rights and Gender Equity										
58. To what extent were gender issues and the inclusion of minority groups considered in the project's activities and results? (especially in intervention areas)	X	X	X	X	X	X				
59. To what extent did the project address human rights and human wellbeing (e.g. access to land and resources, human health, rights to healthy environment)?	X	X	X	X	X	X				
v. Environmental and Social Safeguards										

60. To what extent the Project management reviewed risk ratings, monitored project implementation for possible safeguard issues and responded (when corresponded) to safeguard issues through risk avoidance, minimization, and reported on implementation of measures taken.						X				
vi. Country Ownership and Driven-ness										
61. In how far have the national partners assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project?	X	X	X	X	X	X				
62. How and how well did the project stimulate country ownership of project outputs and outcomes? Is this different by gendered and marginalised groups?	X	X	X	X	X					
vii. Communications and Public Awareness										
63. To what extent did the project achieve effective communications (a) internally, amongst Project team and key stakeholders, and (b) externally, through public awareness and dissemination activities?	X	X	X	X	X					
64. How successful was the project in its knowledge management approach? (exchange of learning among /with project partners and beneficiaries). What were the main challenges and successes relating to knowledge management?	X	X	X	X	X					
65. Was UNEP involved in sharing or communicating on innovations and best practices coming from the project? Was the project connected to any networks or knowledge management platforms for sharing?	X	X	X	X	X					

61. Annex IV - Key Documents Consulted lists the key documents and products consulted during this review.

62. As the project extended for a long time (2010 – 2022) most of the original country stakeholders institutions delegates that were involved during Project design phase (2007 – 2010) and initial Project agreed period (2010 – 2014) were not anymore available at the time of this review, so a deeper, detailed and triangulated examination and study of all available documents, products and reports has been required to assess the different review dimensions.

63. After the preliminary virtual meetings, mainly held by the Project Team, face-to-face and virtual meetings were held with the different stakeholders during the country visit. Stakeholder organizations and institutions delegates were identified according to the inception report stakeholder analysis - available in Annex IX – Stakeholder analysis and with the help of NEA delegate Andrés Factos, and included delegates from:

- *NEA – Biosafety Unit*
- *MAGAP*
- *AGROCALIDAD*
- *INIAP*
- *ESPOL*
- *UDLA*
- *USFQ*
- *MINPRO*
- *Consumers, WWF*
- *IICA*
- *Industry Sector*

64. All meetings, both virtual and face-to-face, were recorded with the express consent of the interviewees. The recordings were subsequently reviewed and summary notes extracted from them. Throughout the review process and in the compilation of the Final Review Report efforts have been made to represent the views of both mainstream and more marginalized groups. All efforts to provide respondents with anonymity have been made.

65. Based on the review framework detailed in Annex III – Review Framework, web-based questionnaires designed specifically for each of the project stakeholder types (PMU, IICA, Academia, Laboratories and Research, Industry, Ministries and other governmental institutions, civil society and NGOs) were developed and the different stakeholders were asked to complete them. These questionnaires are available on line for reference, links are detailed in Annex III-b – data collection tools.

66. The summary of the interviews, meeting notes and questionnaire results were then triangulated in detail with the project design and monitoring documents, periodic reports, financial reports, audit reports and all outputs declared and published on the ANUBIS platform. Some outputs were provided directly by IICA.

C. Review limitations

67. This review has presented several strong challenges and limitations:

68. the period of time available for interacting with country officers was concurrent with the Ecuador National Elections. The previous months, as is common in most

countries, were hectic for all public servants as usually they had to prepare the transition. In Ecuador the winning party was different from the ruling one, so an additional effect that was foreseen was that many authorities, in all ministries (including MAATE) were about to change. This situation produced many difficulties and delays interacting with government officers.

69. As the Project extended way out of its design duration (originally 2010-2014, and finally it was 2010-2022), it developed through several government periods (5), with many changes occurring in the national management authorities, at all levels. Most actors that had been engaged in the initial phase were not available anymore when this review took place. In several of the original participating institutions there were not anymore public servants that had knowledge about the Project (e.g., Public Health Ministry, Industry and Production Ministry, SENESCYT).

70. After 12 years of Project development, the number of products, project review, progress reports and other associated Project tracking tools (37 PERIODS reported in ANUBIS) and audit reports, grew up significantly, making it all the more complex to analyse, triangulate and verify all activities, outputs, outcomes, management and financial reports. Several products and documents related to reported outputs were not available in ANUBIS, some were reported duplicated in different ANUBIS sections or with different names, and some were reported but it was not possible to retrieve them. See Annex IV - Key Documents Consulted.

71. The first PM in the NEA had been also the main Project Designer, with full dedication to the Project Management. After her resignation in 2013 and up to 2022, there were several different officers appointed as Project Manager. The only stable person working in the Biosafety Unit during the following years has been Mr. Andrés Factos, from MAATE, who although not being the NPC in all periods, is closely related to all biosafety matters in the institution.

72. The degree of response from the different institutions and officials to the queries made by this reviewer was varied, in some cases nil. It was not possible to contact or obtain responses from MIPRO, MSP, delegates or representatives of civil society, farmers or farmers' associations.

73. Only a few reports and memories of NSC/NBC have been found in ANUBIS, and only for years 2011-2013. No sessions memories or reports after 2015 have been uploaded. This also made the history reconstruction more difficult for the reviewer.

74. Face-to-face meetings with delegates from different stakeholder institutions were coordinated with the help of Andrés Factos and scheduled several weeks before the mission to the country. Emails with the relevant project documents, a summary of the objectives of the review and the mission, general guidelines for the meetings and questions designed in the review framework were sent to all representatives several days prior to the scheduled meetings. The agenda was accepted and confirmed by each of the delegates (include list of agenda?). However, once in the country during the mission, several confirmed meetings participants did not show, as was the case of the national GEF operational focal point, delegates from AGROCALIDAD – it was possible however to interview one of them via zoom- and MIPRO. It was only possible to meet ESPOL representative by zoom, because of his location in Guayaquil. The meeting with WWF delegate had to be postponed because he was out of the country and was done a few days later by zoom also.

75. After the meetings with representatives, the reviewer sent several different questionnaires to the same interviewees according to their roles, by email. Although repeated several times, the only complete responses came from the academic and industry sectors.

III. THE PROJECT

A. Context

76. The tropical Andes region that spans across Bolivia, Colombia, Ecuador, Peru, and Venezuela is often referred to as the centre of global biodiversity. These ecosystems are extremely vital to conservation efforts as they are home to a vast number of habitats containing endangered plant and animal species. The Andean region is also marked by a high level of species endemism. Ecuador, with its largest number of species per unit area, is one of the 17 mega-diverse countries in the world. Moreover, it is the origin and/or centre of genetic diversity for many globally important crop species.

77. Ecuador ratified the Cartagena Protocol on Biosafety (CP) in 2003 and is also a Party to the Convention on Biological Diversity (CBD). The Global Project on “Development of National Biosafety Frameworks” was implemented with funding from the Global Environment Facility (GEF) and support from the United Nations Environment Program (UNEP) to prepare countries for the entry into force of the CP by developing national regulations and designing a National Biosafety System. In Ecuador, the "Development of National Biosafety Framework" project was launched in June 2003 and concluded in June 2006, resulting. At the time of its submission, there was not sufficient political will to legalize the bylaw in question, which aimed to regulate the Environmental Management Act, in section 9L.

78. As per the new Constitution approved in October 2008, the country strictly prohibits the entry and use of living modified organisms (LMOs) in any way authorized by the government. There is no development of LMOs in the country. However, studies done already in 2009 indicated the possibility of irregular presence of LMOs in the country. Further studies conducted during the implementation of this Project revealed that a significant proportion of soybean and maize crops were using transgenic seeds introduced irregularly or illegally into the country. There have been no recent studies in the last five years, so the current situation is unknown. Although various sectors, mainly industry, academia, and environmental remediation expressed an interest in using LMOs or their derivatives, it's not legal in the country.

79. Even before the design of this project started in 2008, certain environmental non-governmental organizations (NGOs) in Ecuador strongly opposed the use of LMOs and influenced decision-makers to ban them. As a result, the 2008 Constitution banned LMOs in the country. However, this Constitution also mandates the National Assembly and Executive to legislate and regulate the prohibition of GM seeds and crops, as well as their exceptions, and this mandate was therefore interpreted as a very strong driver towards successful project implementation.

80. A nationwide survey of public perceptions of biotechnology and LMOs carried out by the Ministry of Environment in 2007, before Project design, showed that the level of knowledge in the population relating to these issues was quite low, with over 80% of the Ecuadorian population having no information. One of the main components of the Project was consequently designed to address public awareness about biotechnology and biosafety, along with public participation in national decisions related to biosafety issues. Although the public perception about biotechnology and biosafety has slightly improved during the last 15 years (with an impact from the COVID-19 global usage of ARN-based vaccines perception), there is a very widespread feeling of rejection against LMOs and transgenics, at the level of the entire population, which has translated into a strong barrier to the achievement of the final objectives of this project, which has suffered from major impediments in the political decision-

making process. The lack of approved regulations has even prevented the advancement of LMO research in the country, as stated by several academic actors.

81. The Project was executed by MAATE through the National Division of Biodiversity and Natural Protected Areas (of the Natural Heritage Under-secretariat) and had UNEP as its GEF Implementing Agency. Several governmental institutions supported the project design from their jurisdictional roles (agriculture, health, production, academy and research among others) and also the industrial and farmers sectors were involved.

82. The Project was approved by UNEP in November 2010 for an official start in December 2010 with a total duration of 4 years. There was little activity until mid-2012. The Project Midterm Review was developed in March 2013. Due to institutional changes, the Project Manager (and main original Project formulation consultant), resigned in mid-2013. This was followed by several PM changes until the end of the Project. In December 2014 the 1st Amendment extended the project finalization date to April 2016. The Project was stopped between 2016 and 2018 when a new agreement was signed, between UNEP, MAE and IICA, and this Institution collaborated with the Project's final stages, providing technical support, logistics, procurement and administrative services. The Project finalization date was extended to April 2020. An amendment to this agreement was made in 2020, extending the final date to January 2022.

83. The National Biosafety Commission (NBC) presided by MAATE was meant to be an important agent for the project since the beginning, as it performed also as its National Steering Committee. As a multisectoral body, its main purpose was to advise the CNA (MAATE) on biosafety matters. It would incorporate representatives of key sectors in the field, from both public and private organizations. At the time of Project design, its member institutions were: the Ministry of Environment, the Ministry of Agriculture, the Ministry of Health, the Ministry of Industries, a representative of the Chambers of Production from the Sierra Region and one from de Costa, a delegate from CEDENMA and a delegate from SENACYT - SENESCYT. The functioning of the NBC has been heterogeneous during the project time, with difficulties and changes in the official norms that regulate its function, work and composition. It was created originally in 2003. In January 2015 its composition was modified, its role and responsibilities expanded and a first draft rulebook for its work was published by MAATE. The documents available in ANUBIS[5] include the calls for the 1st session - 6 May - and 2nd session - 1 September 2015 -. No session memories or reports of these NBC sessions are available. There are memories uploaded in ANUBIS related to NSC meetings: 8 in total, held between March 2012 and April 2013. There are no NSC sessions reports available after April 2013. The NBC was again officially appointed in the Code of Environment of 2019 and its Rulebook. The NBC first task was to develop and approve its main Rulebook. The reviewer has not found any official publication of this Rulebook or any NBC session memories afterwards.

84. The available Project documents (uploaded in ANUBIS) only include the memories and reports of several (8) NSC meetings held from March 2012 and 2013.

85. The project coordination unit included a National Coordinator, a technical assistant and an administrative and financial assistant. The coordination unit worked in close

[5] "NBC Meetings 1.2.2.b.rar"

relationship with the Biosafety Unit of MAE. The project was supported by the Steering Committee (the NBC itself) as an inter-institutional coordination and advisory body.

86. Due to the delays in project implementation, having extended for about the ***triple*** of the original design time, several changes in Project Management happened during the years, due to political changes and country resources shortages. The Project budget included funds to contract a Project Manager for the project lifespan. When the original cycle concluded, the country had to cover these costs until the end of the Project. Some of these issues also produced delays in project funds disbursements by UNEP as at certain periods there was even a lack of an officially appointed NEA responsible / delegate.

B. Objectives and components

87. The project's Objective as stated in the ProDoc was to "*assist Ecuador in having a workable and transparent national biosafety framework in place, to fulfil its obligations as a Party to the CP and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology*". This would be accomplished through four technical components, and a fifth component covering project management costs.

88. The Results Framework presented in the UNEP ProDoc for the Project is comprehensive, extending up to the Outcome and outputs level. For each Outcome, a full set of indicators, baselines, targets, means of verification and assumptions is provided. These indicators provide an explicit understanding of the Outcome statements, which do not always articulate an Outcome level ambition. The ProDoc's work plan includes activities detailed at the outcome level. The "GEF-4 Tracking Tool for GEF Biodiversity Focal Area Strategic Objective Three: Safeguarding Biodiversity" is included in the ProDoc.

89. Table 2 Original Prodoc results framework shows the original framework at the expected outcomes and outputs level (for detailed activities corresponding to outputs, and indicators, please refer to the original Project Document).

Table 2 Original Prodoc results framework

Project components	Expected outcomes	Expected outputs
1. Finalize the policy and regulatory framework on biosafety	1.1 Biosafety policy and regulations formally approved, sustainably funded and their application initiated 1.2 The management of LMOs is improved through permanent coordination mechanisms and structures	-Policy for the safe use of biotechnology and its ten-year plan of action -New regulations about LMOs and biosafety -Operative Rulebook for the NBC -Sectoral regulations and technical norms harmonized, including trade and LMO products -Annual budgets and/or plans, programs and projects of the NCA and of the entities involved include the management and administrative costs of the national system of security of biotechnology
2. Implementation of a fully functioning system for decision making and control of LMOs	2.1 A fully functional technical and administrative system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio-	-Guidelines for decision-making, including criteria and principles, for use by the National Competent Authority -Guidelines for review of previous decisions on the basis of new information -Methodology for safety assessment of LMO foods and feeds

Project components	Expected outcomes	Expected outputs
	economic criteria and the precautionary principle 2.2 Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution. Biosafety is integrated into border control activities 2.3 Maintenance and updating of the national portal and the information of the BCH by the Competent National Authority	-Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for commercial activities with LMOs -Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for research activities with LMOs -Guidelines and operative manuals for risk management of LMOs in their different applications, to be used by state agencies -Guides about biosafety measures and risk management of LMOs in different applications to be used by petitioners -Institutions and personnel responsible of the different aspects related to biosafety -Instruction manual of procedures and methodologies for the detection of LMOs in crops, food, and feed, according to international standards -Survey to collect data for socio-economic considerations -Policies and guidelines for risk communication -Protocols for emergency responses in case of unintentional LMO introductions into the environment, non-compliance or unauthorized activities -Biosafety Clearing House has all the communication of decisions and other relevant information from Ecuador
3. Building human and institutional capacities for biosafety	3.1 Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs 3.2 Capacity to test for the presence or absence of LMOs in crops, food and feed products established 3.3 Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts.	-Staff trained in biosafety, risk assessment and risk management of LMOs, in the National Competent Authority and other relevant institutions -Training Program for technical staff, with national and international academic collaboration and financial resources identified -Analysis of infrastructure and capacity for LMO detection -Reference laboratories capable of carrying out LMO detection -Agreed Methodology for sampling and analysis of LMOs -Database of institutions, experts and projects related to biosafety -Database with information relevant to the Assessment and Risk Management -Collaboration agreements with the academic sector for initiating biosafety studies -Voluntary agreements with the private sector and NGOs -Cooperation Agreements with other biosafety projects in the region -Cooperation networks with their informative bulletins

Project components	Expected outcomes	Expected outputs
4. Improve public awareness and participation in biosafety	4.1 Public participation in biosafety decision-making is improved and institutionalized. 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed 4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time.	-Mechanisms for public participation, consultation and feedback are established by regulations and use internet media -Communication Strategy about LMOs and biotechnology and its plan of action, which include specific considerations and media for different types of stakeholders -Public information on national use of LMOs, through virtual and document libraries -Updated biosafety information on the national portal of the BCH and on MAE web site -Ongoing partnerships with relevant institutions for the provision and revision of biosafety information -Periodic consultations with stakeholders -Two surveys of public opinion on biosafety, biotechnology and LMOs -Assessment of changes in public opinion -Personnel (1) assigned to collect, process and edit information

90. Project Outcomes, Indicators and Outputs have been reviewed according to UNEP results definitions, Annex X - Adjustment of the project results statements contains a table justifying adjustment of the project results statements as part of the TOC reconstruction. Causal connections are analysed in the reconstructed TOC pathways. The next paragraphs show the revised impact, goal, objective and expected outcomes.

91. Intended Impact: Incremented level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and focusing, in particular, on transboundary movements.

92. Project Goal: Ecuador has established national policies, legal framework and administrative procedures, developed the required human and infrastructural resources to fully evaluate and manage all activities related to LMOs transboundary movements, and improved public participation in LMOs related decisions taking.

93. Project Objective: To implement and operationalize a workable and transparent biosafety framework

C. Stakeholders

94. Annex IX – Stakeholder analysis provides a full stakeholder analysis**,** describing their roles and relevance, in accordance with the ProDoc.

95. Initially, the project involved the main Competent National Authorities (with regulatory and decision-making responsibilities) and other relevant actors in biosafety issues in the country, including civil society (represented by NGO associations), small farmer groups, industry and academia.

96. As the Project has been extended for more than 12 years, many changes have occurred in all these institutions and organizations: some have been transformed

(e.g. SENACYT into SENESCYT), others no longer exist as such with respect to the Project (SENPLADES), and in most cases, the authorities and technicians of the original institutions are no longer available. This report therefore takes as a basis the original information available in the ProDoc, knowing that it will be strongly modified by the analysis of the development of the Project.

97. Likewise, IICA acted in the first years as a normal actor or stakeholder but gaining a more protagonist role starting in 2014. In this year, a collaboration agreement was signed with MAATE to develop the 1st Phase remaining activities and execution of funds ($100,000 from GEF funds were transferred to IICA for executing this agreement). After the 1st Phase (extended) finalized and the Project closed (with a third of the Project funds remaining to be executed), in July 2018 a new collaboration agreement (2nd Project PCA) was signed by UNEP, MAATE and IICA, with the aforementioned collaboration agreement, for developing several remaining core activities of the Project and its effective conclusion in 2020 (later extended to June 2021).

98. MAE-MAATE is the institution that proposes and leads the Project, as the one directly responsible for the implementation of the Constitutional mandate regarding the treatment of LMOs in the country. MAG is a fundamental actor as a CNA with direct responsibility for the release of LMOs into the environment and for research, as well as its dependent entities AGROCALIDAD and INIAP, from the professional technical point of view. MSP likewise has an important role from the point of view of food safety and the eventual affectation of human health. MIPRO, the Chamber of Industries and Producers represent the interests of industry and small producers. However, the ProDoc does not provide detailed information on how these institutions and organizations have collaborated in the design of the project. SENACYT (later SENESCYT) is presented as a relevant actor strongly promoting the development of human resources in the areas related to biosafety, through a strong in-cash contribution for postgraduate scholarships (masters and doctorates), to be carried out during the development of the project.

99. Due to the lack of data, Annex IX – Stakeholder analysis does not analyse whether within stakeholder groups, men and women, the young and old, minorities and mainstream groups, or the able-bodied and those with disabilities or long-term illness, are involved in the project in the same way (i.e., equitably).

100. Stakeholder participation in project steering faded after the initial Phase. No NSC/NBC reports of meetings after 2015 have been uploaded to ANUBIS. The Project was stopped between 2016 and 2018. In the 2nd Phase, stakeholders participation was limited to attending some presentations and workshops.

D. Project implementation structure and partners

101. The Project was implemented under the Ministry of Environment (MAATE) as National Executing Agency, and specifically managed by the Biosafety Unit (Figure 3 Structure of Project NEA arrangement).

102. The main Institutions / Stakeholders involved in this project (more information about their roles can be found in Annex IX – Stakeholder analysis), as identified in the original Project Document by their roles are detailed in Table 3 Project Stakeholders and roles and Figure 2 Stakeholder mapping, taken from Project Document):

Table 3 Project Stakeholders and roles

Regulators	Ministry of Environment Ministry of Agriculture, Livestock, Fisheries and Aquaculture Ministry of Public Health Hygiene Institute "Leopoldo Pérez Izquieta" (Centre for registry and control of products used in health, nutrition and veterinary medicine) Ministry of Industries and Productivity Ministry of Foreign Trade and Integration Ecuadorian Agency for Quality Assurance of Agriculture (Agrocalidad) Ecuadorian Customs Corporation (CAE) Legislators Ecuadorian Institute of Standardization (INEN)
Affected groups	Industry Agribusiness Peasant organizations (small farmers) Dealers of agro-veterinary products Communities and Indigenous Peoples (Indigenous Organizations) Producers Guild
Support groups	National Institute of Agricultural Research (INIAP) Universities (and Academy scientists) National Secretariat of Science and Technology (SENACYT) Local Governments National Fisheries Institute Private Biotechnology Laboratories Codex Alimentarius National Commission National Council of Citizen Participation Ombudsman's Office, Consumer Tribune International cooperation
Other interested groups	Environmental NGOs, social and legal Primary and secondary teachers (education system) Colleges or professional associations Media

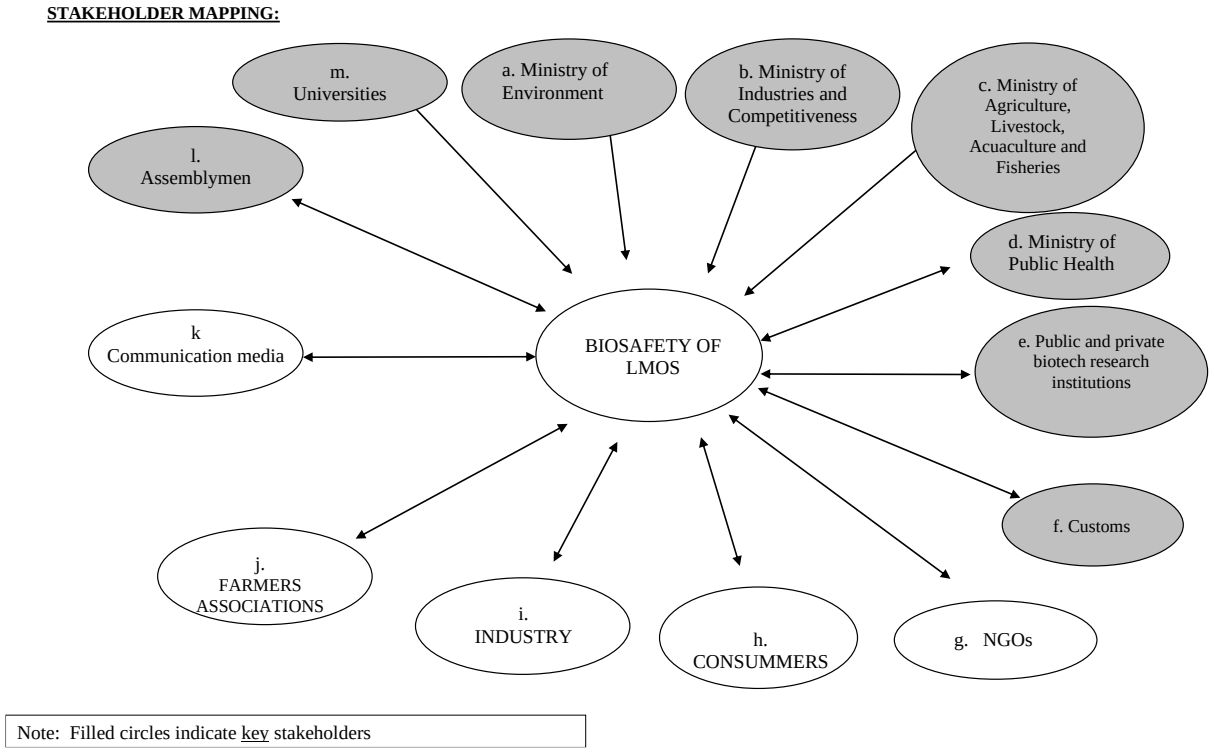

Figure 2 Stakeholder mapping, taken from Project Document

103. During Project execution, the stakeholders and institutions involved slightly varied:

- Ministry of Environment, Water and Ecologic Transition
- Inter-American Institute for Cooperation on Agriculture (IICA)
- MAGAP: Ministry of Agriculture and Livestock
- AGROCALIDAD: Agency for Phytosanitary Control,
- INIAP: National Institute of Agricultural Research,
- SENAE: customs
- SENESCYT: Secretariat of Higher Education, Science, Technology and Innovation
- MIPRO: Ministry of Production, International Trade, Investment and Fishing,
- MSP: Ministry of Public Health
- MRECI: Ministry of Foreign Affairs
- SENPLADES: Secretariat of Planning
- Universities: USFQ, ESPOL, ESPE

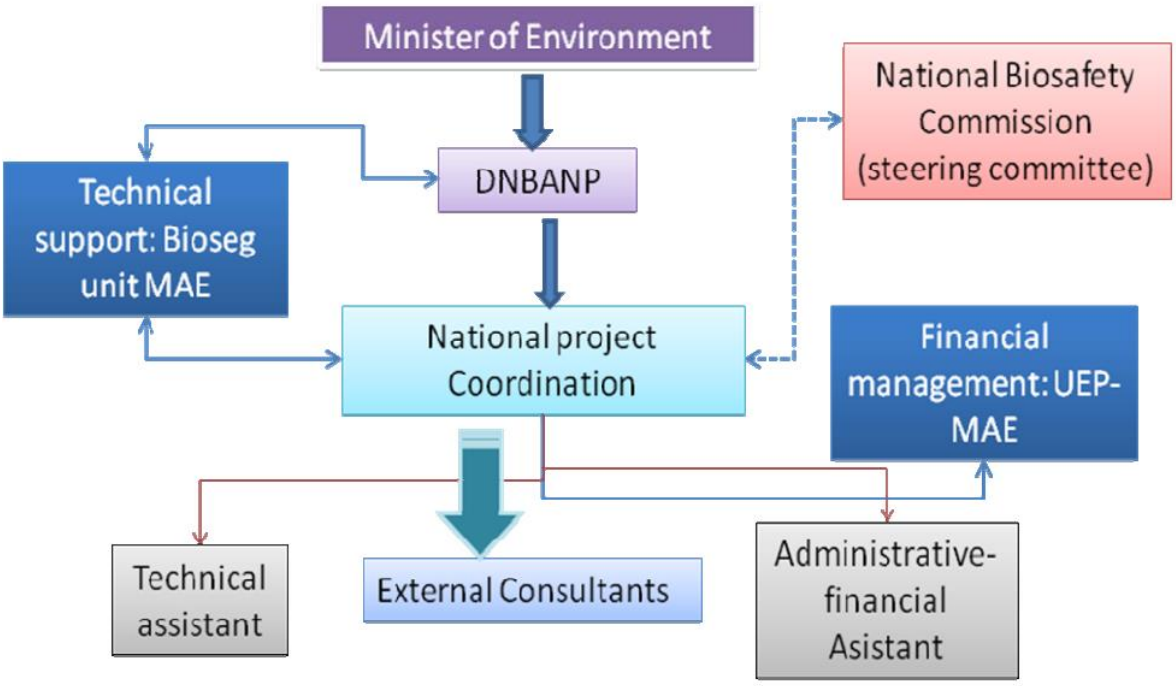

Figure 3 Structure of Project NEA arrangement

E. Changes in design during implementation (including responses to mid-term assessments, where appropriate)

104. Despite the many delays experienced, the Project main outcomes and objectives were not modified, but some activities were adapted during the 2nd phase of the project to address the needs that aroused during the years. Some new outputs were added in the 2nd phase (like the development of the Virtual Course on Biotechnology and Biosafety, published by MAATE)

105. The mid-term assessment was performed in early 2013. No significant modifications where foreseen at that time, although the planned workplan was already delayed.

106. When the Project initial deadline of December 2014 was approaching, it was modified with no cost changes by the 1st PCA Amendment, extending the project technical termination date to December 2015 (April 2016 for reporting purposes).

107. The Project closed and in remaining unspent funds ($ 203,551, 33% of GEF funds allocated for the Project).

108. A new PCA was signed in 2018, involving at this time IICA who would collaborate to implement the remaining activities and provide financial and technical support. In this new PCA the Project finalization date was set for /2020. Due to delays in this phase, motivated in first place by the delay in disbursing funds (occasioned by the lack of responsible NEA signatures of submitted financial and periodic reports), and, afterwards, the COVID-19 pandemic, an amendment to this PCA was signed, granting a no-cost extension, until Jan 2022.

F. Project financing

109. The following tables show the original Project Document planned distribution of GEF funds and co-financing by Project Components:

Table 4 Project planned budget by Components

		GEF	In Cash	In Kind
Component 1	$ 190,368.24	$ 64,605.00	$ 20,044.00	$ 105,719.24
Component 2	$ 236,096.24	$ 105,323.00	$ 64,544.00	$ 66,229.24
Component 3	$ 795,148.24	$ 258,765.00	$ 472,224.00	$ 64,159.24
Component 4	$ 302,028.24	$ 171,125.00	$ 66,744.00	$ 64,159.24
Component 5	$ 214,604.00	$ 66,000.00	$ 96,444.00	$ 52,160.00
PROJECT TOTAL	**$ 1,738,244.96**	**$ 665,818.00**	**$ 720,000.00**	**$ 352,426.96**

110. During the Project lifespan (1st Phase with its extension, 2nd Phase with its extension) there were several revision of the Project Budget (13). The table below shows the comparison between the original Prodoc budget, the latest approved revision and the final budget report:

Table 5 Comparison between Budget at Prodoc approval, last approved budget and final expenditures

Budget Component	Original (Prodoc)	last budget revision	Final
Personnel	337,550.00	250,783.48	249,898.48
Sub-contracts	89,000	25,235.72	25,235.72
Training	130,268.00	272,763.28	272,645.53
Equipment and premises	65,000	45,416.29	45,416.29
Miscellaneous	18,000	71,619.23	46,322.52
TOTAL	639,818.00	665,818.00	639,518.54

111.Table 6 shows the co-finance contributions as stated in Final Report.

Table 6 Co-finance contributions as stated in Final Report

Name of Co-financier (source)	*Type*	*Contribution*
Ministry of Environment MAATE	In-Kind	439,532.54
Ministry of Environment MAATE	In Cash	595,608.02
Ministry of Agriculture MAGAP	In-Kind	11,283.20
Ministry of Public Health MSP	In-Kind	23,104.00
SENESCYT	In Cash	1,764,176.13
National Secretariats	In-Kind	22,394.88
Coordinator Ministries	In-Kind	13,648.00
AGROCALIDAD	In-Kind	104,126.00
INIAP	In-Kind	14,459.40
MIPRO	In-Kind	13,131.88
Aduanas (Customs)	In-Kind	14,674.00
Academic Sector	In-Kind	135,297.00
IICA	In-Kind	63,905.55
Total Co-finance contribution		3,215,340.60

IV. THEORY OF CHANGE AT REVIEW

A. Intervention logic

112. Efforts to establish a functional biosafety system were initiated by the previous UNEP-GEF projects and this project aimed to continue those efforts. The system was designed to comply with the CPB and the commitments made by Ecuador as a Party. Lessons learnt, alliances built, and capacity created during the previous projects have been utilized. The national biosafety system's basal architecture and working parts, such as draft regulations, were defined and various technical aspects were strengthened during the previous projects. However, the proposed framework needed to be adjusted due to Ecuador's 2008 Constitution, which set policies on LMOs and biosafety. Therefore, the project envisaged updating, completing, and reworking certain regulatory and policy components to comply with this updated political guideline.

113. In order to achieve the general Objective ("To assist Ecuador to have a workable and transparent national biosafety framework in place, to fulfil its obligations as a Party to the Cartagena Protocol on Biosafety and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology"), the Project aimed to produce four main outcomes (that are further decomposed in more detailed outcomes and linked by corresponding indicators to measure the adoption and application of the stated outputs):

a) Finalizing the policy and regulatory biosafety framework.
b) Putting in place a fully functional system for decision-making and control of LMOs
c) Building human and institutional capacity for biosafety
d) Improving public awareness and participation in biosafety

114. The approved Results Framework presented 38 detailed Outputs, distributed along each of the 4 technical outcomes. In the original design of the log frame, the components are hierarchically structured, with an architecture that presents them in parallel and concomitantly but does not show explicitly the eventual dependencies among them.

115. The defined activities and outputs are correctly aligned with the stated outcomes, and the indicators, in general terms, are appropriate to be able to measure the degree of achievement of the indicated results. The design of the project was not based on the principles of the Theory of Change, so the original ProDoc does not have a TOC. Annex X - Adjustment of the project results statements has been developed to help reconstruct the TOC.

B. Reconstructed TOC, assumptions and drivers

116. A TOC concept and diagram have been developed taking the ProDoc Annex 4 (Results Framework) as the main basis, from which the outputs, outcomes, goal and impact have been derived. Several outputs and indicators have been reformulated to make them more compatible with current UN standards and aligned with their corresponding outcome (Annex X - Adjustment of the project results statements). At the same time, it was needed to introduce several Intermediate states:

- *"Biosafety regulatory framework finalized and operational",*
- *"System for decision making and control of LMOs is fully functional",*
- *"Adequate level of human and institutional biosafety capacity achieved" and*

- *"Biosafety Public Awareness and Participation improved" in order to visualize the implicit dependencies among the different outcomes in the different pathways.*

117. Aligned with the original Results Framework, 4 basic pathways can be observed, each one corresponding to each outcome. However, when reconstructing the TOC several new dependencies have been made explicit: in order to achieve the intermediate state *"Biosafety regulatory framework finalized and operational"*, along with completing all corresponding activities and outputs, it is also required that other two intermediate states are achieved or in an advanced phase: "*System for decision making and control of LMOs is fully functional*" and "*Adequate level of human and institutional biosafety capacity achieved*". During the development of this review, it has become evident also that the achievement of intermediate state corresponding to the Project Component 4, *"Biosafety Public Awareness and Participation improved",* imposed a dependency to reach the first intermediate state, thus conditioning in a important degree to the achievement of Project Goal.

118. The reconstructed TOC available in Annex VIII – Reconstructed Theory of Change shows all identified Pathways and illuminated the formulation of the questions designed to evaluate the different aspects of the project, as depicted in Annex III – Review Framework.

119. Assumptions and Drivers have been identified from the Prodoc (mainly from Annex 4 and the Risks table). At the same time, the TOC shows how these Assumptions and Drivers impact each one of the Outcomes and Pathways. Table 7 Assumptions and Drivers mapped to Project Outcomes also shows these relationships.

120. Assumptions:

A1. The Ecuadorian government is committed to implementing the National Biosafety framework, its policies and plan of action

A2. There are resources available for biosafety in the SAB

A3. The opposition to LMOs at the National Assembly (some members) and radical groups does not disable the launching of the NBF and its different instruments

A4. The institutions forming part of NBC are committed to harmonizing their juridical frame to include necessary aspects about LMOs and biosafety and to improve their management

A5. Key stakeholders actively and sustainably participate in the implementation and routine application of the NBF

A6. The competent authority of Ecuador is committed to establishing a functional technical-administrative system

A7. The existing draft (at the Project start date) for an administrative system does not undergo major changes or delays in its review and adoption

A8. Received at least one application for LMOs in the first 3 years of the project.

A9. The request(s) to be received provide comprehensive and quality information for risk assessment and will enable analysis and decision-making.

A10. Consensus will exist on the types of LMOs under the CP, LMOs for food, LMOs for production, LMOs for research

A11. Consensus and clear definitions about what risk communication, monitoring of risk management and which state agencies will be responsible

A12. The various stakeholders in academia, public and private sectors actively seek funding sources to support the development of knowledge in biotechnology and biosafety

A13. Trained staff remains in the beneficiary institutions

A14. Detection of LMO presence in crops, food and feed products is routinely requested by regulators, customs, and other interested parties

A15. The Ecuadorian Government and the private sectors have the resources to finance infrastructure and other needs of laboratories to establish themselves as reference laboratories

A16. Other regional and subregional projects are executed during this Project's life

A17. The authorities involved promote public participation under the criteria of transparency and equal opportunities for all stakeholders

A18. The regulatory support for conducting public consultations on LMO is approved

A19. The opposition of radical groups is more flexible as a result of the existing constitutional framework

A20. There are sufficient financial resources in the SAB to maintain and update the mechanisms for public information and to periodically assess its public access

121. Drivers:

D1. The statements of the New Constitution enforce the need to launch the NBF

D2. Ecuador needs to comply with the CPB as a Party

D3. CPB mandates the registration and publication in the BCH of all pertinent information

D4. There is a predisposition of institutions and researchers to share information, participate in networking and promote or engage in research in biosafety

D5. The new Constitution promotes citizen participation

D6. Possibility of the illegal introduction of LMOs to the country

122. Table 7 shows a cross-reference of Assumptions and Drivers to Project Components Outcomes, as can be observed in the diagrams of the reconstructed TOC in Annex VIII – Reconstructed Theory of Change.

Table 7 Assumptions and Drivers mapped to Project Outcomes

Outcomes	Assumptions	Drivers
1.1 Biosafety policy and regulations formally approved, sustainably funded and their application initiated	A1, A2, A3	D1, D6
1.2 The management of LMOs is improved through permanent coordination mechanisms and structures	A4, A5, A6	D6
2.1 A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio-economic criteria and the precautionary principle	A3, A5, A6, A7, A8, A9, A10, A11	D2, D6
2.2 Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution		
2.3 Maintenance and updating of the national portal and the information of the BCH by the Competent National Authority		D2, D3
3.1 Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs	A12, A13	D4
3.2 Capacity to test for the presence or absence of LMOs in crops, food and feed products established	A14, A15	D6
3.3 Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts.	A16	
4.1 Public participation in biosafety decision-making is improved and institutionalized	A17, A18	D5, D2
4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed	A19	
4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time	A4, A5, A17, A18, A20	

C. Stakeholder roles in the results pathways

123.See Annex IX – Stakeholder analysis

V. REVIEW FINDINGS

124. The findings presented in this section provide a summative analysis of all gathered and triangulated information relevant to the parameters of the review criteria. Review findings are objective and evidence-based and directly relate to the review questions under each criterion (Annex III – Review Framework).

125. Each one of the Review dimensions below, A to I, was addressed based on the thorough analysis of all expected outcomes, outputs and activities against the evidence available in all the submitted and officially approved documents, products, and reports (all available in UNEP ANUBIS portal), and then triangulated in each one of the meetings and interviews maintained with NEA and IICA officers, UNEP task managers & administrative assistants, stakeholders delegates and other country actors. Table 8 Detailed analysis of Project outputs achievement compared to planned Project outputs and indicators, and reported output status includes a thorough comparative analysis of each planned project output, based on the original designed corresponding indicators, against the actual availability of the specific output and the summary of attainment as per last PIR with task manager assessment and country Project Final Report. The outcomes of this analysis were triangulated with the results obtained during the on-site and virtual meetings and the online questionnaires completed by the different actors (Annex III-b – data collection tools).

A. Strategic Relevance

Finding: The project objectives and strategies are aligned with policies and plans of GEF, UNEP and national 2008 Constitution mandates and public agencies roles and strategical plans.

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

126. The original Project design was aligned with GEF's Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1) approved in December 2006, and was in line with the Focal Area Strategies and Strategic Programming for GEF-4 (Doc GEF/C.31/10) approved in July 2007. It responded directly to Biodiversity Strategic Objective 3: To safeguard biodiversity - Strategic Programme 6 Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. It is also fully aligned with the key elements emphasized in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol: (i) The need to develop a functional political, legal and regulatory biosafety framework.(ii) The need to strengthen technical and institutional capacity in biosafety, and establish a system for handling requests, carrying out risk assessments, decision-making on LMOs, communicating decisions, monitoring and enforcement. (iii) The need for awareness raising activities, education on biosafety, access to information and public participation on decision-making for LMOs.

127. During Project execution, it has been aligned with:

- ECUADOR UNDAF 2015-2018 Cooperation area 4: Environmental sustainability, resilience and risk management, and UNDAF 2019-2022, Strategic Priority 2: Planet.
- Programme of Work for the Biennium 2020–2021, Subprogramme 3 – Healthy and productive ecosystems and Subprogramme 4 – Environmental governance
- GEF Core Indicator Targets: Subprogramme 3: EA(a), Indicator (iii) and Subprogramme 4: EA(b), Indicator (i)

128. The project contributed to the following Sustainable Development Goals (SDG):

129. Goal 1: End poverty in all its forms everywhere. The project aims at the sustainable use of natural resources, thus contributing to poverty reduction. Access to healthy food is enshrined in the Government's Strategic Plans and reflected in the Project design.

130. Goal 2: Zero Hunger – The activities developed in the Project, being framed within the framework of the Cartagena Protocol, promote the application of mechanisms for the protection of the country's biodiversity, since Ecuador is a megadiverse country with extensive agricultural and livestock production. The care of native species, as well as human health, also contributes to the food security of its population. The targets involved are 2.1, 2.2, 2.3, 2.4, 2.5, 2.a, 2c.

131. Goal 3: Ensure healthy lives and promote well-being for all at all ages: The Cartagena Protocol explicitly aims to "ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health". At the same time, both the 2008 Constitution, the 2007 Sustainable Development Plan, and the subsequent Plans for Good Living (2009-2013, 2013-2017, 2017-2021) contain directives aimed at the protection of biodiversity and human health. The project has been designed and implemented following these national standards and plans. Goal Targets addressed: 3.9 and 3.d.

132. Goal 5: Gender Equality: Although not addressed explicitly at the time of this Project design and was not explicitly tracked during implementation, all activities that were developed (capacity building, coordination meetings, lab preparation among others) have shown attention on gender equality and balance.

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

133. The project design aligns with the priorities outlined in the country's 2008 Constitution. The constitution includes regulations regarding LMOs, which are somewhat restrictive in terms of their importation and use. However, the state is obligated to establish means to handle LMO cases. The new Constitution guarantees the implementation of international agreements signed and ratified by the Government, such as the Convention on Biological Diversity (CBD), to which Ecuador has been a Party since 1993, and the Cartagena Protocol on Biosafety (CP), which Ecuador ratified in January 2003 and became a Party to in September of the same year.

134. The project aligns with the CAN's Regional Biodiversity Strategy (2002), which requires member countries to develop institutional capacities to investigate the advantages and possible adverse effects of LMOs in their ecosystems. The strategy also emphasises the importance of establishing a common policy that defines a consensus Andean position on biosafety, taking into account international agreements such as the CP, and enabling joint operations and mutual strengthening of LMO management.

Complementarity with Existing Interventions/Coherence

135. The project is founded on the 2008 Constitution and established policies, programs, and political commitments set forth in the Government's National Development Program from 2007-2010. This program persisted in subsequent years and was later refined as the National Plan for Good Living from 2009-2013, 2013-2017, and 2017-2021. The program emphasized the importance of regulating living modified organisms (LMOs) and modern biotechnology under strict biosafety regulations. Consequently, the decision to put into effect a full National Biosafety Framework was

taken, and the National Biosafety Committee was fortified. This regulatory mandate for biosafety is also reflected in the National Biodiversity Strategy and the Law of Environmental Management. Furthermore, LMO foods are explicitly mentioned in the Law on Consumer Protection and the National Law on Food and Nutritional Security. Given that the project implementation spanned several governmental periods and dynamic political conditions resulting in numerous changes in biodiversity and biosafety at the national level, the project adjusted its outputs to meet the latest requirements.

136. The Project design builds on top the previous UNEP-GEF Project "Development of the National Biosafety Framework" that was carried out in Ecuador between 2003 and 2006. At the same time, the Project design builds upon the previous BCH-1 Project – "Building Capacity for an effective participation in the Biosafety Clearing House". Ecuador also participated in the BCH-2 Project "Biosafety Clearing House Project Phase II" concurrently with this project, so important synergies were leveraged.

Rating for Strategic Relevance: HS

B. Quality of Project Design

137. A complete assessment of Project Design Quality was presented in the Inception Report, including preliminary ratings. The overall score for the quality of project design is **4.48** which translates into **"Satisfactory"**.

	SECTION	**RATING** (1-6)	**WEIGHTING**	**TOTAL** (Rating x Weighting /10)
A	Operating Context	5	0.4	0.2
B	Project Preparation	4	1.2	0.48
C	Strategic Relevance	5	0.8	0.4
D	Intended Results and Causality	5	1.6	0.8
E	Logical Framework and Monitoring	4	0.8	0.32
F	Governance and Supervision Arrangements	4	0.4	0.16
G	Partnerships	4	0.8	0.32
H	Learning, Communication and Outreach	5	0.4	0.2
I	Financial Planning / Budgeting	5	0.4	0.2
J	Efficiency	4	0.8	0.32
K	Risk identification and Social Safeguards	5	0.8	0.4
L	Sustainability / Replication and Catalytic Effects	4	1.2	0.48
M	Identified Project Design Weaknesses/Gaps	5	0.4	0.2
			TOTAL SCORE:	**4.48**

138. The Project was designed satisfactorily, with a particular focus on problem and situation analysis, results framework, budgeting, and strategic relevance. During the design process, detailed assumptions, risks and drivers were identified, which are discussed in the Theory of Change at Review chapter, along with the analysis of different pathways. The stated Project results meet the SMART (Specific, Measurable, Attributable/Achievable, Realistic/Relevant, Time-bound) standards.

139. The project's design was based on the previous "Development of National Biosafety Frameworks" Project, which demonstrated a good grasp of the needs and key actors in each area of intervention. However, it would have been better to include a description of how the identified main stakeholders and beneficiaries participated or

were consulted in the design phase. The ProDoc describes the roles, official responsibilities and interests in biosafety matters of the different participating actors and main stakeholders, although it does not describe their participation in project design.

140. Minority groups – farmers, and indigenous communities - are mentioned in the ProDoc as primary beneficiaries of the Project outcomes, and are addressed as targets (among others) of some specific activities (e.g. socio-economic analyses as part of the LMO risk assessment and risk management processes, and surveys to collect data for socio-economic considerations).

141. Regarding human rights consideration, the Ecuador 2008 Constitution includes biodiversity as a human right, and the Project was specifically designed to protect it.

142. With regard to potential social risks, the project design envisaged the development of mechanisms for citizen participation during its execution that will balance cultural and gender factors, as needed. Gender considerations are not addressed explicitly in the project design, but, being this a Project that focuses on many aspects that deeply influence civil society, minority groups, farmers and consumers, its Component 4 (Public awareness and participation) implicitly includes gender aspects.

Rating for Project Design: S

C. Nature of the External Context

143. At Project design time, no special issues regarding conflict, natural disaster, political upheaval were foreseen. As The project has spanned more than 4 terms of government, and some economic and climatic crises have impacted on its normal development. The changes introduced in the new Constitution of the Republic in 2008 were interpreted as motivational for the execution of the project and the progress in the implementation of an operational and effective National Biosafety Framework.

144. During Project execution, several important assumptions that were foundational to the Project success did not hold, some drivers did not occur and several potential risks did materialize. When the Project was being designed, it was not possible to foresee or imagine how public perception and political priorities and support for issues related to living modified organisms would evolve as a result of the changes introduced in the 2008 Constitution (banning LMOs in the country with only strong exceptions). The adverse public perception of GMOs in Ecuador, coupled with the lack of consensus and political support at the highest levels of the political hierarchy, thus constituted powerful barriers that hindered the achievement of the Project's main outcomes and reduced its expected impact.

145. An important subset of the assumptions (see **Error! Reference source not found.**) on which the Project design was founded did not hold, or existed only partially:

- A1. The Ecuadorian government is committed to implementing the National Biosafety framework, its policies and plan of action.
- A3. The opposition to LMOs at the National Assembly (some members) and radical groups does not disable the launching of the NBF and its different instruments.
- A4. The institutions forming part of NBC are committed to harmonizing their juridical frame to include necessary aspects about LMOs and biosafety and to improve their management.

- A5. Key stakeholders actively and sustainably participate in the implementation and routine application of the NBF.
- A6. The competent authority of Ecuador is committed to establishing a functional technical-administrative system.
- A7. The existing draft (at the Project start date) for an administrative system does not undergo major changes or delays in its review and adoption.
- A8. Received at least one application for LMOs in the first 3 years of the project.
- A9. The request(s) to be received provide comprehensive and quality information for risk assessment and will enable analysis and decision-making.
- A14. Detection of LMO presence in crops, food and feed products is routinely requested by regulators, customs, and other interested parties.
- A18. The regulatory support for conducting public consultations on LMO is approved.
- A19. The opposition of radical groups is more flexible as a result of the existing constitutional framework.

146. Important drivers identified at Project design did not effectively push the Project successful execution:

- D1. The statements of the New Constitution enforce the need to launch the NBF.
- D5. The new Constitution promotes citizen participation.
- D6. Possibility of the illegal introduction of LMOs to the country.

147. When interviewing the different actors involved in this Project and reviewing the implementation with an historical perspective, the reviewer could observe:

- The declaration of a "GMO-free country" in the 2008 Constitution of the Republic, instead of acting as a stimulus for the implementation of the MNSB, has in fact become a barrier to the development of any kind of activities related to LMOs in Ecuador.
- Public perception of the issue of biosafety/biotechnology, and particularly LMOs, is very poor and has not improved throughout the project, except perhaps marginally because of COVID-19 pandemic use of ARN-based vaccines.
- There exists a broad negative perception of LMOs among politicians, assembly members, middle managers, NGOs and civil society. This perception is very different among professionals, academy, middle-level public institutions managers and technicians.

Finding: the external context for the project implementation has been unfavourable, with several strong barriers at high-level political decision taking authorities. These barriers are the main cause of the failure to operationalize a concrete system for biosafety decisions, although most of the required technical instruments and human resources have been properly achieved.

Rating for Nature of the external context: U

D. Effectiveness

Availability of Outputs

148. Table 8 presents a detailed analysis of Project outputs, stating the original Project planned outputs, targets and indicators for each component, the reported status of each output / activity as in the received Project Final Report, a synthesis of concepts related to each output / indicator in the last Periodic Reports, and, finally, the reviewer assessment of each output / indicator, based on available data, Prodoc stated means of verification and outcomes of interviews.

149. The next paragraphs state a synthesis of the observed availability of the outputs, at Project Component level:

150. Component 1: Finalizing the Policy and Regulatory Biosafety Framework

Finding: Most outputs were developed and finalized during the Project: Plan of action for 10 years, biosafety policies and regulations, the National Environmental and its rulebook, draft biosafety law for LMOs and its regulation – that has not been approved officially.

Finding: Not all the CNAs and other Institutions have permanently included management and administrative costs of a national system of security of biotechnology, only MAATE, AGROCALIDAD and MAGAP have stable positions.

Finding: The functioning of the National Biosafety Commission has been irregular during the entire lifespan of the Project. Initially created in 2003, after the new 2008 Constitution it was not until 2015 that its integration was officially approved. Its operating Rulebook was drafted and proposed in 2014, and again in 2019-2021, agreed by all participating Institutions, but still not officially approved. This also affected the Project Management, as (stated in the Prodoc) the Project National Steering Committee was the NBC itself.

Finding: Harmonized sectorial regulations have been drafted during the 1st Phase and updated during 2nd Phase of the Project, but have not been officially approved at higher level**.**

151. Component 2: Putting in place a fully functional system for decision making and control of LMOs.

Finding: Guidelines for decision-making, including criteria and principles, for use by the National Competent Authority have been produced during the 1st Phase and updated in the 2nd Phase, but are still being under consideration by CNAs and not officially approved.

Finding: There is no officially approved flowchart to coordinate the steps and actions needed to handling applications and risk assessments of LMOs.

Finding: High quality Instruction manual of procedures and methodologies for the detection of LMOs in crops, food and feed have been developed and socialized.

Finding: Methodologies for safety assessment of LMOs for foods and feeds, environmental risk assessment of LMOs both for commercial and research activities, and for reviewing previous decisions have been successfully developed.

Finding: Guidelines to be used by petitioners have not been developed (initial step in the applicant procedure under CP).

Finding: No practical cases have been developed and used to demonstrate the functionality of the operating system (no actual application has been reported and no decision has been registered in the Central BCH- CP).

Finding: Extensive and complete sets of Guidelines, Manuals and Protocols for Risk Management have been produced. Harmonization between existing Competent Authorities and official approval is still an ongoing process.

Finding: Ecuador CP required biosafety information has been updated in the Central Biosafety Clearing House (no decisions or Risk Assessments reported). The National Biosafety Portal (www.bioseguridadecuador.gob.ec) is not currently operative.

152. Component 3: Building human and institutional capacity for biosafety.

Finding: Databases of institutions, experts and projects related to biosafety, and of information relevant to the Assessment and Risk Management are not publicly available (National BCH is not operative).

Finding: A very ambitious and detailed Training Program was designed for Biosafety and Technology, and several hundred technicians participated in more than 15 training workshops developed during the Project.

Finding: In 2021 an additional significant training tool was created: Biotechnology and Biosafety Virtual Course hosted in MAATE virtual education platform. Issues related to this platform infrastructure user registering functionality prevented the reviewer from assessing this course.

Finding: The reviewer could confirm that MAATE Biosafety Unit officers are personally very well connected and interact routinely with several relevant academic institutions (UFSQ, UDLA, ESPOL. ESPE), research groups (INIAP), labs (AGROCALIDAD and ESPOL) and industry in the country.

Finding: Analysis of existing Analysis of infrastructure and capacity for LMO detection was very thoroughly developed in the 1st Phase of the Project

Finding: Staff from CNAs and other relevant institutions have been trained in biosafety, risk assessment and risk management of LMOs in different instances throughout the Project, creating significant technical capacity.

Finding: Capacity for LMO detection has been built in AGROCALIDAD and ESPOL laboratories.

Finding: A Methodology for sampling and analysis of LMOs has been developed and agreed.

Finding: The Project has collaborated effectively with the academic sector and with other biosafety Project in the region.

153. Component 4: Improving public awareness and participation in biosafety.

Finding: High level legislation in Ecuador mandates the public access to information and participation and consultation in all government decisions and information**;** however, Mechanisms for public participation, consultation and feedback established by regulations and using internet media are not available as Project outputs**.**

Finding: As the National Biosafety Portal is not operative, it has not been possible to verify the existence and functioning of a system for public participation and feedback on LMOs related decisions.

Finding: Public awareness activities strategy and products were developed but are not available**.**

Finding: One public opinion survey about biosafety and biotechnology was developed and carried out in the 2nd Phase of the Project, with IICA Collaboration - 2020. As there had been no other survey during the Project, its results have been compared to the baseline Project data that had been taken from a 2008 survey. General outcome was that "there has not been a significant improvement in scientific knowledge dissemination in Ecuador".

Finding: As the National Biosafety Portal is not operative, public information about the usage of LMOs in the country and updated information about biosafety are not available.

Finding: There is a shortage of technical human resources to update and maintain information on the National BCH and persisting technical issues to maintain the Portal active and accessible (not accessible at least since June 2023).

Finding: There are no formal, public and stable procedures or partnerships with relevant institutions to provide and review biosafety information in place.

Table 8 Detailed analysis of Project outputs achievement compared to planned Project outputs and indicators, and reported output status

Component 1: Finalizing the Policy and Regulatory Biosafety Framework				
Outcome 1.1 Biosafety policy and regulations formally approved, sustainably funded and their application initiated				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**[6]	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Availability of: Inter-ministerial agreement approving policy on biosafety	Policy for the safe use of biotechnology	Completed		**HS** The reviewer confirmed the availability of this product
Plan of action for the Biosafety policy and NBF implementation with a 10 years scope	10 year plan of action	Completed		**HS** the 10 year plan of action was completed in Nov. 2011 and submitted together with the complete proposal of Biosafety Policy (Output 1.1.1)
Biosafety regulations	New regulations about LMOs and biosafety	*Submitted for approval (draft biosafety law)*	*The new Environmental Code Rulebook approved in 2019 has an exclusive chapter on Biosafety that outlines the National Biosafety System, creates the National Biosafety Committee, and officially acknowledges risk assessment as the technical mechanism upon which decisions on*	**S** Several drafts of the biosafety law have been developed during the lifetime of this Project (The Environmental Code approved effectively contains some provisions for dealing with biosafety. The draft biosafety law and its rulebook generated in 2014 address the mechanisms specified in the Cartagena Protocol for

[6] comments transcribed literally

Component 1: Finalizing the Policy and Regulatory Biosafety Framework				
Outcome 1.1 Biosafety policy and regulations formally approved, sustainably funded and their application initiated				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report[6]**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
			Biosafety should rely, and puts the National Biosafety System in place. In 2019, the project has technically backstopped the Ministry of Agriculture's Agency on Phyto and Zoo Sanitary Control and to Customs.	dealing with LMOs transboundary movements (particularly release into the environment, contained use, unintentional/illegal transboundary movements, emergency measures), However, this law and its rulebook have not been promulgated.
State annual budget (SAB) includes resources for biosafety	Annual budgets and/or plans, programs and projects of the NCA and of the entities involved include the management and administrative costs of the national system of security of biotechnology	*Partial completion, "MAATE, MAG and AGROCALIDAD have personnel dedicated to biosafety issues"*	*"Until new regulations are established for the NBC, the project Steering Committee PSC is being used as coordinating instance amongst institutions"*	**MU** No reports of job descriptions are available for the personnel dedicated to biosafety in the main stakeholder Institutions or the ones that integrate the NBC, The reviewer has accessed the formal designation in 2015 of MAATE AND MAGAP delegates and technical secretary teams for the NBC. MAATE has a stable Biosafety Unit in its organic structure. There is no SAB available in ANUBIS to verify these funds and resources allocations by the country.

Component 1: Finalizing the Policy and Regulatory Biosafety Framework				
Outcome 1.2 The management of LMOs is improved through permanent coordination mechanisms and structures				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Availability of: Rulebook for NBC functioning. *Target: Rulebook for NBC function approved and emitted* NBC is well conformed, operating and includes delegates from key stakeholders. *Targets: NBC includes at least 1 qualified personnel assigned for biosafety from MAE, MAGAP, MIPRO, MSP, chambers of production, OCs, CEDENMA, SENACYT and it has been decided*	Operative Rulebook for the NBC NBC annual working plans and session minutes	Completed. *"Actually the NBC are working in the final rulebook to call the meeting to approve this rulebook and start officially the NBC work"*	*"In 2019 through the Rulebook of Environmental Organic Code establish the new National Biosafety Committee. Nowadays, Ministry of Environment have the rulebook of NBC ready in the legal department in the Ministry of Environment."* *"A new NBC has been recently created. No meetings have therefore taken place"*	**S** The rulebook has been drafted and agreed between institutions, but not formally approved. During the 2nd Phase of the Project, with IICA collaboration, a consultancy was performed and one of its products was a new/updated rulebook for the NBC: "REGLAMENTO INTERNO DEL COMITÉ NACIONAL DE BIOSEGURIDAD" This document is included in ANUBIS "Output 1.2.1 NBC rulebook and Output 1.2.3 Review sectorial norms". **MU** The NBC has had irregular functioning during the entire lifespan of the Project. Initially created in 2003, after the new 2008 Constitution it was not until 2015 that its integration was officially approved. Its operating Rulebook was drafted and proposed in 2014, and again in 2019-2021, agreed by all participating Institutions, but still not officially approved.

Component 1: Finalizing the Policy and Regulatory Biosafety Framework				
Outcome 1.2 The management of LMOs is improved through permanent coordination mechanisms and structures				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
whether other entities should be participates *The NBC operates regularly, with annual work plans and complete quorum*				There are no NBC session memories, annual plans or reports available in ANUBIS
Biosafety is mainstreamed into sectoral regulations through harmonization *Target: sectoral regulations have been harmonized to include LMOs and biosafety and to support NBF implementation*	Sectoral regulations contain the required specific clauses for Biosafety management, focused on LMOs and aligned with national Constitution, Laws and the CPB	Submitted for approval	*"Review of related sectoral legislation undertaken. Harmonization limited."*	**MS** Several consultancies were developed and draft proposal for harmonized sectorial legislation has been submitted. Not approved officially yet. In the 2nd Phase, with IICA collaboration, further work has been developed towards the harmonization of sectoral regulations, available in ANUBIS " Output 1.2.1 NBC rulebook and Output 1.2.3 Review sectorial norms": CONSULTORÍA: "REGULACIONES SECTORIALES Y NORMAS TÉCNICAS ARMONIZADAS PARA LA GESTIÓN INTEGRAL DE ORGANISMOS *GENÉTICAMENTE MODIFICADOS EN EL ECUADOR"* **DOCUMENTO QUE CLASIFICA Y ANALIZA INFORMACIÓN RELEVANTE SOBRE LAS MEDIDAS REGULATORIAS INTERNACIONALES Y NACIONALES PARA LA*

Component 1: Finalizing the Policy and Regulatory Biosafety Framework				
Outcome 1.2 The management of LMOs is improved through permanent coordination mechanisms and structures				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
				GESTIÓN DE LOS ORGANISMOS GENÉTICAMENTE MODIFICADOS **DOCUMENTO QUE CONTIENE UNA PROPUESTA DE HOJA DE RUTA PARA LA IMPLEMENTACIÓN AL CORTO, MEDIANO Y LARGO PLAZO DE LAS NORMATIVAS QUE SON NECESARIAS PARA LOGRAR UN MARCO NACIONAL REGULATORIO PARA EJECUTAR MEDIDAS DE BIOSEGURIDAD PARA LA GESTIÓN DE OGM EN EL ECUADOR Y LOGRAR EL CUMPLIMIENTO DE LA REGULACIÓN NACIONAL E INTERNACIONAL VIGENTE* **REGLAMENTO INTERNO DEL COMITÉ NACIONAL DE BIOSEGURIDAD* *NORMA TECNICA PARA LA DETERMINACIÓN DE ORGANISMOS PROVENIENTES DEL MEJORAMIENTO GENÉTICO DE ESPECIES QUE NO POSEAN ADN RECOMBINANTE O FORÁNEO EN EL GENOMA RESULTANTE*

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Operative flowchart for handling applications and risk assessments of LMOs is designed and approved by related regulators and stakeholders. *Target: PY2 administrative - technical system has a flow chart for its operation, which sets deadlines, benchmarks, requisites and steps for handling applications and risk assessments of LMOs*	Approved Operative flowchart	N/A	*"The Organic Environmental Code considers the principles and the general steps about risk analysis, however the specifically flowchart will build in the NBC in order to do this job will a coordinated way with all Biosafety competent authorities."* *"Dependent on functional National Biosafety Commission."* *"Activity 2.1.1 (a) Design of administrative - technical system, flowchart: This activity depends the Activity 1.2.1 because the administrative and technical system needs many political negotiations in the NBC."*	**U** No operative flowchart to coordinate the steps and actions needed to handling applications and risk assessments of LMOs has been approved.
Guidelines, methodologies, manual, guides and protocols are established as tools for risk assessment and decision taking	Guidelines for decision-making, including criteria and principles, for use by the National Competent Authority	Completed *"There are flowcharts for the handling of LMOs, but needs to be validated and approved. The NBC will play a key role on*	*"In 2019, Ecuador in its regulation take into account the main general topics around the biosafety issues, for that reason the last technical methodologies produced by Biosafety project and this material is analysing*	**MS** Drafts have been produced during 1st Phase and updated during last phase, but no officially approved integrated guideline or protocol for decision – making by CNAs (as instructed by CP) is yet formally in place.

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Target: *Guidelines for decision making, for use by NCA*		*this. The project produced many technical guidelines and has trained personnel from competent authorities, so there is capacity for processing applications, but the administrative procedures are not quite ready. Some hands-on training has taken place".*	*for competent authorities in order to apply the new regulations when NBC start its work. Also in 2020 – 2021 the project have been working on new guidelines as technical tools"*	
Target:PY3 the system has an instruction manual of procedures and methodologies for the detection of LMOs in crops, food and feed, approved and in accordance to international standards	Instruction manual of procedures and methodologies for the detection of LMOs in crops, food and feed, according to international standards	Completed	*"In 2019, Ecuador in its regulation take into account the main general topics around the biosafety issues, for that reason the last technical methodologies produced by Biosafety project and this material is analysing for competent authorities in order to apply the new regulations when NBC start its work. Also in 2020 – 2021 the project have been working on new guidelines as technical tools"*	**HS** Several versions of the different technical manuals and Guidelines for LMOs detection, Risk Assessment, Risk Management and Communication have been developed during the entire lifespan of the Project. Each version adapted and updated according to the latest trends in biotechnology at a global and national level. Ecuador has several very well prepared technicians on these subjects. The Study on

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Target : PY3 system has the following tools approved and based on scientific, technical and socioeconomic criteria for decision-making: *Methodology for assessing the safety of LMOs food and feed*	Methodology for safety assessment of LMO foods and feeds	Completed *"Is not just guidelines, nowadays risk assessment is the official tool to take decisions on Biosafety issues. Is important to clarify Ecuador divided the scientific analysis and socioeconomic and commercial activities with LMOs."*		socio-economic considerations was completed during 1st phase. Updated versions were produced 2nd Phase of the Project, with IICA collaboration:
Target: Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria of commercial activities with LMOs	Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for commercial activities with LMOs	Completed Completed	*No information available.*	**S** Available in ANUBIS as "Output 2.4. and Output 2.5. Draft methodology for environmental risk assessment" develops general criteria for risk assessment both for commercial and research activities. Last budget report QR37 includes expenditures on BL of USD 12.500 for Technical Guidelines for LMO research

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
Target: Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria of research activities with LMOs *Target:. Guidelines for the review of previous decisions on the basis of new information*	Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for research activities with LMOs Guidelines for review of previous decisions on the basis of new information Guides about biosafety measures and risk management of LMOs in different	Completed Completed	*Studies undertaken, National Biosafety Commission approval pending.*	($10,000) and Technical Guides Design and Diagramation ($2,500) No information available about this activity products in ANUBIS. Not reported in Final Report **S** Addressed in the 2nd Phase of the Project with IICA Collaboration, consultancy: *"Elaboración de propuestas de actos normativos para la revisión de decisiones anteriores sobre la base de nueva información"* Submitted document provided by IICA, not available in ANUBIS. Not officially approved yet. **U** Product Not available to verify

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
	applications to be used by petitioners			
Practical cases demonstrate the functionality and improvements to the system. *Target: through practical cases, the robustness and operability of the risk assessment system is verified and a 70% effectiveness is attained*	N/A	N/A	*In 2019, the project developed a workshop in order to create capacities about monitoring and detection with expert regulator from Argentina Government.* *The workshop provided many helpful insights on the implementation of risk management strategies and GMO detection.*	**U** No practical cases are available for reviewing. No decision for transboundary movement – and its corresponding Risk Assessment research - has been published (according to CP) in the Biosafety Clearing House. National biosafety portal is not available. The referred workshop memories, outcomes or reports are not available in ANUBIS.
Personnel is assigned from each competent entities *Target: each entity with jurisdiction over LMOs has appointed at least one person to working on the issue of LMOs and biosafety, which may or may not be the same as the delegate to de NBC*	Institutions and personnel responsible of the different aspects related to biosafety	Partial completion *"MAE, AGROCALIDAD and MAG personnel dedicated to Biosafety issues"*	*"There are officials who work on biosafety topics among many other subject-matters including agriculture, trade, health public, and other issues. It is expected that as national regulations are implemented, national authorities will assign official exclusively dedicated to biosafety issues.* *Nowadays, there are three institutions to had assigned official only for Biosafety issues (Agriculture,*	**MS** No legal documents assigning personnel dedicated to biosafety in the main stakeholder Institutions or the ones that integrate the NBC for biosafety are available in ANUBIS Project Reporting. MAATE its stable Biosafety Unit. AGROCALIDAD has several technicians trained and working on biotechnology tasks. The reviewer was not able to confirm the formal assignment of LMOs related

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36**	**Rating of output by reviewer and comment**
			Environment and Phyto sanitary and Zoo sanitary control Agency (Agrocalidad))" *"MAE has already four officials to work in biosafety issues and have a technical biosafety unit into its organic structure.* *It is important to mention, nowadays as a part of project activities, the competent institutions have delegated officials to work in biosafety issues.* *MAE is looking for to promote an official designation when the NBC starts"*	biosafety tasks in MAGAP (except for the designation in 2015 to participate in NBC)
	Survey to collect data for socio-economic considerations	Completed	*Completed during 1st Phase*	**HS** Very complete study on socio-economic considerations is available in ANUBIS as Output 2.10 Socio-economic considerations consultancy, available in ANUBIS, developed during 2013.

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.2: Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Guidelines, manuals and protocols for risk management developed *Targets:* *Risk management is carried out under the following tools based on scientific, technical and socioeconomic criteria:* *1 Guidelines on biosafety measures and monitoring procedures, to support the authorities' activities;* *2 Operational manual for monitoring compliance of risk management plans and control of illegal introduction of LMOs for use by the state personnel;* *3 Guides on biosafety measures and the scope of risk management that the applicant must meet. Each guide is specific to each of the different areas of use of LMOs.* *4 Policies and guidelines for risk communication* *5 Protocols for emergency responses in case of unintentional introductions of LMOs into the environment, non-compliance or unauthorized activities*	Guidelines and operative manuals for risk management of LMOs in their different applications, to be used by state agencies	Completed	*The project has edited and improved all the risk guides and finally include all the information into a general guide for stakeholders. These products was produced in the first period of project. The guides will be discussed into the NBC and is expected to be deliver in the second semester of 2021.* *"Studies undertaken, National Biosafety Commission approval pending.* *Staff engaged in the project has devoted time to developing some protocols to be discussed with the relevant entities."* *"Nowadays have done nearly all protocols, guides and methodologies for example: proposals of risk assessment guides including scientific and social economic criteria in order to take informed decisions from stakeholders and others."* *"Those protocols, guides and methodologies needs the final approval in the new NBC. Did many*	**MS** Draft guidelines and protocols have been produced and updated several times during project lifespan, but have not been officially approved or it has not been possible to access them. Harmonization between existing Competent Authorities is still an ongoing process. The capacity has been built, but currently no operational active processes are in place to routinely control the illegal introduction of LMOs Operative harmonized Protocols for emergency response in case of unintentional introduction (according to CP) have not been officially approved.

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.2: Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
			meetings in order to define some Biosafety issues about the technical guidelines in these methodologies". "Those protocols, guides and methodologies needs the final discussions in the new NBC."	
Procedures, deadlines, personnel and institutions in charge of risk management and its monitoring *Targets:* *PY4 Control procedures have been documented and the institution (s) responsible to carry it out has (have) been designated* *PY3 criteria, procedures, deadlines have been established and the professionals responsible for communicating the risk associated with the authorization of LMOs.*	Institutions and personnel responsible of the different aspects related to biosafety	Partial completion *"MAE, AGROCALIDAD and MAG personnel dedicated to Biosafety issues"* *See Outcome 2.1*	Completed during 1st Phase *Institution responsible for control procedure have been identified (Agrocalidad), their detection labs are being implemented.*	**MS** The coordinated control procedures of each National Biosafety System participating Institution are not yet officially approved nor harmonized. Professionals responsible for communicating the risk associated with the authorization of LMs not yet formally appointed.

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.2: Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Practical cases demonstrate the cost-effectiveness of the risk management system *Target: PY4 through practical (or in the absence, hypothetical) cases, it is verified the functionality and effectiveness of procedures for risk management and monitoring of LMOs*	Practical application cases	N/A	N/A	**U** No reports have been found describing the development of these practical cases. The reviewer specifically requested the PMU – without success - to provide examples of cases or simulations that could demonstrate the integrated functioning of all the Biosafety System that would be activated by applications (as considered in different articles of the CP).

Component 2: Putting in place a fully functional system for decision making and control of LMOs				
Outcome 2.3: Maintenance and updating of the national portal and the information of the BCH by the Competent National Authority				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Information available at the national portal of the BCH. *Targets:* *PY2 A schedule for updating and maintaining the information of Ecuador at BCH is established Information is generated on a regular basis to be included in the BCH, following the guidelines and fields established by the BCH* *PY3 The records for which there is information on, have been entered in each field as set by the BCH*	Biosafety Clearing House has all the communication of decisions and other relevant information from Ecuador	Complete *BCH actually working without problems*	*The National BCH has been updated (100%) with the help of the Biosafety Project staff.* *BCH operational, regular updates pending*	**U** The National Biosafety Portal[7] (http://www.bioseguridadecuador.gob.ec/) is not accessible online, and has not been since at least June 2023. The reviewer warned several times the PMU about this situation, that impacts on several important outputs of the Project. Latest updates of the information published in the central Biosafety Clearing House were[8]: National Focal Points: January 2022 Competent National Authorities: June 2021 Biosafety Laws, Regulations, Guidelines and Agreements: October 2019 National Biosafety Website or Database: September 2011 Biosafety Expert: November 2014 There are no Country Decisions or any other Communications published There are no Risk Assessment generated by a regulatory process published.

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Increased availability of data about experts, institutions and projects. *Target:* *PY1 a current and complete database of experts, institutions and projects in various disciplines related to biosafety is available on the BCH and printed for public knowledge*	Database of institutions, experts and projects related to biosafety	Completed *Databases are updating constantly in MAE rosters.*	*Actually, the Ministry of Environment through the Biosafety Project has identified many specialists in Biosafety issues through the training events and the Biosafety Unit has taken this information in order to classify and will publish in the BCH web page when will necessary.* *Completed during 1st phase* *Activities 3.1.1 and 3.1.2 were completed during 1st Phase, and the Database published in CD*	**MU** The reviewer did not have access to these databases. The National Biosafety Portal[9] (http://www.bioseguridadecuador.gob.ec/) is not accessible, so the reviewer has not been able to confirm the availability of these Databases. In the Biosafety Clearing House there is 1 national biosafety expert registered, since 2004 No organizations or laboratories are registered in the BCH. No such database is available in ANUBIS.
Increased availability of basic information for RA&M *Target: PY1 it has been developed a database of available research*	Database with information relevant to the Assessment	Completed	*The technical information from many ministries have developed indirectly in the framework of their competences*	**MU** The reviewer did not have access to these databases.

[7] Accessed on 9 March 2024

[8] Accessed on 9 March 2024

[9] Accessed on 9 March 2024

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
related to LMOs, biosafety and risk assessment for Ecuador (Examples: wild relatives of cultivated species, phenology of species for use in agriculture, micro-organisms used in bioremediation and wild relatives)	and Risk Management	*Databases are updating constantly in MAE rosters.*	*and all that information will support the further risk analysis around the GMOs in a medium term.* *Work in progress, needs National Biosafety Commission clearance.*	The National Biosafety Portal[10] (http://www.bioseguridadecuador.gob.ec/) is not accessible, so the reviewer has not been able to confirm the availability of these Databases. No such database is available in ANUBIS.
Number of people trained on RA&M and in-office, from key institutions, governmental and civilian *Targets: PY2 A training program on biosafety is designed with national and international cooperation and various financial sources.*	Training Program for technical staff, with national and international academic collaboration and financial resources identified	Completed *Five year training program was executed [11]and actually Ecuador have some ways to create and strengthen the national capacities on Biosafety issues.*	*Completed during 1st phase.*	**HS** Five year training program developed by ESPOL-TECH, available in ANUBIS as Output 3.2, ¨Capacitación en Bioseguridad y Biotecnología, Plan Quinquenal de Capacitación¨, December 2012. This document was extremely valuable for the Project, as it fully analyses different aspects related to Biotechnology in Ecuador, up to 2012: existing biotech labs, specialized professionals, research institutions, academic offering, industrial companies, regulatory framework and

[10] Accessed on 9 March 2024

[11] Should say “developed”

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
PY3 the training program in biosafety has been launched *PY4 the NCA and each institution belonging to the NBC have at least 2 personnel trained or in training on risk assessment and management and other related subjects.*	Staff trained in biosafety, risk assessment and risk management of LMOs, in the National Competent Authority and other relevant institutions	Completed *512 officials from national authorities was trained.*	*Actually, the Ministry of Environment through the Biosafety Project has identified many specialists in Biosafety issues through the training events and the Biosafety Unit has taken this information in order to classify and will publish in the BCH web page when will necessary.* *Most trainings undertaken; delays associated with Covid.* *Activity 3.1.4.(c) With funding from SENACYT at least 3 professionals each year from various institutions are sent to complete graduate studies in biotechnology, biosafety and related subjects – continuous, 100%*	competent authorities, political and public perception about LMOs. Based on this situation analysis this document then proposes a detailed plan of training activities, its logistics and required funding. **S** The report in ANUBIS for Output 3.1 "Staff trained in biosafety" contains a spreadsheet of trained personnel between 2011 and 2015 totalling 328 different participants in 15 training activities, plus another 49 participants that only attended the 3 training workshops developed under the concurrent UNEP-GEF BCH-2 Capacity Building Project (2011 – 2012). Several other training activities are reported in some PPRs, but the reviewer did not find any corresponding memories or reports. Some workshops were also planned for the 2nd Phase with IICA collaborations, but no information about their development is available in ANUBIS nor in the package received from IICA.

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
	ADDITIONAL OUTPUT added in 2021: Biotechnology and Biosafety Virtual Course			Several additional activities and outputs where developed during the 2nd Phase of the Project, with IICA collaboration: Risk Management manual for GM seeds In the original Prodoc SENESCYT committed to collaborate with an in-cash contribution of USD 420,000, that would be applied to fund fourth-level studies on biosafety. Starting 2015, PPRs (and final report) show that this amount was increased to USD 1,764,176 (although not reflected in the corresponding audit reports). It has not been possible to obtain the evidence of these scholarships and corresponding post-degrees achieved. There is no report available in ANUBIS. This virtual course was designed and implemented by UDLA for MAATE, with a cost of $18500 as appears in the last budget report QR37. It is a general course on biotechnology and biosafety published in MAATE virtual education platform at http://educavirtual.ambiente.gob.ec

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
				It was not possible for the consultant to review and confirm the public availability of this course, as the registering procedure was not working. The reviewer interviewed personnel from UDLA that had designed and implemented the course. At the time of this final report, the virtual course registration functionality is not yet working. The reviewer could not obtain information about the amount of users that had taken and approved this course.
Intersectoral cooperation consolidated to support the NBF *Targets: PY1 At least one cooperation network for research on biotechnology and biosafety has been consolidated, amongst academia, government and the private sector* *•PY3: At least 2 public – private alliances have been established at the national or international level in order to have technical and expert support for the training program*	Cooperation networks with their informative bulletins Collaboration agreements with the academic sector for initiating biosafety studies	Partial complete *Especially MAE share information with some networks such as: ArgenBio, ChileBio, AgroBio and others* Complete *Ecuador have an important nexus with many national and international academic institutions*	*Alliances in Biosafety with some sectors, especially in trade, regulatory and academic fields are ongoing. Nowadays, MAE has created new alliances with universities in order to continue creating the base line for stakeholders in Biosafety Competent Institutions and looking for other alliances in order to support the future actions about Biosafety management*	**MU** The reviewer could confirm that MAATE Biosafety Unit officers are personally very well connected and interact routinely with several relevant academic institutions (UFSQ, UDLA, ESPOL. ESPE), research groups (INIAP), labs (AGROCALIDAD and ESPOL) and industry in the country. However, it has not been possible to verify the existence of consolidated, formal, operating cooperation networks on biosafety or biotechnology fostered by the

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
				Project (involving academia, government and private sector) Activity 3.1.9., reported as been completed by the end of 2012 was specifically focused on "Consultancy for the design of a information technology tool for network operation". It has not been possible to appreciate the output of this activity (not available in ANUBIS nor any other accessible tool).

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.2: Capacity to test for the presence or absence of LMOs in crops, food and feed products established				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
There is better knowledge on the	Analysis of infrastructure and	Completed	*Situation analysis of biotech labs for establishing a reference lab for GMO*	**HS** Completed in 2012

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.2: Capacity to test for the presence or absence of LMOs in crops, food and feed products established				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
analytic capacity related to biotechnology *Target: PY1 there is a situation analysis of biotech laboratory infrastructure, equipment and facilities to maintain stock of reagents*	capacity for LMO detection		*detection was finished in the first period.* *Completed during 1st phase, 2012*	Available as ¨Output 3.3. Analysis of infrastructure and capacity for LMO detection¨ and "C.3 3.1.3+3.2.1+3.2.2 C6-1102 Informe Final Maria Isabel Rojas-Especial Biotecnología" in ANUBIS. This last one contains also a study of situation of different crops in Ecuador in 2012.
Number of people trained on LMO detection and in-office, from key institutions *Target:* *PY4 the State has a laboratory equipped for detection of LMOs in crops, food and feed, and at least 4 employees trained in detection of LMOs…*	Staff trained in biosafety, risk assessment and risk management of LMOs, in the National Competent Authority and other relevant institutions	Completed See Outcome 3.1	*The Biosafety Project has trained 15 officials from many competent institutions in topics related to Biosafety regulations, risk assessment, detection methodologies and other technical issues.*	**S** See Outcome 3.1
Availability of reference labs, certified or in process of certification for LMO detection *Targets:* *PY2 there is a plan to establish a system of reference laboratories taking advantage of partnerships at*	Reference laboratories capable of carrying out LMO detection	Complete *Through this action the project establish two important partners to detect LMOs in raw materials and processed food.*	*Now, in Agrocalidad there are three technical officials trained in detection methodologies, besides, the Biosafety Project bought lab supplies for this Institution too, in order to strengthen the detection process in Agrocalidad. Nowadays, this laboratory is close to obtain 17025 ISO standard.*	**S** Capacity for LMO detection has been built in AGROCALIDAD and ESPOL laboratories (Output 3.4 in ANUBIS). Currently, logistics of supplies – reagents, primers and other - (that were provided by the Project as seed support) depend on the demand of their offered services.

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.2: Capacity to test for the presence or absence of LMOs in crops, food and feed products established				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
national, regional and subregional levels *PY4 the State has a laboratory equipped for detection of LMOs in crops, food and feed, and at least 4 employees trained in detection of LMOs; the laboratory is in the process of certification by the relevant international agencies, with funding to maintain its stock of reagents and to obtain supplies. Alternatively, the State signs 2 agreements with entities that provide infrastructure, laying down the obligations of each party, among those the state provides supplies and reagents (primers and other products) and finances the salaries of at least 2 operators and the entities insure the attainment of the international certification*				

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.2: Capacity to test for the presence or absence of LMOs in crops, food and feed products established				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
It is confirmed and ensured an appropriate methodology for sampling and analysis of LMOs, the availability of supplies and reagents, and the provision of services for the State, for the detection of LMOs *Target: PY3: a methodology for sampling and identification of LMO crops and foods has been developed, that conforms to international standards (eg ISO 21.570)*	Agreed Methodology for sampling and analysis of LMOs	Completed	*Completed during 1st phase*	**HS** ANUBIS Output 2.9. Detection Methodologies – 2012 and "C.3 3.1.3+3.2.1+3.2.2 C6-1102 Informe Final Maria Isabel Rojas-Especial Biotecnología" - 2012 Output 3.5. Agreed Methodology for sampling and analysis of LMOs – 2014

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.3: Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Number of strategic alliances formed *Target: Cooperation agreements are established with other regional and subregional initiatives on biosafety , as these initiatives are developed*	Collaboration agreements with the academic sector for initiating biosafety studies	Completed *Ecuador have an important nexus with many national and international academic institutions*	*The Ministry of Environment is looking for facilitate a cooperation agreement south - south between Ministry of agriculture and Government of Argentina, in order to receive training from the Argentinian Ministry of Agriculture trough FOAR system. The Ministry of Environment always looking for ways to obtain new strategic alliances, in 2019 begin negotiation process with Alliance for Science, IICA, INASE (Arg) and local Universities.* *Difficulties in mobilizing the private sector*	**MS** The reviewer has not been able to confirm the existence of collaboration agreements with the academic sector based on available documents.
	Voluntary agreements with the private sector and NGOs	Completed *Ecuador have important work with some private sector and NGOs in order to continue the actions related on Biosafety.*		The reviewer has not been able to confirm the existence of agreements with the private sector and NGOs based on available documents.
	Cooperation Agreements with	Completed		Several technical activities have been developed in collaboration with other biosafety projects in the region.

Component 3: Building human and institutional capacity for biosafety				
Outcome 3.3: Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
	other biosafety projects in the region	*Ecuador support and interacting with other biosafety projects in order to share our experience and lesson learned*		

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.1 Public participation in biosafety decision-making is improved and institutionalized				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Procedures for public consultation in decision-making with LMOs are applied *Target: PY2 Biosafety regulatory framework contains provisions for public participation and the NBC ensures their compliance*	Mechanisms for public participation, consultation and feedback are established by regulations and use internet media	Partially completed *In Ecuador have an especial procedure to executing mechanism to participation, consultation and obtain feedback for environmental decisions and regulations (Participation Law, Norm of Regulatory Quality Index) this mechanism will use when the country is ready to take decisions.*	*Special legislation exists in Ecuador for public participation in governmental decision-making process which will be utilized for LMOs* *See activity 1.1.6. Special legislation exists in Ecuador for public participation in governmental decision making process which is analyzed for use in GMOs consultation.* *The National Survey on Public Perception of Biotechnology, LMOs and Biosafety was finalized in the present reporting period.*	**U** High level legislation in Ecuador mandates the public access to information and participation and consultation in all government decisions and information. The Ecuador 2004 *law "LEY ORGANICA DE TRANSPARENCIA Y ACCESO A LA INFORMACION PUBLICA¨* of 18/05/2004 is available in ANUBIS as *¨Output 2.11 and Output 4.1. Mechanisms for public participation, consultation and feedback"* The reviewer found no specific reports or products about mechanisms for public participation, consultation and feedback related to LMOs available as Project outputs. The National Biosafety Portal is not available / operative, so the reviewer has not been able to confirm the existence of internet media systems for public participation in decisions about LMOs Assumption "The regulatory support for conducting public consultations on LMO is approved" did not materialize.

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.1 Public participation in biosafety decision-making is improved and institutionalized				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Number of public consultations carried out *Target: PY3 at least one public consultation is carried out for each decision to be taken by the NCA*			*Public consultations depend of the number of decisions from NBC*	**MU** No documented decisions on LMOs transboundary movements have been reported to the BCH, and the National Biosafety Portal is not available, so it has not been possible to review the amount of public consultations performed.

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Public opinion polls show an increase in the percentage of	Communication Strategy about	Completed	*Strategy designed, issues with outreach and continued efforts over time.*	**MU**

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
people who know about biotechnology and biosafety as a result of the communication strategy. *Targets:* *PY1 The communication strategy on LMOs and biosafety is being executed at the national level.* *PY2 The NBC conducts monitoring of the communication strategy and its performance has a positive evaluation*	LMOs and biotechnology and its plan of action, which include specific considerations and media for different types of stakeholders	*Communicating Strategy and its action plan was executed through the actual regulation. The main strategy have been to connect frequently with people who participate in the project activities, in order to share information in a more easy way.*	*Activity 4.2.1. Adjusting communication strategy and starting its execution including new considerations on regulatory framework : Limited Outreach* *Activity 4.2.2. Design and printing of media: Limited Outreach* *Activity 4.2.3. Development of radio and TV spots Limited Outreach* *Activity 4.2.4. Contracts with TV and radio Stations Limited Outreach* *Activity 4.2.5. Round tables and public forums on biotechnology and biosafety (3): The Project needs the final round table in order to show all the products and derive the public perception about the Project work.* *Activity 4.2.6 (5.7.) Communication materials about biosafety and projects progress for authorities and decision makers: Modest systematic communication on project progress with key decision-makers. Intense change of personnel at MAE.*	Communication strategy products resulting from the consultancy developed in 2012 and reported in ANUBIS as "Comunication strategy products. activity 4.2.1. D2-1102" where not possible to download (broken links). In the interviews with the PMU, the reviewer was shown some TV-RADIO communication pieces related to biotechnology and biosafety that were designed and implemented by the Project. Due to political issues, these materials could not reach the expected audience.

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
PY4 Executing the communication strategy allows to reduce at least 5% the ignorance related to LMOs and Biosafety, as measured by the public opinion polls	Two surveys of public opinion on biosafety, biotechnology and LMOs	Completed *The national survey biosafety, biotechnology and LMOs made in 2021*	*NBC has not been active due to broader legislative changes.* *The NBC treated this issue and all the delegates coincided in work these topics in a coordinate way.* *All the communication initiatives generated by MAE will be presented in the NBC in order to generated an evaluation of this issue* *Second public opinion study as a part of the actions to second semester of 2019.*	No reports from NBC about the outcomes of the communication strategy are available **MS** One public opinion survey about biosafety and biotechnology was developed and carried out in the 2nd Phase of the Project, with IICA Collaboration - 2020. The corresponding outputs are not available in ANUBIS nor in the packaga that was provided by IICA. IICA provided the reviewer a printed copy of the survey results booklet "Estudio Nacional sobre percepción pública en biotecnología, OGM y bioseguridad". In the section ¨Hallazgos adicionales¨ of this document some comparisons with the 2008 pre-project survey are described, with no conclusive outcomes, mostly because

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
				of different dimensions and population have been considered. In its conclusions, this report states that *"Los hallazgos identificados demuestran que no ha existido un incremento significativo en la difusión de conocimiento científico en Ecuador"* **U** Only one poll developed at the end of the project, no Project attributable changes assessment available.
	Assessment of changes in public opinion	N/A	N/A	

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time.				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
Number of visits to MAE project' s website, number of opinions and consultations on biosafety received *Targets:* *PY2 MAE's website includes a space for the project, links to other relevant organizations and includes a section of opinions and questions from readers* *PY4 The number of visits to the website biosafety has increased 20% and 20% the number of views and consultations received, relative to PY1* Increased availability to the general public of unbiased information on biosafety and biotechnology in MAE	Public information on national use of LMOs, through virtual and document libraries Updated biosafety information on the national portal of the BCH and on MAE web site	Completed *National BCH contain update information and document libraries* Completed *BCH is updated*	*In national BCH (www.bioseguridadecuador.gob.ec) exists information on Biosafety* *Further work will be necessary to establish the mechanism to* *Completed, issues with links to other institutions and up-to-date information.*	**U** The National Biosafety Portal[12] (http://www.bioseguridadecuador.gob.ec/) is not accessible online and has not been since at least June 2023, so this information is not currently available. No reports are available in ANUBIS related to biosafety website hits analysis. **U** Idem above. **U** Idem above.

[12] Accessed on 9 March 2024

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time.				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
website, in digital format and in print *Targets:* *PY1 Based on partnerships / agreements with key players, a mechanism for regularly providing and qualifying information on biosafety is established* *PY3 a virtual basic library on biosafety has established for public access, which is in MAE's website and is also distributed through CDs every two years* *• PY3 a documentary library on biosafety has been established for public access* *• PY2: A person has been appointed to the task of collecting, processing and editing information to be disseminated to the public by MAE.* Generating entities provide information to the public	Personnel (1) assigned to collect, process and edit information	Partially Complete *Only in MAE have a personnel to collect, process and edit*	*Issues with up-to-date information*	No biosafety information available in MAATE website[13].

[13] Verified on 9 March 2024

Component 4: Improving public awareness and participation in biosafety				
Outcome 4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time.				
Outcome Indicators and targets (taken from Project Document)	**Planned Outputs**	**Reported output status and Results/Outcomes (measured against the performance indicators stated in the project document) in Project Final Report**	**Summary by the EA of attainment of the indicator & target as of 30 June 2021 – last PIR PERIOD 36 (comments transcribed literally)**	**Rating of output by reviewer and comment**
benefit, and its dissemination is institutionalized by the State	Ongoing partnerships with relevant institutions for the provision and revision of biosafety information	*information (BCH focal point)* Partially Completed *Many channels are open to provision and revision of biosafety information*	*As Biosafety unit in MAE has limited personnel (only three persons) other options have been used until more personnel is assigned.* *Through the work of the NBC are coordinating actions to generate definitive communication channels in order to publish the information in media channels.* *Issues with up-to-date information*	**U** No information available about the procedures by relevant partner institutions to provide and review biosafety information. As above, the National Biosafety Portal is now working.
	Periodic consultations with stakeholders	Not Developed	*N/A*	**U** No information available about this output.

Achievement of Project Outcomes.

Component 1: Finalizing the policy and regulatory biosafety framework

154. Continuous work has been developed during Project implementation active periods (2011-2015 and 2020-2021) towards advancing the legal framework for dealing with biosafety and LMOs, in the unfavourable context of the 2008 Constitution, lack of high-level political support and a broad negative public perception against LMOs.

Outcome 1.1: Biosafety policy and regulations formally approved, sustainably funded and their application initiated.

155. Biosafety Policy, Environmental Code and its Environment Code Rulebook[14] and several other high-level regulations (Organic Seeds Law, Health public Code Proposal) have been approved. Biosafety and LMOs provisions have been included in the Environmental Code and its regulation in 2019.

156. The funding for supporting the national biosafety system is yet to be secured in all the CNAs and in the State Annual Budget.

Finding: Top-level legal context exists in Ecuador for implementing an operative national biosafety framework to manage LMOs related decisions.

Outcome 1.2: The management of LMOs is improved through permanent coordination mechanisms and structures

157. Secondary level regulations have been drafted by the Project since 2012, updated in 2nd Phase and discussed among the different institutions that are related to biosafety and LMOs decisions in the country. In the 2nd Phase, the Project has supported creation of new technical regulation harmonized with other laws, especially with agricultural laws. The products of this consultation proposal include draft considerations for dealing with Synthetic Biology derived products (that, according to the interviews, would not fall under the restrictions imposed in the Article 401 of the 2008 Constitution). These proposals are under consideration of the CNAs and pending higher-level approval.

158. An indicator stated in the Prodoc for this outcome is: "Biosafety is mainstreamed into sectoral regulations through harmonization" with a defined target: "sectoral regulations have been harmonized to include LMOs and biosafety and to support NBF implementation". This target has been reached partially throughout all the CNAs regulations. Latest seed regulation approved in 2017 (reported in the Project Final Report), "Ley Orgánica de Agrobiodiversidad, semillas y fomento de agricultura"[15], Art. 56 & 57, reflects Art. 401 of 2008 Constitution prohibition except for research purposes and special cases, and states the related sanctions.

Finding: Permanent inter-institutional coordination mechanisms were not yet formally installed by the end of the Project, although informal channels between the involved institutions do exist (NBC expected to be the operative nexus).

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[14] https://www.ambiente.gob.ec/wp-content/uploads/downloads/2021/06/REGLAMENTO-AL-CODIGO-ORGANICO-DEL-AMBIENTE.pdf Not registered in the BCH

[15] https://www.ambiente.gob.ec/wp-content/uploads/downloads/2018/05/Ley-Organica-Agrobiodiversidad-Semillas-y-Fomento-de-Agricultura.pdf Not registered in the BCH

159. The National Biosafety Committee was identified in the original ProDoc design (and previous Project for Developing National Biosafety Framework) as a key element of the national biosafety system / framework. As such, one important indicator for this Project Component Outcome was stated as "*NBC is well conformed, operating and includes delegates from key stakeholders target*" with the following targets: i) *¨PY1 NBC includes at least 1 qualified personnel assigned for biosafety from MAE, MAGAP, MIPRO, MSP, chambers of production, OCs, CEDENMA, SENACYT and it has been decided whether other entities should be part¨ and ii) "PY1 The NBC operates regularly, with annual work plans and complete quorum"*.

160. The NBC has had an irregular and mostly ad-hoc functioning during the entire lifespan of the Project. Initially created in 2003, after the new 2008 Constitution it was not until 2015 that its integration was officially approved by the first time. In 2019 the Rulebook for the Organic Code of Environment (CODA) formally updated its integration. NBC operating Rulebook was drafted and proposed first time in 2014, and then re-drafted in 2021after the approval of CODA Rulebook, as part of the 2nd Phase consultancies and submitted (attached to ANUBIS "Output 1.2.1 NBC rulebook and Output 1.2.3 Review sectorial norms" on 01/09/2021). The Project Final report (reporting up to June 2021) indicates that it was still under consideration by CNAs and approval. A news dated 22/12/2021 ("Boletín Nº 486",) published in MAATE website (https://www.ambiente.gob.ec/ministerio-lidero-reunion-del-comite-nacional-de-bioseguridad/) indicated the official initiation of the National Biosafety Committee activities, along with the investment of the appointed Institutions delegates and the approval of the internal Rulebook. The reviewer has not been able to find more reports on these matters.

161. No memories of NBC Session acts nor Annual NBC working plans have been available to the reviewer. MAATE and MAGAP designation of delegates for NBC in 2015 were made available in ANUBIS in 2016. No records of delegates appointed after 2019 have been found. There are available reports of National Steering Committee meetings in 2012 and 2013 (taking into account that the Prodoc states that the NSC would be the NBC itself).

Finding: NBC, a key element of the National Biosafety System, has been officially approved in 2019, and its activities officially inaugurated in December 2021, after Project finalization.

Component 2: Putting in place a fully functional system for decision making and control of LMOs

Outcome 2.1: A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio- economic criteria and the precautionary principle

162. Several versions of the different technical manuals and Guidelines for LMOs detection, Risk Assessment, Risk Management and Communication have been developed during the entire lifespan of the Project: products developed during 1st Phase (mostly in 2012 and 2013) and some of them updated in the 2nd phase (2020). Each version adapted and updated according to the latest trends in biotechnology at a global and national level. Ecuador has several very well prepared technicians on these subjects. The Study on socio-economic considerations was completed during 1st phase.

163. In the 2nd phase, the Project produced also a regulation proposal for Synthetic Biology based products.

164. Guidelines for decision making by CNAs were drafted at high level during 1st Phase, but no actual integrated, officially approved concrete protocols for managing LMOs

related decisions are still functionally in place, as happens also with Guides to be used by petitioners in different applications. No operative flowchart to coordinate the steps and actions needed to handling applications and risk assessments of LMOs has been approved.

165. Practical cases that demonstrate the functionality and improvements to the system are not available in the reported Project products in ANUBIS and the National Biosafety Portal is not operative. There are no Country Decisions for transboundary movement – and its corresponding Risk Assessment studies - published (according to CP) in the Biosafety Clearing House.

166. The Environmental Code Regulation Rulebook in its Art. 241 defines the National Biosafety System (***SINABIO*** *"Sistema Nacional de Bioseguridad"*) and assign the task of interinstitutional coordination to the National Biosafety Committee. The reviewer has not found any more information about this SINABIO.

167. Allocation of Personnel in the different biosafety related CNAs is partial: MAATE, MAGAP and AGROCALIDAD have stable personnel that have tasks related to LMOs biosafety.

Finding: With the help of the Project, country capacity for risk assessment of LMOs based on technical, scientific and socio- economic criteria and the precautionary principle has been built.

Finding: A fully functional formal and operative administrative – technical system for handling requests is not yet in place.

Outcome 2.2: Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution

168. Guidelines, manuals and protocols for risk management, technical manuals for LMOs detection and risk communication have been developed during the 1st Phase of the Project, and some of them updated during the 2nd phase. Harmonization between existing Competent Authorities is still an ongoing process. The capacity has been built, but currently no operational active processes are in place to routinely control the illegal introduction of LMOs. Operative harmonized Protocols for emergency response in case of unintentional introduction (according to CP) have not been officially approved.

Finding: The Project has produced sound methodologies and technical manuals for Risk Assessment, Risk management, communication and LMOs detection.

Outcome 2.3: Maintenance and updating of the national portal and the information of the BCH by the Competent National Authority

169. The national portal of the BCH[16] (http://www.bioseguridadecuador.gob.ec/) is not accessible online, and has not been since at least June 2023, so it is not possible to verify if all biosafety relevant information is available and updated.

170. Regarding the required information in the Central Portal of the Biosafety Clearing House, the reviewer found that most relevant and mandated information is available, with the few exceptions of latest CODA Rulebook, NBC Committee regulations, and updates to the latest changes in Authorities (Competent National Authorities, Focal

[16] Accessed on 12 March 2024

Points, national websites). Latest updates of the information published in the central Biosafety Clearing House were[17]:

- National Focal Points: January 2022
- Competent National Authorities: June 2021
- Biosafety Laws, Regulations, Guidelines and Agreements: October 2019
- National Biosafety Website or Database: September 2011
- Biosafety Expert: November 2014
- There are no Country Decisions or any other Communications published
- There are no Risk Assessment generated by a regulatory process published.
- There are no biosafety Organizations, Laboratories or Capacity Building projects registered.

Finding: Biosafety information is not available at the National Biosafety Portal, because it is not currently operational online. This issue affects several expected outcomes of the Project.

Component 3: Building human and institutional capacity for biosafety

Outcome 3.1: Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs

171. The five year training program developed by ESPOL-TECH in December 2012 , available in ANUBIS as *Output 3.2, ¨Capacitación en Bioseguridad y Biotecnología, Plan Quinquenal de Capacitación¨* was extremely valuable for the Project, as it fully analyses different aspects related to Biotechnology in Ecuador, up to 2012: existing biotech labs, specialized professionals, research institutions, academic offering, industrial companies, regulatory framework and competent authorities, political and public perception about LMOs. Based on this situation analysis this document then proposes a detailed plan of training activities, its logistics and required funding.

172. Several hundred officers from different CNAs, project stakeholders, industry, academia, were successfully trained in all required topics related to LMOs biosafety during the 1st phase of the Project, between 2011 and 2015. The Project also had training synergies with the concurrent UNEP-GEF Project BCH-2 ("Continued Capacity Building for an Effective Participation in the Biosafety Clearing House" 2011-2012).

173. Some other training activities (mainly about Risk Assessment and LMOs detection methodologies) have been reported as being done during the 2nd Phase of the Project, with IICA collaboration, but no information about their development is available in ANUBIS nor in the package received from IICA.

174. In the original Prodoc SENESCYT committed to collaborate with an in-cash contribution of USD 420,000, that would be applied to fund fourth-level studies on biosafety. This is defined in the Prodoc Activity 3.1.4.(c) "*With funding from SENACYT at least 3 professionals each year from various institutions are sent to complete graduate studies in biotechnology, biosafety and related subjects"*. The Periodic Project Report for Fiscal Year 15 states that *"This activity has been delayed until the biosafety*

[17] Accessed on 12 March 2024

institutional framework is clearer". Starting 2015, PPRs (and final report) show that this amount was increased by the country to USD 1,764,176 (although not reflected in the corresponding audit reports). It has not been possible to obtain the evidence of these scholarships and corresponding identification of post-degrees achieved. There is no report available in ANUBIS.

175. An important addition to the dissemination of biotechnology and biosafety has been the development and implementation of a virtual Course that is published in MAATE virtual education platform and biosafety published in MAATE virtual education platform at http://educavirtual.ambiente.gob.ec. This virtual course was designed and implemented by UDLA for MAATE, with a cost of $18500 as appears in the last budget report QR37. It was not possible for the consultant to review and confirm the public availability of this course, as the user registration (the course is not available for guests) subsystem /procedure of the premises platform is not working[18]. The reviewer interviewed personnel from UDLA that had designed and implemented the course. At the time of this final report, the virtual course registration functionality is not yet working. The reviewer could not obtain information about the amount of users that had taken and approved this course.

Finding: An important effort was done during 1st Phase of the Project towards building capacity in human resources, mainly through training workshops on all important topics related to LMOs biosafety, Risk Assessment and Management, LMOs detection, and some officers from CNAs participated in no-line trainings on RA and detection in 2nd Phase.

Finding: As most training activities occurred more than 9 years ago, with the usual attrition in public offices, and not having the opportunity to apply the acquired skills to real situations ("special cases" are the only exception to the prohibition stated in Art. 401 of the 2008 Constitution, and these cases had not been regulated), the existing knowledge base is fading and becoming obsolete.

Finding: although allowed in the 2008 Constitution and some intents for regulating the introduction of LMOs for research activities have been drafted, no supporting framework is actually in place. As a consequence, biotechnology researchers in Ecuador focus on other areas but transgenics. The reviewer has not been able to find any country decision allowing the importation of LMOs for research, in the Biosafety Clearing House or any other place.

176. Other aims of this Component include to increase the public availability of data about experts, institutions and projects, and to increase the public availability of basic information on RA & RM. The reviewer has not been able to review the related databases as are not available in ANUBIS, and the National Biosafety Portal is not operative (the databases neither being available in the MAATE website).

Finding: the lack of National Biosafety Portal availability and maintenance impacts on the public access to important biosafety information.

177. The reviewer could confirm that MAATE Biosafety Unit officers are personally very well connected and interact routinely with several relevant academic institutions (UFSQ, UDLA, ESPOL. ESPE), research groups (INIAP), labs (AGROCALIDAD and ESPOL) and industry in the country. However, it has not been possible to verify the existence of consolidated, formal, operating cooperation networks on biosafety or biotechnology fostered by the Project (involving academia, government and private sector). Activity 3.1.9., reported as been completed by the end of 2012 was specifically focused on "Consultancy for the design of an information technology tool

[18] Checked several times since September 2023, last check on 12 March 2024.

for network operation", but this tool has not been made available as Project Output in ANUBIS and the reviewer has not been able to see it.

Finding: collaboration networks and alliances on biotechnology and biosafety, at national and international levels have been developed (and some collaborative activities occurred) but still need to be consolidated and formalized.

Outcome 3.2: Capacity to test for the presence or absence of LMOs in crops, food and feed products established

178. A very complete and thorough assessment of the national capacity and infrastructure for LMO detection was developed in 2012. It also contains a detailed analysis of the different crops that were being planted in Ecuador at that time, along with a review of the seeds that were available to be imported into Ecuador from neighbouring and other producers countries, focusing on the identification of LMO seeds. This study was the basis for identifying suitable national institutions and biotechnology laboratories that could develop the capacity to detect LMOs in crops, food and feed. With the help of this Project, capacity for LMO detection was built in AGROCALIDAD and ESPOL laboratories (Output 3.4 in ANUBIS), by providing technical standards, training and lab resources (supplies and reagents). Currently these laboratories offer LMOs detection for several crops, under demand.

179. Staff from different CNAs and other relevant institutions has been trained in RA and RM, as described in paragraph 172 above.

180. LMOs Detection methodologies were developed and reported by the Project in 2012 and a methodology for sampling and analysis of LMOs in 2014.

Finding: The capacity to test for the presence or absence of LMOs in crops, food and feed has been created and is available on-demand.

Outcome 3.3: Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts

181. Throughout the development of this Project, several instances of collaboration and synergies with other related projects initiatives at national and international levels occurred. At national level, the project activities actively involved the private industry, academic and research sectors (active stakeholders during the 1st Phase), and was also concurrent with the UNEP-GEF BCH-2 Capacity Building Project. At international level, the project developed training activities with the collaboration of recognized Institutions from Argentina, Brazil, USA. No formal agreements have been reported in Anubis, so the number of strategic alliances achieved could not be assessed.

Finding: The Project developed several synergies and collaborations with national and international related organizations, networks, private industrial sector, academy and research organizations.

Component 4: Improving public awareness and participation in biosafety

Outcome 4.1 Public participation in biosafety decision-making is improved and institutionalized

182. High-level framework exists in Ecuador for Public Participation: at 2008 Constitution level, and then a Law of Citizen Participation ("*LEY ORGANICA DE PARTICIPACION CIUDADANA*") exists since 2011[19], stating the general guidelines and structures that

[19] https://www.gob.ec/sites/default/files/regulations/2018-09/Documento_Ley-Org%C3%A1nica-Participaci%C3%B3n-Ciudadana.pdf

shall be implemented in different levels for ensuring the Public Consultation. The reviewer found no specific reports or products about mechanisms for public participation, consultation and feedback related to LMOs publicly available.

183. There is also a Law for Transparency and Public information access, 2004 **"LEY ORGANICA DE TRANSPARENCIA Y ACCESO A LA INFORMACION PUBLICA¨** of **18/05/2004** is available in ANUBIS as ¨Output 2.11 and Output 4.1. Mechanisms for public participation, consultation and feedback").

184. The National Biosafety Portal is not available / operative, so the reviewer has not been able to confirm the existence of any internet media systems (a planned output for this Project Output) for public participation in decisions about LMOs.

185. No documented decisions on LMOs transboundary movements have been reported to the BCH, and the National Biosafety Portal is not available, so it has not been possible to review the amount of public consultations performed.

Finding: an operational system for public participation in biosafety decision-making is not available.

Outcome 4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed

186. Communication strategy products resulting from the consultancy developed in **2012** and reported in ANUBIS as ***"Communication strategy products. activity 4.2.1. D2-1102"*** where not possible to download (broken links). No reports from NBC about the outcomes of the communication strategy are available. No other public awareness products are available as Project outputs in ANUBIS.

187. In the interviews with the PMU, the reviewer was shown some TV-RADIO communication pieces related to biotechnology and biosafety that were designed and implemented by the Project. Due to political issues, these materials could not reach the expected audience.

188. One public opinion survey about biosafety and biotechnology was developed and carried out in the 2nd Phase of the Project, with IICA Collaboration - 2020. The corresponding outputs are not available in ANUBIS nor in the package that was provided by IICA. IICA provided this reviewer a printed copy of the survey results booklet **"Estudio Nacional sobre percepción pública en biotecnología, OGM y bioseguridad"**. In the section "Additional Findings" ("*Hallazgos adicionales*") of this document, some comparisons with the 2008 pre-project survey are described, with no conclusive outcomes, mostly because of different dimensions and population have been considered. In general terms an increase in popular knowledge about biotechnology can be observed in the survey results, although not conclusive nor attributable to the Project dissemination activities.

189. In its conclusions, this report states that "The findings identified demonstrate that there has not been a significant increase in the dissemination of scientific knowledge in Ecuador" (*"Los hallazgos identificados demuestran que no ha existido un incremento significativo en la difusión de conocimiento científico en Ecuador")*

Finding: the Project faced very important barriers and challenges in deploying general biotechnology and, particularly LMOs related knowledge dissemination campaigns, due to lack of political support, general adverse perception of transgenics and strong lobby and counter-influence from environmental NGOs

Outcome 4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time.

190. Stated indicators for this outcome all refer to the availability of up-to-date relevant biosafety information, opinions and consultations on the national portal of the BCH, MAATE website and virtual / document libraries. The National Biosafety Portal is not currently functioning The National Biosafety Portal (http://www.bioseguridadecuador.gob.ec/) is not accessible online and has not been since at least June 2023, so this information is not currently available.

191. No reports are available in ANUBIS related to biosafety website hits analysis. No biosafety information available in other MAATE website pages.

192. Stable personnel to maintain and update biosafety information is only available in MAATE (BCH National Focal Point).

193. The reviewer has not found any reported procedures to provide and review biosafety information by relevant partner institutions.

Finding: the main channel to publicly share updated and relevant national biosafety information is not working, due to infrastructure issues. The National Biosafety Portal (http://www.bioseguridadecuador.gob.ec/) is not online since at least June 2023.

Achievement of Likelihood of Impact

194. The Project Objective stated in the Prodoc was "To assist Ecuador to have a workable and transparent national biosafety framework in place, to fulfil its obligations as a Party to the Cartagena Protocol on Biosafety and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology".

195. The Project Goal derived from the Project Objective when building the reconstructed ToC, (see Chapter Theory of Change at Review and Annex VIII – Reconstructed Theory of Change) states: "*Ecuador has established national policies, legal framework and administrative procedures, developed the required human and infrastructural resources to fully evaluate and manage all activities related to LMOs transboundary movements, and improved public participation in LMOs related decisions taking*".

196. According to the reconstructed ToC identified pathways, this Goal would be achieved if achievement of the intermediate states have been attained. The following table shows the reviewer conclusions about the degree of achievement of these intermediate states:

Intermediate State	**Degree of achievement**
"Biosafety regulatory framework finalized and operational"	**S** – the general high-level regulations needed to implement an operative Biosafety Framework are in place in Ecuador, starting from the 2008 Constitution, Environmental Code and its Rulebook. Harmonized 2nd level regulations for all involved institutions are still under consideration.
"System for decision making and control of LMOs is fully functional",	**MS** All the required technical aspects needed for implementing this system have been developed. Formalization of concrete inter-institutional mechanisms and processes for dealing with LMOs related decisions according to CP, once applications have started the workflow, are yet being agreed. (e.g. there have been no applications related to LMOs introduction into the environment or for research / contained use that trigger this mechanisms and allow for the

Intermediate State	Degree of achievement
	verification of the functional coordinated system).
"Adequate level of human and institutional biosafety capacity achieved" and	**S** – Human and Institutional biosafety capacity has been achieved. Several hundred people from all involved institutions have been trained in all the relevant topics related to LMOs decision-taking (e.g.: Risk Assessment, Risk Management, Detection, Risk Communication).Complete manuals and guidelines have been produced. Laboratories for analysing and detection of LMOs have been leveraged and are currently capable of performing these tasks with approved standards. Actors from engaged institutions MAATE, MAGAP, INIAP, AGROCALIDAD and ESPOL are now moving towards the relatively new area of Synthetic Biology technologies, building on the previous generated knowledge.
"Biosafety Public Awareness and Participation improved".	**MU** – although the Project developed many activities towards Public Awareness and Public Participation, at the time of this review most of the products are not publicly available (being the National Biosafety Portal www.bioseguridadecuador.gob.ec, the main channel for these outputs, not currently available online). However

197. Based on the previous analysis, the reviewer considers that the Project Goal has been partially achieved.

198. The ToR (Annex VII. Review TORs) for this review specifically include some Key Strategic Questions that should be addressed. **Q1** (*"To what extent has the project achieved an effective application of the Cartagena Protocol on Biosafety, implemented the national biosafety regulatory framework and developed national capacities to properly handle LMO to safeguard biodiversity?)* and **Q2** (*"What impact has been achieved by actors engaged in the project moving on and deploying their knowledge in novel areas? How were the lessons learned used in applying agile and adaptive management of the project?"*) are relevant for assessing the level of achievement of the intended impact.

199. The level of achievement of the intended impact can be derived as a consequence of the level of realization of the project goal. Based on the previous reasoning, the reviewer considers that the Intended Impact for this Project ("*Incremented level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and focusing, in particular, on transboundary movements")* has been ***partially achieved*** and that it is still an ongoing process, that is also evolving towards considering new biotechnologies.

Finding: The Project has successfully developed national capacities to handle LMOs to safeguard biodiversity.

Finding: The Project has achieved a partial application of the CPB through general regulations, but implementation of the functional, operative national biosafety framework is still delayed.

Finding: Some actors engaged in the project are currently having an impact in addressing the issues arising from new biotechnologies (e.g., Synthetic Biology), building on-top of the knowledge and expertise developed during the Project.

Rating for Effectiveness: MS

E. Financial Management

Adherence to UNEP's Financial Policies and Procedures

200. In general, the project followed the financial policies and procedures of UNEP. These policies were outlined in the Project Cooperation Agreement (PCA) signed between UNEP and the Ministry of Agriculture and Environment (MAE) at the start of the project. The PCA included information on cash advances, procurement procedures, and the terms and obligations related to project execution, sub-contracts, personnel administration, cost overruns, project management costs, record-keeping, unspent balances, and reporting/audit requirements. Audit reports of years 2014 – 2017 were not developed nor submitted on time, and were finally developed retrospectively during the 2nd phase of the project, by contracts managed by IICA. Cash advancements supporting documents for years 2018-2022 were not submitted to ANUBIS.

201. Quarterly and final Expenditure Reports, Cash Advance documents, budget revisions, inventory reports, annual audits and other financial records have been reviewed by the consultant.

202. Audit reports for years 2010, 2011, 2012 and 2013 were submitted and uploaded to ANUBIS on time.

203. Audit reports for years 2014, 2015, 2016, 2017 and 2018 were developed during 2nd phase with IICA collaboration, completed and uploaded to Anubis on August 2019 and accepted on January 2021. Audit reports for year 2019 were uploaded to ANUBIS in March 2022, accepted September 2022. Audit reports for years, 2020, 2021 were uploaded in April 2022 to ANUBIS, accepted September 2022.

204. The reviewer analysed all these audit reports and concluded that the auditors found that funds had been used properly, with very minor observations.

205. Funds have been transferred to the Project using UNDP services, from 2011 to 2014, and Cash Advancements #1 to #8 documents are available in ANUBIS. For the 2nd Phase, Cash Advancements #10, #11 and #12 supporting documents are not available nor accepted by FM in ANUBIS.

Finding: UNEP financial policies and procedures have generally been applied throughout the Project. Audit reports for years 2014-2017 were not produced on time and were developed, submitted and approved during the 2nd Phase of the Project (2019 onwards).

206. **Error! Reference source not found.** compares the budget at Prodoc approval, latest approved budget revision and final reported budget execution, by UNEP standard budget lines. Several budget revisions (15) occurred during project implementation as can be appreciated in ANUBIS budget "*rephasals*" and reviews reports, using an adaptive management approach according to the context.

Table 9 Comparison between Budget at Prodoc approval, last approved budget and final expenditures

Budget Component	Original (Prodoc)	last budget revision	Final	Difference
Personnel	337,550.00	250,783.48	249,898.48	-0.35%
Sub-contracts	89,000	25,235.72	25,235.72	0.00%
Training	130,268.00	272,763.28	272,645.53	-0.04%
Equipment and premises	65,000	45,416.29	45,416.29	0.00%
Miscellaneous	18,000	71,619.23	46,322.52	-35.32%
TOTAL	639,818.00	665,818.00	639,518.54	-3.95%

Completeness of Financial Information

207. The financial information provided is complete. The original Prodoc document contains detailed budget tables organized by component, by calendar year and by each UNEP expenditure category. There are also detailed tables of planned expenditures for each activity and output and separated by GEF funds and national contribution funds.

208. Periodic expenditure reports have been made according to UNEP standards, following the same expenditure categories and lines, and these have been analysed by independent audits following the same format. Audit reports are very comprehensive and contain all details about the financial movements history. Final financial report adheres to the required standards, is complete and was approved by the Fund Manager. It is coherent with PIR and budget reviews that had been approved during the Project.

209. In 2014 the Project signed an agreement with IICA for developing several products and services. The budget report submitted by IICA is complete and has been validated by the external audits. The same applies to the 2nd Phase of the Project, when IICA had several assigned tasks and managed all remaining funds: the budget reviews are complete, comprehensive and have been reviewed and approved by the external auditors.

Finding: the financial information of the Project tracking and management is complete and correct.

210. With regards to co-financing, the ProDoc included a total cofinancing amount of $1,072,427.27, from 7 institutions, as can be seen in Table 10 Co-finance commitment at Project approval. Letters from all these institutions indicating the commitment to participate in the Project and (with the exception of the letter from SENACYT/SENESCYT) the committed cash or in-kind amount were attached to the approved PCA / Prodoc.

Table 10 Co-finance commitment at Project approval

Name of Co-financier (source)	*Classification*	*Type*	*Contribution*
Ministry of Environment MAATE	Exec. Agency	In-Kind	236,647.00
Ministry of Environment MAATE	Exec. Agency	In Cash	300,000.00
SENACYT	Nat'l Gov't	In Cash	420,000.00
SENACYT	Nat'l Gov't	In-Kind	19,296.61
MAGAP	Nat'l Gov't	In-Kind	19,296.61
AGROCALIDAD	Nat'l Gov't	In-Kind	19,296.61
INIAP	Nat'l Gov't	In-Kind	19,296.61
MIPRO	Nat'l Gov't	In-Kind	19,296.61
Aduanas (Customs)	Nat'l Gov't	In-Kind	19,296.61
Total Co-financing			**1,072,427.27**

211. During the Project lifetime the contribution from different stakeholders varied. In the final report the type and amount of the updated contributions are informed as in Table 11 Co-finance contributions as stated in Final Report.

Table 11 Co-finance contributions as stated in Final Report.

Name of Co-financier (source)	*Type*	*Contribution*
Ministry of Environment MAATE	In-Kind	439,532.54
Ministry of Environment MAATE	In Cash	595,608.02
Ministry of Agriculture MAGAP	In-Kind	11,283.20
Ministry of Public Health MSP	In-Kind	23,104.00
SENESCYT	In Cash	1,764,176.13
National Secretariats	In-Kind	22,394.88
Coordinator Ministries	In-Kind	13,648.00
AGROCALIDAD	In-Kind	104,126.00
INIAP	In-Kind	14,459.40
MIPRO	In-Kind	13,131.88
Aduanas (Customs)	In-Kind	14,674.00
Academic Sector	In-Kind	135,297.00
IICA	In-Kind	63,905.55
Total Co-finance contribution		3,215,340.60

212. There are no available detailed letters from the contributors confirming the funds that have been contributed and the corresponding products, services and other expenditures (e.g., the reviewer has not been able to obtain a list of all the fourth-level degrees achieved with the support of SENESCYT scholarships, to confirm the realization of this contribution).

Table 12 Financial Tables

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[20] to UNEP or donor policies, procedures or rules		No	Audit reports for years 2014-2018 were not developed on time and not available/accepted until 2019
2. Completeness of project financial information[21]:			
Provision of key documents to the reviewer (based on the responses to A-H below)		**HS**	
A.	Co-financing and Project Cost's tables at design (by budget lines)	Yes	Detailed co-financing budget in Prodoc, by Component and stakeholder. Stakeholders co-finance commitment letters annexed to Prodoc.
B.	Revisions to the budget	Yes	Available in ANUBIS
C.	All relevant project legal agreements (e.g. SSFA, PCA, ICA)	Yes	Available in ANUBIS
D.	Proof of fund transfers	Yes	Available in ANUBIS (except for Cash Advances #10, #11 and #12)
E.	Proof of co-financing (cash and in-kind)	Partially	Stakeholders co-finance commitment letters annexed to Prodoc There are no letters from partners confirming fund mobilization at project end. No reports have been found of the SENESCYT outcome (fourth-level degrees scholarships for Project participating Institutions Professionals, Ac, Prodoc pp98)of the in-cash declared contribution.
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	Available in ANUBIS
G.	Copies of any completed audits and management responses *(where applicable)*	Yes	Available in ANUBIS
H.	Any other financial information that was required for this project (list): Inventory reports	Yes	Available in ANUBIS
3. Communication between finance and project management staff		**HS**	
Project Manager and/or Task Manager's level of awareness of the project's financial status.		HS	

[20] If the Review raises concerns over adherence with policies or standard procedures, a recommendation maybe given to cover the topic in an upcoming audit, or similar financial oversight exercise.

[21] See also document 'Criterion Rating Description' for reference

Fund Management Officer's knowledge of project progress/status when disbursements are done.	HS	ANUBIS budget reports, PIR
Level of addressing and resolving financial management issues among Fund Management Officer and Project Manager/Task Manager.	HS	
Contact/communication between by Fund Management Officer, Project Manager/Task Manager during the preparation of financial and progress reports.	S	Submission and approval dates in ANUBIS
Project Manager, Task Manager and Fund Management Officer responsiveness to financial requests during the review process	S	
Overall rating	**HS**	

Rating for Financial Management: S

F. Efficiency

213. The Project suffered several major delays, which resulted in a planned extension of 4 years (2010-2014) ending up with an implementation that took almost 12 years. Project activities were halted for a long period between 2015 and 2019, with the consequent loss of momentum and dilution of resources achieved during the first years.

214. The 2nd phase was impacted by the COVID-19 epidemic, and thanks to adaptive management it was still possible to complete the remaining planned activities, including some outputs that were not originally planned.

215. Most activities planned in the original Prodoc were developed, although many of them were delayed in time, but he total project cost for UNEP-GEF remained unchanged.

216. Due to the passage of time and corresponding evolution of global biotechnology methods and procedures, some technical products (manuals, guidelines) as well as training required updating, with the consequent additional cost.

217. Due to the fact that the project took place during several periods of government, with some changes in political orientations, involving the change of political authorities at various levels, the processes of generating and approving regulations related to biosafety were often interrupted and delayed. The cost in contribution from Government and related institutions increased significantly due to project delays.

218. The continuous changes of Project staff, especially from mid-2013 onwards, as well as the absence of responsible staff at various periods of the project, resulted in loss of momentum and increased time needed to resume activities and complete planned outputs.

219. The extension in time of the project also resulted in the dilution of interest and participation of several stakeholder institutions. During the second phase of the project, involvement was scarce, reduced to a few training workshops and meetings to disseminate technical products. There are no reports of Steering Committee or NBC meetings, a critical element for the functioning of the National Biosafety System.

220. As a consequence of the extensions and delays, three Task Managers have been in charge of this Project on behalf of UNEP, also with important periods of absence due to the time it took to hire a new Task Manager each time the previous one left.

221. Resources mobilized by UNEP for managing the Project were significantly extended (Task Managers, Fund Managers, Administrative assistants, approval procedures, systems and infrastructure), to almost a 3 fold in Project time. At national level, the

mobilized resources for Project management, administration and technical tasks, infrastructure, required services, systems and supplies were also significantly increased.

Finding: the Project was delayed several times and its implementation ended up extending from 4 to almost 12 years, with multiple effects in terms of loss of momentum, obsolescence of products, reduced stakeholder interest and participation.

Finding: Despite delays, most of the planned activities were implemented under an adapted budget. Administrative and financial management had an increment of cost, due to extended amount of audits, UNDP service charges, funds transfer operations.

Finding: UNEP resources had to be allocated (Task Manager, Fund Manager, Administrative Assistance and other related staff and services) for 12 years management instead of 4. At the same time, the management, administrative and technical resources mobilized by the Government and Stakeholder Institutions did have to be significantly increased during implementation.

Rating for Efficiency: MU

G. Monitoring and Reporting

Finding: Monitoring and Evaluation plan was correctly designed in the Project Document. Monitoring of Project implementation was affected by the several delays experienced, the continuous changes of NPC after 2013 and the closure of the project between 2016 and 2018. IICA participation (by an agreement with MAATE in 2014, taking care of the execution of several 1st Phase pending activities for $100,000, and later with the 2nd PCA signed in 2018 for the remaining funds) helped significantly to manage and develop several activities and products, along with several important administrative and financial tasks). In total, IICA has been tasked with the execution and control of around 50% of the total GEF budget allocated to this Project.

Monitoring Design and Budgeting

222. The design of M&E was complete and contained SMART indicators at the outputs level. In general, no specific budgeting for the different M&E indicators was developed, stating in most cases "included in component costs". The M&E plan is included in the approved Prodoc as Section 6 and Annexes 6 and 7.

223. Monitoring plan was appropriate for the initial Project phase, with an intended duration of 48 months. Reporting tasks were the responsibility of the NPC (no specific M&E officer was appointed for this project), and the NPC had the responsibility of reporting all activities, products, Budget reviews, Periodic for all reporting.

224. A central M&E role was assigned in the Project Document to the Project National Steering Committee, (the National Biosafety Commission itself), to whom the NPC would have to report Project advances and issues. NPC was responsible of implementing NSC recommendations.

225. Under the first Project extension (December 2014 to December 2015) and the 2nd Phase including its extension to June 2021, the same M&E general framework was in place, with the same reporting requirements.

Monitoring of Project Implementation

226. The project M&E has been satisfactorily implemented, although several important delays occurred during the different phases of the project. The reviewer has studied

all reported PIRs, and observed that the lack of a regular NBC (that was also the NSC) impacted strongly on Project actions and activities.

227. Midterm was scheduled for January 2012, and was done in April 2013. Shortly after this MTR was submitted by UNEP, the NPC resigned. Some recommendations of the MTR were addressed. The Project finally extended to June 2021.

228. GEF funds allocation for NPC salary were exhausted at the end of 2014 when the Project reached the finalization agreed in the first PCA. After this, several partial – dedication officers appointed by the NEA performed as NPC, with an impact on the timeliness, completeness and quality of periodic project reports and developed products reports.

Finding: The lack of a regular NBC (that was also the NSC) impacted strongly on Project actions and activities.

Project Reporting

229. The PMU has in general produced all required periodic reports during 2011-2015 and 2019-2021. There are no Progress Reports available in ANUBIS for periods #22 to #26, years 2016, 2017 and 2018 (the extended project finalized in December 2015, and the new PCA was signed in July 2018).

230. At the end of the Project extended 1st Phase (April 2022) the audit reports for years 2014, 2015 and 2016 were not submitted. These audits were then a pre-requisite, under the 2nd PCA (July 2018) for UNEP to disburse the first cash advance. The audits were developed as part of this 2nd Phase agreement, submitted to ANUBIS and approved by UNEP task manager.

231. Some documents and / or products of the developed activities have not been uploaded in ANUBIS (e.g., 1st collaboration agreement with IICA, 2014, final activities report and complete products descriptions, and 2ND PCA products : documents with the description of the developed Virtual Course by UDLA, technical guidelines for LMO management for research)

232. Final Report Annexes have not been made available in ANUBIS.

Rating for Monitoring and Reporting: MS

H. Sustainability

Socio-political Sustainability

233. There still exist in Ecuador a strong perception among politicians and general public against LMOs issues, along with a very active opposition by environmental NGOs, that still prevents the approval of several harmonized laws and regulations to enable the full operational functioning of a National Biosafety System / Framework.

234. At the same time, the Art. 401 of the 2008 Constitution places a very hard restriction on the importation of LMOs, with very few exceptions that have not been regulated at high level yet, with the outcome that on application to introduce any LMO to the country has taken place in many years.

235. The situation impacts also the academic and research sector: as there is currently no clear, stable framework in place to manage the introduction of LMOs in the country for research activities, and still being “transgenics” a very controversial subject in Ecuador, biotechnology researches prefer to focus on less problematic areas.

236. MAATE and other Institutions are currently working on newer biotechnology subjects (e.g. Synthetic Biology based products). This area could be a new driver for political engagement in the near future, thus helping to acquire the political will and support.

Finding: the political and public negative perception of LMOs status, with the hard restrictions mandated in the 2008 Constitution regarding LMOs, results in a very strong barrier against further development of a national integrated and operational biosafety system to address LMOs decision – making.

Financial Sustainability

237. Most efforts related to the implementation of NBF in the country have been supported by UNEP-GEF projects since 2003. Current participation of involved stakeholders is very heterogeneous, and the same happens with the support that these institutions apply to continue developing, implementing and operating a NBF. While MAATE counts with a consolidated Biosafety Unit, the situation of other institutions is not the same. The reviewer has not been able to interview delegates from MSP, MIPRO, SENESCYT or Ministry of Foreign Affairs, as the PMU indicated that there were no officially appointed delegates for biosafety in these Institutions. At the research or detection labs level – AGROCALIDAD, INIAP, ESPOL – the resources for biosafety are implicitly included in their usual tasks. In the specific case of the laboratories (AGROCALIDAD, ESPOL) their LMOs detection sustainability depend strongly on the demand that the whole system puts on their services. At the time of this review, no official system is yet in place for the routinely inspection and detection of LMOs (although mandated by regulations and by some Court decisions).

238. Several outputs and products of this Project (Public access to national updated biosafety information, and public participation on LMOs biosafety decision – taking procedures, National Biosafety Committee information, among other) depend on the availability and continuous updating of the National Biosafety Portal (www.bioseguridadecuador.gob.ec). This website is not currently available, since at least June 2023. Maintenance of online websites and portals require human resources and infrastructure, that has not been evident, to this reviewer, as available and functioning. Stakeholders commitment (e.g. human and material resources assigned) to providing updated information about biosafety from their perspectives is not yet in place.

Finding: At the time of this review, there is no significant evidence that the finalization and continuous operation of a National Biosafety Framework for dealing with LMOs related decision – taking will count with the allocation of required resources from all the CNAs and other Institutions involved.

Institutional Sustainability

239. The Biosafety Unit at MAATE has now been established as the main recognized actor related to biosafety regulations in the country, having been working in biosafety projects and issues for more than 20 years. Other institutions that were originally first – level stakeholders do not have the same level of involvement in biosafety issues. At the time of this review, there are no formally approved and operative official regulations that mandate and define the roles of the different biosafety – related national ministries and other institutions, and not formal designation of human, technical and funding resources for participating in an inter-sectorial biosafety system.

240. In 2014, last year of the 1ST Phase of the Project, many activities were delayed. In order to try to finalize these activities and execute the remaining funds, an agreement was done with IICA, transferring $100,000 of the GEF allocated funds. After the

closure of the Project in April 2016, when around 30% of the total funds remained unspent and many activities pending, in 2018 a new PCA was signed between MAATE and UNEP, this time with the participation of IICA, for taking care of the development of all the Project remaining activities, funds and audits. An important portion of the total Project funds has been executed by IICA collaboration (around 50%).

Finding: Biosafety Unit in MAATE is recognized as a reference, sustained technical authority in the field of Biosafety in the country. However, the lack of enough assigned personnel may pose a high risk on the capacity to operate, manage, and coordinate a National Biosafety System. The involvement of other institutions has decayed over the years, and the inter-sectorial coordination is yet to be formalized and functional.

Rating for Sustainability: MU

I. Factors Affecting Performance and Cross-Cutting Issues

Preparation and Readiness

241. The Project was designed by the same staff and consultants that had been involved in the previous "Development of National Biosafety Framework", and with the participation of knowledgeable professionals from the different Stakeholders and Institutions, with several years of experience in the fields of biotechnology and biosafety. The Project planned outcomes, outputs and activities were thus greatly grounded in real needs and existing resources and capabilities.

242. Due to an adverse context, the high-level assumptions and drivers identified at Project Design did not materialize, becoming barriers that would later impede the timely and full achievement of the pursued outcomes.

Quality of Project Management and Supervision

243. The PMU was integrated from the beginning by high-level professionals, as stated previously. Due to political changes and Project delays, after 2013 there were many changes in Project Management. In MAATE there has been an important technical continuity, based on the existing Biosafety Unit and its permanent professional officers.

244. The Prodoc defined that the Project National Steering Committee was the National Biosafety Committee itself. During the years that the Project extended, the functioning of the NBC has been very irregular, with several changes and delays in its official, organic integration and operative rules. The NSC was then integrated informally by the group of stakeholders / institutions most related to biosafety. The reviewer has not found any memories or reports of the NSC sessions after 2013.

245. UN Environment support was limited to support by the GEF task manager and administrative staff at the Regional Office for Latin America and the Caribbean in Panama. The collaboration with the Panama team has been considered optimal from all sides. PMU and Task – Manager also exchanged experiences and coordinated activities with the BCH-2 Capacity Building Project, that took place in Ecuador between 2011 and 2013.

Stakeholders Participation and Cooperation

246. Stakeholders identified in the original Prodoc participated in the Project design, through several meetings. During the 1st Phase of the Project, 2011 – 2014, there was a very active participation of the stakeholders mostly in training and capacity building activities (technical workshops and meetings on LMOs detection, Risk Assessment

and Management) and some participation in the coordination for developing the inter-sectoral regulations needed for implementing an operative administrative- technical National Biosafety System for LMOs decision-taking.

247. Not all the initially identified stakeholders participated in the Project implementation. Although convocated for several meetings and training workshops, delegates from NGOs, farmers associations and other civil society representatives did not participate. A very strong lobby by environmental NGOs against all treatment of LMOs in the country is one of the main reasons for this lack of participation.

248. According to the interviews, the reviewer observed that after 2015 the participation of most stakeholders had been limited to attending a few training workshops and informative meetings.

Responsiveness to Human Rights and Gender Equality

249. The Project was designed 2008-2010, so the original Prodoc does not specifically address Gender Equality nor Human Rights responsiveness.

250. In compliance with constitutional law, the State seeks equal treatment of men and women and the Ministry of the Environment implements national policies on gender equity, environmental management and sustainable development in all projects.

251. This project addresses implicitly some basic rights that are defined in Ecuador Constitution and several other national regulations (e.g., "Plan Nacional del Buen Vivir").

252. The reviewer has observed, based on the available reports, that in all the activities developed and carried out by the project (courses, workshops, meetings, consultancies for technical aspects related to biotechnology, risk assessment & management, regulations, etc.) the participation has been balanced.

Environmental and Social Safeguards

253. In compliance with constitutional and sectorial laws, the Ministry of the Environment implements environmental and social management and sustainable development in all projects.

254. The approved Project Document in its section 3.11 contains provisions for addressing Environmental and Social Safeguards:

- Given the nature of the project, which aimed at developing skills, tools and implementing the administrative and technical systems for the safe use of GM organisms, the occurrence of negative environmental impacts was not foreseen as a result of its implementation. It was intended to have beneficial effects on the environment and socio-economic conditions of the country and the region.

- There is opportunity in this project for farmers and indigenous communities to gain equal participation and a "level-playing field" in respect of biosafety measures.
- The project envisaged the development of mechanisms for citizen participation during its execution that would balance cultural and gender factors, as needed. The reviewer could not find any evidence of these mechanisms being in place.
- Socio-economic analyses as part of the LMO risk assessment and risk management processes were considered in the Project design and were developed in project activities.

Country Ownership and Driven-ness

255. Country ownership is derived from the active involvement of all the stakeholders and institutions that are related or interested in the safe handling of LMOs. As stated above in section Stakeholders Participation and Cooperation, actual involvement of many stakeholders has significantly diminished. The reviewer had important limitations to even meet or talk with delegates from several important Institutions, like MSP, MIPRO, SENESCYT. In other cases, like MAGAP (one of the most important institutions related to biosafety) it was only possible to meet technicians that had not participated during the majority of the Project implementation and with limited decision – making authority. No involvement was appreciated from NGOs, civil society, small farmers or seed associations. It was not possible even to have a meeting with the National GEF operational Focal Point. Due to the lack of regulations for the management of LMOs for research, academic institutions that perform biotechnology research tend to focus in different subjects but LMOs.

Communication and Public Awareness

The original Project specifically included Component 4, Improve public awareness and participation in biosafety aimed at changing perceptions of the public on GM organisms and enhancing their participation in decision-making processes related to these. The project would promote greater awareness and understanding on issues related to biosafety, and will indeed evaluate the level of awareness and understanding achieved.

256. Communication strategy products resulting from the consultancy developed in **2012** and reported in ANUBIS as ***"Communication strategy products. activity 4.2.1. D2-1102"*** where not possible to download (broken links). No reports from NBC about the outcomes of the communication strategy are available. This reviewer has not found nor received for review other public awareness products developed by the Project, and not available as Project outputs in ANUBIS.

257. In the interviews with the PMU, the reviewer was shown some TV-RADIO communication pieces related to biotechnology and biosafety that were designed and implemented by the Project. Due to political issues, these materials could not reach the expected audience.

258. Component 4 includes the development of mechanisms for public access and exchange of information on biosafety and a system for public consultation on LMOs related decisions, including:

- a mechanism for provisioning and evaluating information on biosafety through alliances and agreements with key stakeholders, and to make this information available through the National Portal of the BCH.
- a project website will be established in MAATE website, which should contain links to other relevant agencies and will include a section for readers to express their views and make consultations on LMOs and biosafety in relation to processes and applications that are running.
- a basic library of public access on biosafety, hosted by MAE's website
- a section on biosafety documents open to public access and mostly fuelled by donations from allied organizations, as part of MAATE's public library.

259. The National Portal of the BCH, or National Biosafety Portal, was not functioning at the time of this review (and has not been online since at least June 2023), so none of the above listed expected Project products are currently available for the general public.

260. One public opinion survey about biosafety and biotechnology was developed and carried out in the 2nd Phase of the Project, with IICA Collaboration - 2020. There were

no other surveys developed during the Project. Some comparisons with an existing pre-project -2008 - survey were described, showing a general increase in popular knowledge about biotechnology, although not conclusive nor attributable to the Project dissemination activities. In its conclusions, that report states that "The findings identified demonstrate that there has not been a significant increase in the dissemination of scientific knowledge in Ecuador".

Finding: the Project faced very important barriers and challenges in deploying general biotechnology and, particularly LMOs related knowledge dissemination campaigns, due to lack of political support, general adverse perception of transgenics and strong lobby and counter-influence from environmental NGOs. An operational system for public participation in biosafety decision-making is not available. The main channel to publicly share updated and relevant national biosafety information is not working, due to infrastructure issues. The National Biosafety Portal (http://www.bioseguridadecuador.gob.ec/) is not online since at least June 2023.

Rating for Factors Affecting Performance and Cross-Cutting Issues: MU

VI. CONCLUSIONS AND RECOMMENDATIONS

A. Conclusions

261. Based on the findings from this review, the project demonstrates performance at the **MS** level (a table of ratings against all review criteria is found in the Conclusions section, below). The project has demonstrated strong performance in the area of technical capacity building (trained several hundreds of people in all the required biosafety subject topics, created capacity for LMOs detection in national laboratories, addressed the complex issue of national LMO surveillance, risk assessment and risk management). Areas that would benefit/would have benefited from further attention are final political and high level approval of the harmonized drafted laws and regulations related to a functional, operative system for managing LMOs transboundary movements (as stated in CP), and an improvement of mechanisms for public awareness on biosafety and biotechnology, along with an operational system for public participation and feedback on decisions taken about LMOs.

262. The Project was effective to produce several technical outputs and to create human and laboratories capacities to manage the technical aspects of LMOs related decision – making.

263. High level norms have been approved during the years, but the lack of political support and the barriers imposed by the 2008 Constitution have in fact prevented the instalment and operation of a functional LMOs decision – making inter-institutional administrative system, despite the existence of all technical capacities needed.

264. The analysed barriers also played a role against the Project efficiency: spanning through several government periods and pollical changes, the Project suffered from many changes in authorities, NPC, and national resources allocation.

265. The Project has been an important mechanism for maintaining the issue of LMOs transboundary movements in the country agenda, and currently there exists in Ecuador a consolidated Biosafety Unit in the Ministry of Environment, with a lot of experience and very valuable national and international relationships, that permits Ecuador to continue working with novel biotechnologies and the regulation of their products.

266. The delays in Project duration caused significant increments of costs for the Government and committed national stakeholders and other institutions (Project management, administration, infrastructure). For UNEP-GEF, extending from the initial planned 4 years to a total duration of about 12 years implied important increment in management and administrative costs.

B. Summary of project findings and ratings

267. The table below provides a summary of the ratings and finding discussed in Chapter V. Overall, the project demonstrates a rating of MS.

UNEP Evaluation Office Validation of Performance Ratings:

The UNEP Evaluation Office formally quality assesses (see Annex XII) management led Terminal Review reports and validates the performance ratings therein by ensuring that the performance judgments made are consistent with evidence presented in the Review report and in-line with the performance standards set out for independent evaluations.

The Evaluation Office assesses a Terminal Review report in the same way as it assesses the initial draft of a Terminal Evaluation report. It applies the following assumptions in its validation process:

– That what is being assessed is the contents of the report and the extent to which it makes a consistent and justifiable case for the performance ratings it records.

- That the consultant has, within the report, presented all the evidence that was made available to them.

- That the Review has been based on a robust Theory of Change, reconstructed where necessary, which reflects UNEP's definitions at all levels of results.

- That the project team and key stakeholders have already reviewed a draft version of the report and provided substantive comments and made factual corrections to the Review Consultant, who has responded to them. The Evaluation Office assumes, therefore, that it has received the Final (revised) version of the report.

In this instance the Evaluation Office validates the overall project performance rating at the **'Moderately Unsatisfactory'** level.

Table 4: Summary of project findings and ratings

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
Strategic Relevance	The project objectives and strategies are aligned with policies and plans of GEF, UNEP and national 2008 Constitution mandates and public agencies roles and strategical plans.	**HS**	The rating is validated	HS
1. Alignment to UNEP MTS, POW and strategic priorities	The original Project design was aligned with GEF's Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1) approved in December 2006, and was in line with the Focal Area Strategies and Strategic Programming for GEF-4 (Doc GEF/C.31/10) approved in July 2007. It responded directly to Biodiversity Strategic Objective 3: To safeguard biodiversity - Strategic Programme 6 Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. During project execution it has been aligned with Ecuador UNDAF 2015-2018 and with SDGs1 ,2, 3 & 5	HS	The assessment does not provide a description of anticipated identified contributions to UNEP's MTS, PoW, Expected Accomplishments and strategic priorities, rather, focus is given to the project's linkages to GEF, SDGs, and UNDAF. This is necessary for a Highly Satisfactory rating. The Evaluation Office validates this criterion at the level of 'Satisfactory'.	S
2. Alignment to Donor/Partner strategic priorities	Alined with GEF Strategy, Biodiversity Strategy Objective 3 SP6	HS	The rating is validated	HS
3. Relevance to global, regional, sub-regional and national environmental priorities	Aligned with priorities outlined in Ecuador 2008 priorities, CAN Regional Biodiversity Strategy	HS	The project is well aligned with global and regional environmental priorities (on account of ratifying the Cartagena Protocol on Biosafety), however the review notes some contention at the national level. It states that "the lack of political support and the barriers imposed by the 2008 Constitution have in fact prevented the instalment and operation of a functional LMOs decision-making inter-institutional administrative system, despite the existence of all technical capacities needed" (para 262) The Evaluation Office validates this criterion at the level of 'Satisfactory'.	S
4. Complementarity with relevant existing interventions/coherence	Based on the previous Project UNEP-GEF Project "Development of National Biosafety Frameworks", coherent with the 2008	HS	The rating is validated	HS

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
	Constitution changes and concurrent with UNEP-GEF BCH-2 Project			
Quality of Project Design		**S**	The rating is validated	S
Nature of External Context	The external context for the project implementation has been unfavorable, with several strong barriers at high-level political decision taking authorities. These barriers are the main cause of the failure to operationalize a concrete system for biosafety decisions, although most of the required technical instruments and human resources have been properly achieved.	**U**	The nature of the external context affecting project implementation– and especially regarding the socio-political dimensions of this intervention – has been described in detail. The review notes that, over time, public perception and political priorities support regarding LMOs evolved because of the changes introduced in the 2008 Constitution, banning LMOs in the country with only strong exceptions. While this adversely impacted project implementation (and several TOC assumptions could not hold), lack of action at high-levels of government, while unfavourable, did not constitute a conflict, natural disaster, or political upheaval. The Evaluation Office validates this rating at the level of 'Moderately Unfavourable'	MU
Effectiveness		**MS**	Rating based on a weighted aggregation of the sub-categories below.	MS
1. Availability of outputs	Most outputs were developed and finalized during the Project. Some important legal and regulatory instruments are not yet in place	S	The evidence presented shows that most of the outputs were delivered, but about 65% which is within the Moderately Satisfactory rating. The review indicates that several outputs under Component 2 (fully functional system for decision making and control of LMOs) and Component 4 (public awareness and participation in biosafety) are rated in the 'unsatisfactory' range, implying a less than optimal overall performance in this sub-criterion (based on the reconstructed TOC, the policy and regulatory framework underpinning LMOs, and public participation on the same, are important elements in achieving a functional national biosafety system). The Evaluation Office validates this criterion at the level of 'Moderately Satisfactory'.	MS

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
2. Achievement of project outcomes	Technical capacities have been built, and high-level regulatory norms exist. 2nd level specific regulations are still not harmonized, and an operational system for LMOs related decision – making, fully compliant with the CP, is not yet in place	MS	The rating is validated	MS
3. Likelihood of impact	Intended Impact for this Project ("*Incremented level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and focusing, in particular, on transboundary movements")* has been ***partially achieved*** and that it is still an ongoing process,	ML	The review indicates that achievement of the intended Impact is still an ongoing process. It further states that Impact will only be achieved if the Intermediate States are attained, but finds that these are only partially in place (para 195-198). The Project also faced "very important barriers and challenges in deploying general biotechnology ... due to lack of political support, general adverse perception of transgenics and strong lobby and counterinfluence from environmental NGOs" (page 87). Although the required technical aspects needed for implementing the system have been developed, there are challenges from the perspective of the legal framework and socio-political good-will. Para 144 also indicates that an important subset of assumptions on which the project was founded did not hold (Table2) The Evaluation Office validates the rating for this criterion at the level of "Moderately Unlikely'	MU
Financial Management		**S**	Rating based on a weighted aggregation of the sub-categories below.	S
1. Adherence to UNEP's financial policies and procedures	UNEP financial policies and procedures have generally been applied throughout the Project, although with several delays during its execution.	**S**	The rating is validated	S
2. Completeness of project financial information	The financial information of the Project tracking and management is complete and correct. Several budget revisions (13) occurred during project execution.	S	The rating is validated but with some reservation because evidence points to a lack of documented evidence of in-kind contributions - a commonly occurring problem in projects.	S
3. Communication between finance and project management staff		S	There is no sub-section (or reference) providing an assessment of this dimension of financial management. The sub-criterion is rated 'highly satisfactory' in Table 13, but there is no supporting evidence provided.	Not rated

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
Efficiency	The Project was delayed several times and its implementation ended up extending from 4 to almost 12 years, with multiple effects in terms of loss of momentum, obsolescence of products, reduced stakeholder interest and participation	**MU**	The project was extended by nearly 8 years with adverse effects identified in the review. The Evaluation Office validates the rating for this criterion at the level of "Unsatisfactory'	U
Monitoring and Reporting		**MS**	Rating based on an aggregation of the sub-categories below.	MS
1. Monitoring design and budgeting	The design of M&E was complete and contained SMART indicators at the outputs level.	HS	The report states that the indicators at the Output level at SMART but does not state the same for the Outcome level indicators. There is no information on the data collection methods/frequency or on whether data was to be disaggregated by groups. The Evaluation Office validates the rating for this criterion at the level of "Satisfactory'	S
2. Monitoring of project implementation	The project M&E has been satisfactorily implemented, although several important delays occurred during the different phases of the project.	MU	The rating is validated	MU
3. Project reporting	The PMU has in general produced all required periodic reports during 2011-2015 and 2019-2021.At the end of the Project extended 1st Phase (April 2022) the audit reports for years 2014, 2015 and 2016 were not submitted. These audits were later developed as part of this 2nd Phase agreement Several Project activities outputs or products are not available publicly nor in ANUBIS. Final report annexes have not been uploaded to ANUBIS	MU	The rating is validated	MU
Sustainability		**MU**	Rating based on a weighted aggregation of the sub-categories below.	U
1. Socio-political sustainability	There still exist in Ecuador a strong perception among politicians and general public against LMOs issues, that still prevents the approval of several harmonized laws and regulations to enable the full operational functioning of a	MU	The government is a key player in controlling the introduction of LMOs intro the country, as such the dependency on this dimension is high. In addition to the strong sentiments among politicians and general public against LMOs, as indicated by findings, the review also states (para 146) "the declaration of	U

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
	National Biosafety System / Framework.		a GMO-free country in the 2008 Constitution of the Republic, instead of acting as a stimulus for the implementation of the MNSB, has in fact become a barrier to the development of any kind of activities related to LMOs in Ecuador". Also, that there are "several strong barriers at high-level political decision taking authorities". This has significant implications on the socio-political dimension of sustainability. The Evaluation Office validates this rating at the level of 'Unlikely'.	
2. Financial sustainability	There is no significant evidence that the finalization and continuous operation of a National Biosafety Framework for dealing with LMOs related decision – taking will count with the allocation of required resources from all the CNAs and other Institutions involved.	ML	The evidence presented implies a relatively low probability that dedicated funding for sustained work on LMOs and biosafety will continue to be available/sufficient beyond the GEF intervention. Findings in other criteria, especially regarding sub-optimal socio-political goodwill, also support this argument (e.g. under the sections covering 'effectiveness' and 'nature of external context'). The Evaluation Office validates this rating at the level of 'Moderately Unlikely'	MU
3. Institutional sustainability	Biosafety Unit in MAATE is recognized as a reference, sustained technical authority in the field of Biosafety in the country. However, the lack of enough assigned personnel may pose a high risk on the capacity to operate, manage, and coordinate a National Biosafety System. The involvement of other institutions has decayed over the years, and the inter-sectorial coordination is yet to be formalized and functional	ML	The review points to significant shortcomings in the institutional set-up required to sustain the project's outcomes in the longer-term ('Finding' on page 98), including strong barriers within high-level authorities which are the main cause of the failure to operationalize a concrete system for biosafety decisions ('Finding' on page 43) The Evaluation Office validates this rating at the level of 'Moderately Unlikely'	MU
Factors Affecting Performance		**MS**	Rating based on an aggregation of the sub-categories below.	MS
1. Preparation and readiness	The project was well designed by experienced professionals, and all Institutions involved had skilled personnel to develop the Project activities.	S	Rating is validated	S
2. Quality of project management and supervision		S	Rating adjusted based on an aggregation of the sub-criteria	S

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
2.1 UNEP/Implementing Agency:	Adhered to UNEP – GEF standards. Three Task Managers have been in charge of this Project throughout its extended lifetime, with gaps between the corresponding relays.	S	This was a Medium-sized Project that suffered several major delays (4-year extended to 12-year duration). The project also suffered continuous changes of staff, as well as the absence of responsible staff (including Task managers) at various periods of the project (para 217-219). Para 15 notes that most recommendations related to delays were not effectively addressed. Further, the review could not find records of meeting sessions by the Steering Committee after April 2013, which consequently affected project management (paras 20, 149) The Evaluation Office validates this rating at the level of 'Moderately Satisfactory'	S
2.2 Partners/Executing Agency:	During the lifetime of the Project, which spanned several government periods and suffered from political changes, several different NPC were in charge of this Project after 2013. Interaction with UNEP-GEF Task Manager and administrative assistance was in many cases very slow and non-responsive, with significant delays in reporting and uploading outputs products to ANUBIS	MS	Rating is validated	MS
3. Stakeholders' participation and cooperation	Participation was very active during Project design and the first years of implementation 2011-2014. It decayed significantly for the 2nd Phase, limited mostly to participation in training events, and it was also impacted by the COVID-19 Pandemic	MS	Rating is adjusted (refer to the Reviewer's assessment of the sub-category '*Country ownership and driven-ness*' below, which actually discusses stakeholder participation)	MU
4. Responsiveness to human rights and gender equality	Implicitly addressed in Project design	S	There is no evidence in the Review that gender and human rights issues were considered during implementation, except for the reviewer's observation that project's meetings and events were "balanced". Since 2015, UNEP has had a comprehensive gender policy and strategy to guide its projects. Although the prodoc was not explicit on gender and human rights, the review does not provide evidence that project management was sufficiently responsive to gender	MU

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
			equality and human rights issues, even by adaptive management. The Evaluation Office validates this rating at the level of 'Moderately Unsatisfactory'	
5. Environmental and social safeguards	Implicitly addressed in Project design	S	UNEP has had an environmental and social safeguard framework since 2014 (and revised in 2020); project could have been responsive through adaptive management. Further, the review indicates that the prodoc had envisaged the development of mechanisms to balance cultural and gender factors, there was no evidence found on these mechanisms being in place (para 253). The Evaluation Office validates this rating at the level of 'Moderately Satisfactory'	MS
6. Country ownership and driven-ness	Several actors that had been identified during Project design (farmers, civil society, seeds associations, NGOs) did not actively participate in the Project. Current stakeholders involvement is very limited.	MU	In addition to weak support from high-level political / decision-making authorities, as well as the absence of key actors that were previously identified at project design, the review also brings to light the negative public perception of LMOs and GMOs. The Evaluation Office validates this rating at the level of 'Unsatisfactory'	U
7. Communication and public awareness	the Project faced very important barriers and challenges in deploying general biotechnology and, particularly LMOs related knowledge dissemination campaigns, due to lack of political support, general adverse perception of transgenics and strong lobby and counter-influence from environmental NGOs. An operational system for public participation in biosafety decision-making is not available. The main channel to publicly share updated and relevant national biosafety information is not working, due to infrastructure issues. The National Biosafety Portal (http://www.bioseguridadecuador.gob.ec/) is not online since at least June 2023.	U	The rating is validated	U
Overall Project Performance Rating		**MS**	Although the Project was effective in producing several technical outputs	**Moderately**

Criterion	Summary assessment	Rating	Justification for any ratings' changes due to validation (to be completed by the UNEP Evaluation Office – EOU)	EOU Validated Rating
			and developing human and laboratories capacities to manage LMOs in Ecuador (Component 3), the national biosafety regulatory framework did not materialise, and application of the Cartagena Protocol was only partially achieved (Component 1). The review also points to a lack of political goodwill as well as adverse public perception regarding LMOs (Components 2 & 4). In addition, this was a MSP that was extended from an initial planned 4 years to a total duration of about 12 years, and the review notes that despite the MTR conducted in 2013, most recommendations related to delays were not effectively addressed. The Evaluation Office validates the overall project performance rating at the level of 'Moderately Unsatisfactory'.	**Unsatisfactory (3.44)**

C. Lessons Learned

268. Lesson 1: This Project has faced a very challenging context, with strong barriers to achieve some of the outcomes, derived from the current national legislation and adverse public perception of LMOs and lack of high-level support. In all the interviews and conferences maintained by the reviewer, the dedication and professionalism of the NEA appointed officers and particularly the NPC and biosafety officer has been commended. However, due to the previously mentioned barriers, many regulations and harmonized norms that were drafted as Project outputs did not count with the required high-level political authorities support. The lack of governmental decision to approve proposed regulations and implement the system actually acted as a barrier to achieve some high-order Project outcomes.

269. Lesson 2: The development of all technical outputs and products has been effective and of high quality, and the training activities reached many hundreds of biosafety involved professionals. The Project Team

270. Lesson 3: The collaboration of IICA in several stages of the Project was key for the successful development of many outputs.

271. Lesson 4: An important result of the Project has been the formal and sustainable creation and operation of the Biosafety Unit inside MAATE, not only for this Project management but for other issues related to Biosafety in general. Particularly, this Unit is now working on new biotechnology matters (Synthetic Biology) that need to be addressed at a national level.

272. Lesson 5: Although the Project included a Component specifically addressing Public Awareness, its outcomes have not been enough to overcome the existing general resistance to address and legislate specific norms to deal with LMOs related biosafety decision – making. When the Project was designed using the methodology of logic framework, the risk inherent to the existing pathway that is evident in the RToC from Public Awareness (particularly focused on political awareness and buy-in) to the intermediate state *"System for decision making and control of LMOs is fully functional",* was not sufficiently valued. During Project implementation this issue proved to be critical.

D. Recommendations

273. Recommendation 1 (to NEA, Government): As the Project has already finished and some final outcomes not fully achieved, the most important immediate recommendation is to continue working for the approval of the complete set of harmonized intersectoral regulations, and make the National Biosafety System operational (complying with the CP), by approving and installing the necessary administrative procedures and coordination among the involved CNAs and other related Institutions.

274. Recommendation 2 (to NEA, Government): Closely linked to the previous recommendation is one of promptly addressing the budget needs to be able to operate this system, considering human resources and infrastructure (including logistics for detection laboratories).

275. Recommendation 3 (to NEA, Government): As the country faces (and has been demonstrated) the illegal introduction and planting of LMOs, it is imperative to put in place regulations, procedures and measures to be taken to address this reality.

276. Recommendation 4 (to NEA, Government): In order to promote the research on LMOs in the country, revise and approve the required regulations that address the

introduction of LMOs for research (contained use as specified in the CP). Drafts have been produced by the Project.

277. Recommendation 5 (to NEA, Government): Continue fostering the regular functioning of the recently approved National Biosafety Committee, not only to address LMOs related decisions but also to have installed an expert inter – agencies able to address next generation technologies (e.g. products derived from Synthetic Biology).

ANNEX I. RESPONSE TO STAKEHOLDER COMMENTS

Table 5: Response to stakeholder comments received but not (fully) accepted by the reviewers, where appropriate

Page Ref	Stakeholder comment	Reviewer Response
	NO COMMENTS WERE RECEIVED FROM STAKEHOLDERS	

ANNEX II - KEY PERSONS CONTACTED / INTERVIEWED

- Tea García – Huidobro, UNEP GEF Project Task Manager 2010 - 2011 (Biodiversity /Land Degradation)
- Marianela Araya – Quesada, UNEP GEF Project Task Manager 2013 - 2016 (Biodiversity /Land Degradation)
- Thais Narciso, UNEP GEF Project Task Manager 2018 - 2021(Biodiversity /Land Degradation)
- Robert Erath, UNEP GEF Task Manager (Biodiversity /Land Degradation)
- Gloritzel Frangakis, UNEP GEF Programme Assistant
- David Veintimilla, MAATE, Biodiversity Unit Director (2023)
- Andrés Factos, MAATE, Biodiversity Unit, Biosafety Officer (2023)
- María de Lourdes Torres, USFQ, Vice-Dean, Faculty of Environment and Biologic Science
- Julio Escobar, IICA Especialista Biotecnología y Bioseguridad, Innovación para la Productividad y Competitividad
- Maria Irene Schuldt, Ecuador GEF focal point
- Luis Cumba, MAATE, Subsecretaría de Patrimonio Natural
- Ana Garrido, AGROCALIDAD
- Verónica Manrique, AGROCALIDAD
- Efrén Santos, ESPOL
- Germán Romo, PRONACA
- Eduardo Morillo, INIAP
- Byron Sanchez, MAG
- Edwin Alvarez, MAG
- Andrés Quiroz, MIPRO
- Emilia Vásquez Domínguez, UDLA

ANNEX III – REVIEW FRAMEWORK

			Evaluation Criteria & Key Strategic Questions (KSQ)									
EVALUATION QUESTIONS	**Indicators**	**Potencial Data Sources**	**KSQ**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
A. STRATEGIC RELEVANCE												
1. To what extent were project objectives and implementation strategies consistent with: (a) UNEP's mandate and policies at the time? (b) Regional, Sub-regional and National Environmental Priorities, (c) UN Environment Medium Term Strategy (MTS) and Programme of Work (POW), and (d) GEF Strategic Priorities ?	degree of alignment with UNE, GEF and national policies	interviews /questionnaires ProDoc, including Letters of Endorsement UNEP policies 2013 Mid-Term Strategy and POW GEF-3 programming priorities		**i** **ii** **iii**								
2. Why did UNEP choose this project? How was UNEP role defined?	indication of active vs passive choices	interviews /questionnaires ProDoc	**1.a**	**i**								
3. Were the objectives and implementation strategies complementary with relevant existing interventions from the project partners and /or other stakeholders?	indication of synergies and complementarities achieved	interviews /questionnaires ProDoc periodic reports MTR NSC minutes		**iv**								
B. QUALITY OF PROJECT DESIGN												
see section 3 and Annex B		quality of project design form			**x**							
C. NATURE OF EXTERNAL CONTEXT												

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
4. Did the (political, environmental, social, institutional) context change during project implementation and how did the project adapt to this?	Reported adaptive management measures in response to changes in context	Project progress reports/PIR Interviews with project team and key stakeholders			x							
D. EFFECTIVENESS												
i. Availability of Outputs												
5. How successful was the project in delivering its Outputs both in quantity and quality, as well as their usefulness and timeliness?	Output level indicators of Results Framework (RF)	Interviews /questionnaires periodic reports, NSC minutes, mission reports MTR, Terminal reporting institutional websites and documents, technical publications					i		x			
6. To what extent did project Outputs contribute to achieving expected Outcomes and Intermediate States? (i.e., do causal pathways have a sound technical logic?)	indication of closeness to project's Intermediate States; views on causal relationship between Outputs and Outcomes	interviews /questionnaires periodic reports NSC minutes MTR; terminal reporting institutional websites and documents	3				iii					
7. To what extent is there a sense of ownership over project Outputs and results?	indications of degree of ownership achieved; indication of sustainability /continuity of project results	interviews /questionnaires periodic reports, NSC minutes; workshop reports; MTR, terminal reporting					i ii iii vi					
8. Were UNEP tools or methodologies (a) used or upscaled? or (b) developed that could be used in other Projects (within or beyond UNE)?	# of UNEP tools and methodologies identified	interviews /questionnaires correspondence between UNEP and project team institutional websites and documents, technical publications	3.b				i					

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
9. Were key stakeholders (including project baneficiaries) appropriately involved in producing the programmed outputs?	Stated contribution of stakeholders in achievement of outputs	Citation of stakeholders' roles in tangible products (publications, studies, etc.)Interviews with partners in implementation and project beneficiaries					i					
10. Did the project face any technical or political constraints in generating its Outputs? If yes, please explain. Were these identified, communicated and overcome opportunely? (i.e. before affecting the project)	# and type of constraints identified	interviews /questionnaires periodic reports, NSC minutes, mission reports terminal reporting				x	ii iii				iii	
ii. Achievement of Project Outcomes												
11. How successful was the project in Finalizing the Policy and Regulatory Biosafety Framework (Biosafety policy and regulations formally approved, sustainably funded and their application initiated; Management of LMOs improved through permanent coordination mechanisms and structures)	project delivery and performance against targets and indicators; Biosafety specific National Policy and Regulatory Framework approved and in-force	interviews /questionnaires periodic reports, NSC minutes, workshop reports, mission reports MTR, terminal reporting institutional websites and documents					ii iii				iii	
12. How successful was the project in Putting in place a fully functional system for decision making and control of LMOs?	% of biosafety - related institutions that have operational regulations, procedures and resources for LMOs related decision making	interviews /questionnaires periodic reports, NSC minutes, workshop reports, mission reports MTR, terminal reporting institutional websites and documents					ii iii				iii	iii
13. How successful was the project in Building human and institutional capacity for biosafety? (describe how many people have finalized biosafety - related graduate and post-graduate formation, specific training workshops on Risk Assessment, Risk Management, LMOs detection, other biosafety closely related capacity building efforts due to or influenced by the Project; describe how the technical infrastructure has evolved and (if) operative - e.g. detection labs-)	amount of people with post-degrees related to biosafety issues amount of people (individuals) trained on specific biosafety issues - risk assessment, risk management, LMOs detection, BCH registering, etc.)	MTR, terminal reporting					ii iii				iii	iii

			Evaluation Criteria & Key Strategic Questions (KSQ)									
EVALUATION QUESTIONS	**Indicators**	**Potencial Data Sources**	**KSQ**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
14. How successful was the project in Improving public awareness and participation in biosafety? Describe institutional websites or portals (e.g., Ecuador Biosafety Portal, biosafety - related institutions websites, general Government websites) that currently address biosafety information and issues. Describe established and operational systems for public participation in LMOs decision making.	availability of updated National Biosafety Website and main biosafety - related institutions portals with relevant biosafety information availability of public participation systems, and usage participation statistics LMOs and biosafety public awareness and understanding surveys	institutional websites and documents					**ii** **iii**				**i**	**iii**
15. To what extent can achieved Outcomes be directly attributed to project actions?	level of confirmation or agreement on degree of attribution;	interviews /questionnaires periodic reports, NSC minutes, workshop reports, mission reports MTR, terminal reporting institutional websites and documents	x				**i** **ii**				**iii**	
16. Did the assumptions hold/were drivers positively influenced (as included in the ToC)	Number of assumptions and drivers (included Section 3.5 and Annex 4 in Prodoc, and in reconstructed ToC) hold. (Potential) influence of the assumptions that did not hold on project implementation.	interviews / questionnaires, Prodoc, MTR, terminal reporting					**iii**				**i** **iii**	**iii**
iii. Likelihood of Impact												
17. To what degree the project is likely to create long-term impact (established policies, regulations, processes and resources both public and private to effectively and co-ordinately manage biosafety in the country)	indications of NBF acceptance and uptake; # of different actors (regulators, public and private actors) currently requiring and using Project outputs related products (policies, operational	interviews /questionnaires national published and in-force policies, regulations, procedures periodic reports MTR, terminal reporting					**iii**					

			Evaluation Criteria & Key Strategic Questions (KSQ)									
EVALUATION QUESTIONS	**Indicators**	**Potencial Data Sources**	**KSQ**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
	regulations or procedures, human and infrastructure resources)											
18. To what extent has the project helped to promote institutional changes, changes in behaviour or perception, policy changes, and new opportunities? Were these changes or new decisions prompted by increased scientific evidence/knowledge or capacity?	indications of catalytic effects; relevance of acquired scientific evidence/knowledge or capacity in change /decision processes	interviews /questionnaires periodic reports, NSC minutes, workshop reports, mission reports MTR, terminal reporting institutional websites and documents	**4.c**				**iii**					
19. Has the Project participant Institutions addressed other related lines beyond the original scope of work? If yes, please specify	indications of catalytic effects	interviews /questionnaires periodic reports, NSC minutes, workshop reports, mission reports MTR, terminal reporting institutional websites and documents					**iii**					
20. Did the assumptions hold / were drivers positively influenced in the transition from outcomes to impact? (as included in the RF and TOC)	Level of compliance of assumptions, particularly the ownership of project results by public agencies, Willingness for development, support and maintenance of public policies and financial mechanisms	Project progress reports/PIR Interviews with project team and key stakeholders					**iii**					
21. Have desired outcomes and impacts occurred amongst all stakeholder groups (and if not, why this might be).	Benefits among different stakeholder groups	Project progress reports/PIR Interviews with project team, key stakeholders, project beneficiaries Field visits					**iii**					**iii**

			Evaluation Criteria & Key Strategic Questions (KSQ)									
EVALUATION QUESTIONS	**Indicators**	**Potencial Data Sources**	**KSQ**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
22. Did the project result in any unplanned positive effects? Did it lead to any unintended negative effects? If yes, please explain	# of unplanned effects and value ascribed to them (+ve /-ve)	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes •terminal reporting institutional websites and documents					**iii**					
23. Are there any particular innovations and best practices coming from the project? Were there any gaps or potentials in innovation not realized?	# of innovations and best practices identified; # of missed innovation opportunities or gaps identified	interviews /questionnaires periodic reports, NSC minutes MTR,terminal reporting institutional websites and documents	**3.c**				**iii**					
E. FINANCIAL MANAGEMENT												
24. Was financial information and communication between financial and project management staff complete and transparent?	Completeness of financial information and communication	Interviews with administrative support agency (IICA) and UN Environmental administrative staff Interviews with project team Financial reports and audit reports						**x**				
25. Were GEF financial resources disbursed by UNEP in a timely manner? If not, what were the obstacles faced? (financial, administrative, managerial)	# and date of UNEP disbursements; timeliness of disbursements	interviews /questionnaires correspondence between UNEP and project team periodic reports terminal reporting						**x**				
26. Were administrative processes (procurements, cooperation agreements, etc.) conducted efficiently and in a timely manner by MATE and/or IICA-Country Office?	# and type of administrative issues appearing in reports /minutes	interviews /questionnaires correspondence between UNE, project team and IICA-Country Office periodic reports terminal reporting						**x**				
27. Were co-financing commitments met as programmed and made available in a timely manner?	% of co-financing achieved	interviews /questionnaires correspondence between PM and co-financiersperiodic reportsterminal reporting						**x**				

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
28. Were communications with the UNEP Fund Management Officer (in Nairobi) fluid and timely? Was the FMO involved in adaptive management decisions?	# and type of fund management issues appearing in reports /minutes	interviews /questionnaires correspondence with FMO NSC minutes						x				
29. Did any irregularities arise in procurements, use of financial resources and human resource management? If yes, describe these irregularities, together with any measures taken to correct/prevent them.	indications of documented irregularities or interrupted procurement/disbursement processes	interviews /questionnaires correspondence between UNE, PMT and/or partners periodic reports, NSC minutes						x				
F. EFFICIENCY												
30. How was the operational execution vs. original planning (budget wise)? Was the project implemented cost effective? (were the results achieved at the lowest possible cost	Level of compliance with project financial planning / annual plans	Project financial reports Interviews with project team Interviews with financial staff							X			
31. How was the operational execution vs. original planning (time wise)?	Level of compliance with project planning / annual plans	Project progress reports/PIR Interviews with project team		iv					x			
32. If present, what have been the main reasons for delay/changes in implementation? Have these affected project execution, costs and effectiveness?	List of reasons, validated by project team	Interviews with project team Interviews with project partners Project reports (Progress reports,PIR)							x			
33. Was adaptive management applied adequately? Were any cost- or timesaving measures put in place in attempting to bring the project as far as possible in achieving its results within its secured budget and time?	Measures taken to improve project implementation based on project monitoring and evaluation.	Project progress and implementation reports MTR report and management response Interview with project team and UN Environment task manager							x			
34. Did the project build adequately (create complementariness) on existing institutions, lessons of other initiatives, data sources, partnerships with third parties and ongoing projects?	Level of inclusion of preexisting initiatives and institutions	Project document Interviews with key stakeholders (preexisting initiatives and other institutions) Evaluation of project design							x			

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
G. MONITORING AND REPORTING												
i. Monitoring Design and Budgeting												
35. To what extent was the project M&E plan viable, Outcome-based and included SMART indicators?	quality of project design; indications of viability /clarity of M&E plan; indicator achievement levels	interviews /questionnaires ProDoc, MTR periodic reports terminal reporting								**i**		
36. Were M&E responsibilities clearly defined across project teams? Did the project include an M&E budget? Were project stakeholders involved in monitoring?	quality of project design; indications of viability /clarity of M&E roles; % of M&E expenditures	project or UNEP Task Manager inception report (if available) correspondence between UNEP and MATE interviews /questionnairesProDoc, MTRperiodic reports, NSC minutes terminal reporting								**i**		
ii. Monitoring of Project Implementation												
37. Was the M&E system operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period?	Level of implementation of M&E	interviews /questionnaires periodic reports terminal reporting								**i** **ii**		
38. How did project teams monitor the participation of disaggregated groups (gendered, marginalised or vulnerable groups, including those with disabilities) in project activities?	indications of disaggregated monitoring in reports (e.g. in participant lists)	interviews /questionnaires periodic reports terminal reporting								**ii**		**iv**
39. Did monitoring lead to adaptive management and contribute to resolving implementation problems?	views on, and evidence of, technical or management decisions based on monitoring; # adaptive management decisions after MTR and Project Amendments	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes terminal reporting								**ii**		

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
iii. Project Reporting												
40. Were the required progress, expenditure and terminal reports prepared satisfactorily by the national project team and submitted on time? Were all reporting requirements met?	# of progress, expenditure and terminal reports submitted; approval rates of reports	interviews /questionnaires periodic reports, NSC minutes terminal reporting								iii		
H. SUSTAINABILITY												
i. Socio-political sustainability												
41. In the absence of external support from UNEP and GEF, is there sufficient government and stakeholder commitment to continue using, enforcing and improving the developed NBF to guide management decisions?	indications of commitment levels; # of government policies and/or staff allocations aimed at NBF; # of stakeholder plans aimed at NBF	interviews /questionnaires institutional websites and documents (e.g. relevant plans)									i	
42. How likely are the government and other stakeholders to continue with individual capacity development efforts for implementing NBF activities?	likelihood of individual capacity building efforts; # capacity development plans	interviews /questionnaires capacity building plans (if available)									i	
43. What are the key factors that contributed to the sustainability of project results and impacts?	# and type of key factors identified	interviews /questionnaires periodic reports, NSC minutes MTR, terminal reporting institutional websites and documents	4.f								i iii	vi
ii. Financial sustainability												
44. To what extent is the continuity of project results and their impact dependent on continued financial support?	indications of financial dependency; institutional budgets and/or staff allocations; # of new financial mechanisms	interviews /questionnairesinstitutional websites and documentsinstitutional budgets (if available)									ii	

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
45. What is the likelihood that adequate financial resources will be or will become available to continue implementation the programs, plans, agreements, monitoring systems etc. prepared and agreed upon under the project?	level of likelihood; # and volume of financing commitments	interviews /questionnaires; institutional websites and documents; institutional budgets (if available)									ii	
iii. Institutional sustainability												
46. How likely are the plans, programmes, structures, capacities or collaborations strengthened by the project (either at the site or national level) to remain in place over time for continued support to NBF efforts?	indications of likelihood of capacities remaining in place; # institutional plans, policies, budget, agreements and/or staff allocations aimed at NBF	interviews /questionnaires terminal reports institutional websites and documents plans, programmes, budgets or agreements (if available)									iii	
47. How likely are the government and other stakeholders to continue with institutional capacity development efforts for NBF?	views /ratings on likelihood of capacities remaining in place; # of plans, programmes, budget or staff allocated to NBF	interviews /questionnaires terminal reports capacity building plans (if available)									iii	
48. Are there complementary frameworks, mechanisms or processes that already exist that could contribute to the sustainability of NBF efforts?	# of complementary frameworks, mechanisms or processes identified	interviews /questionnaires periodic reports, NSC minutes MTR, terminal reporting institutional websites and documents									iii	
I. FACTORS AFFECTING PROJECT PERFORMANCE												
i. Preparation and Readiness												
49. Was the project ready for implementation reasonably soon after project approval? Were appropriate measures 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?	Time between project approval, first disbursement and actual implementation (first technical activity) Examples of measures taken to address weaknesses to respond to changes.	First PIR/Progress reports, MTR and project inception reporting (quality of project design) Interview with UN Environment, project team and executing partners)			x	x			x			i

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
ii. Quality of Project Management and Supervision												
50. How effective and efficient was project management by MATE and IICA? How well did they adapt to changes during the project lifetime?	indications of appropriateness of UNE's project management; project delivery trends and performance	interviews /questionnaires periodic reports, MTR, amendments, NSC minutes correspondence between UNEP and project team terminal reporting										**ii**
51. To what extent did the National Steering Committee (NSC) provide guidance and oversight, and contribute to effective project implementation?	indications of value ascribed to Committee roles; # and type of Committee recommendations /guidance	interviews /questionnaires periodic reports, NSC minutes MTR, terminal reporting										**ii, iii**
52. To what extent did the project team respond to the guidance/recommendations provided by: (a) the National Sterring Committee (NSC)? (b) the UNEP GEF Task Manager?	indications of project team responsiveness; degree of implementation of guidance/ recommendations	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes MTR, terminal reporting										**ii iii**
53. Did the project face any operational or institutional constraints that influenced its implementation? If yes, please explain. Were these identified, communicated and overcome opportunely?	# and type of constraints identified; # and type of remedial actions taken	interviews /questionnairescorrespondence between UNEP and project teamperiodic reports, NSC minutesMTR, terminal reporting					**i**				**i**	**iivi**
54. How effective and efficient was UNE's project supervision as GEF Agency? (includes monitoring, reporting, risk management, and participation in Steering Committee meetings)	indications of value ascribed to UNE's supervisory role; # and type of decisions /recommendations involving UNEP Task Manager	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes MTR, terminal reporting							**x**			**ii**
55. Did UNEP provide technical support? If so, what kind? Was it timely and effective?	indications of value ascribed to UNE's technical support	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes MTR, terminal reporting		**i**					**x**			**ii**

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
iii. Stakeholder Participation and Cooperation												
56. To what extent did the project achieve effective stakeholder participation and/or collaboration?	level of, and value ascribed to, sectoral engagement; # and type of participatory activities	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents										iii
57. To what extent were stakeholders (local or national) involved in: (a) project design; (b) the sharing of lessons learnt from the project; or (c) the sharing of expertise and technical knowledge, or the pooling of resources?	quality of project design; degree of stakeholder involvement; # and type of shared lessons, knowledge or resources	ProDoc interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents			x				x			iii vii
iv. Responsiveness to Human Rights and Gender Equity												
58. To what extent were gender issues and the inclusion of minority groups considered in the project's activities and results? (especially in intervention areas)	indications of gender considerations; # of gender-related stakeholders involved	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents										iv
59. To what extent did the project address human rights and human wellbeing (e.g. access to land and resources, human health, rights to healthy environment)?	indications of human rights considerations; # of minority /community groups represented	interviews /questionnaires periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents	3.e									iv
v. Environmental and Social Safeguards												

EVALUATION QUESTIONS	Indicators	Potencial Data Sources	Evaluation Criteria & Key Strategic Questions (KSQ)									
			KSQ	A	B	C	D	E	F	G	H	I
60. To what extent the Project management reviewed risk ratings, monitored project implementation for possible safeguard issues and responded (when corresponded) to safeguard issues through risk avoidance, minimization, and reported on implementation of measures taken.	existence of completed SRIF forms (or previous ESSFEN forms)	interviews, terminal reporting										v
vi. Country Ownership and Driven-ness												
61. In how far have the national partners assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project?	Endorsement of project by governmental agencies Provision of counterpart funding	Interviews with national partners, UN Environment and project team Project progress reports / PIR Documented endorsements and cofinancing									i	iii vi
62. How and how well did the project stimulate country ownership of project outputs and outcomes? Is this different by gendered and marginalised groups?	Perception of ownership by national and local agencies	NSC minutes Interviews with SC members and other key stakeholders at national and local government level										iii iv vi vii
vii. Communications and Public Awareness												
63. To what extent did the project achieve effective communications (a) internally, amongst Project team and key stakeholders, and (b) externally, through public awareness and dissemination activities?	# and type of communications /outreach activities; level of effectiveness ascribed to internal /external communications	interviews /questionnaires correspondence between project team and stakeholders periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents										vii
64. How successful was the project in its knowledge management approach? (exchange of learning among /with project partners and beneficiaries). What were the main	# and type of successes and challenges identified concerning knowledge management	interviews /questionnaires correspondence between project team and stakeholders periodic reports, NSC minutes, workshop reports										vii

			Evaluation Criteria & Key Strategic Questions (KSQ)									
EVALUATION QUESTIONS	**Indicators**	**Potencial Data Sources**	**KSQ**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
challenges and successes relating to knowledge management?		MTR, terminal reporting institutional websites and documents										
65. Was UNEP involved in sharing or communicating on innovations and best practices coming from the project? Was the project connected to any networks or knowledge management platforms for sharing?	# and type of communications /exchange activities by UNE	interviews /questionnaires correspondence between UNEP and project team periodic reports, NSC minutes, workshop reports MTR, terminal reporting institutional websites and documents	**3.c**									**vii**

ANNEX III-b – DATA COLLECTION TOOLS

An initial guide was sent to stakeholder representatives with whom a face-to-face interview was held during the on-site mission, asking them to prepare information around the following high–level lines (in Spanish language):

- *¿En qué medida los objetivos del Proyecto se han alcanzado?*
- *¿Cuáles han sido los productos y efectos del Proyecto, en particular los que se han instalado en forma permanente y sostenible?*
- *¿Cuáles han sido las limitaciones más relevantes para obtener los resultados esperados del Proyecto (organizacionales, administrativas, políticas, sociales, etc.)?*
- *¿Cuáles han sido otros productos, actividades o beneficios derivados de las actividades del Proyecto, que no se hubieran previsto originalmente y se encuentren hoy funcionales?*
- *¿Cuáles han sido las lecciones aprendidas, que puedan ser tenidas en cuenta para otros Proyectos?*

Surveys and questionnaires were sent to the interviewed and other emergent actors, based on the following developed question bank. Each questionnaire was customized according to stakeholder / actor role. All questions were translated to Spanish for constructing the web questionnaires. The questionnaires are available at:

NPC – IICA: https://forms.gle/fgwPHFEypVZt2XZh6

Academy and Laboratories: https://forms.gle/w9t6C9DpDk6sdK4i6

Industry: https://forms.gle/4vGGxWuaQsSB4s2y7

Ecuador Ministries: https://forms.gle/KAZxksFf9KPH2nGY6

Civil Society, NGOs, Public Awareness and Participation: https://forms.gle/NTAkVDDqwWUXPW199

QUESTION BANK FOR INTERVIEWS AND QUESTIONNAIRES

EVALUATION QUESTIONS	Civil Society / Consumers / NGOs	Academy	Industry Sector	Govt Stkholders: Ministries,	Govt - NPC - IICA	UNEP GEF Task Manager		HIGHLY SUCCESSFUL	MODERATEL SUCCESSFUL	MODERATELY UNSUCCESSFUL	DEFICIENT
A. STRATEGIC RELEVANCE											
1. To what extent were project objectives and implementation strategies consistent with: (a) UNE's mandate and policies at the time? (b) Regional, Sub-regional and National Environmental Priorities, (c) UN Environment Medium Term Strategy (MTS) and Programme of Work (POW), and (d) GEF Strategic Priorities ?						X					
2. Why did UNEP choose this project? How was UNEP role defined?						X					
3. Were the objectives and implementation strategies complementary with relevant existing interventions from the project partners and /or other stakeholders?					X	X					
B. QUALITY OF PROJECT DESIGN											
see section 3 and Annex B											
C. NATURE OF EXTERNAL CONTEXT											
4. Did the (political, environmental, social, institutional) context change during project implementation and how did the project adapt to this?											
D. EFFECTIVENESS											
i. Availability of Outputs											
5. How successful was the project in delivering its Outputs both in quantity and quality, as well as their usefulness and timeliness?	X	X	X	X	X	X					

6. To what extent did project Outputs contribute to achieving expected Outcomes and Intermediate States? (i.e., do causal pathways have a sound technical logic?)	X	X	X	X	X	X				
7. To what extent is there a sense of ownership over project Outputs and results?	X	X	X	X	X	X				
8. Were UNEP tools or methodologies (a) used or upscaled? or (b) developed that could be used in other Projects (within or beyond UNE)?					X	X				
9. Were key stakeholders (including project beneficiaries) appropriately involved in producing the programmed outputs?	X	X	X	X	X	X				
10. Did the project face any technical or political constraints in generating its Outputs? If yes, please explain. Were these identified, communicated and overcome opportunely? (i.e. before affecting the project)	X	X	X	X	X	X				
ii. Achievement of Project Outcomes										
11. How successful was the project in Finalizing the Policy and Regulatory Biosafety Framework (Biosafety policy and regulations formally approved, sustainably funded and their application initiated; Management of LMOs improved through permanent coordination mechanisms and structures)	X	X	X	X	X	X				
12. How successful was the project in Putting in place a fully functional system for decision making and control of LMOs?	X	X	X	X	X	X				
13. How successful was the project in Building human and institutional capacity for biosafety? (describe how many people have finalized biosafety - related graduate and post-graduate formation, specific training workshops on Risk Assessment, Risk Management, LMOs detection, other biosafety closely related capacity building efforts due to or influenced by the Project; describe how the technical infrastructure has evolved and (if) operative - e.g. detection labs-)	X	X	X	X	X	X				

14. How successful was the project in Improving public awareness and participation in biosafety? Describe institutional websites or portals (e.g., Ecuador Biosafety Portal, biosafety - related institutions websites, general Government websites) that currently address biosafety information and issues. Describe established and operational systems for public participation in LMOs decision making.	X	X	X	X	X	X				
15. To what extent can achieved Outcomes be directly attributed to project actions?	X	X	X	X	X	X				
16. Did the assumptions hold/were drivers positively influenced (as included in the ToC)	X	X	X	X	X	X				
iii. Likelihood of Impact										
17. To what degree the project is likely to create long-term impact (established policies, regulations, processes and resources both public and private to effectively and co-ordinately manage biosafety in the country)	X	X	X	X	X					
18. To what extent has the project helped to promote institutional changes, changes in behaviour or perception, policy changes, and new opportunities? Were these changes or new decisions prompted by increased scientific evidence/knowledge or capacity?	X	X	X	X	X					
19. Has the Project participant Institutions addressed other related lines beyond the original scope of work? If yes, please specify	X	X	X	X	X					
20. Did the assumptions hold / were drivers positively influenced in the transition from outcomes to impact? (as included in the RF and TOC)	X	X	X	X	X					
21. Have desired outcomes and impacts occurred amongst all stakeholder groups (and if not, why this might be).	X	X	X	X	X					
22. Did the project result in any unplanned positive effects? Did it lead to any unintended negative effects? If yes, please explain	X	X	X	X	X	X				

23. Are there any particular innovations and best practices coming from the project? Were there any gaps or potentials in innovation not realized?	X	X	X	X	X	X				
E. FINANCIAL MANAGEMENT										
24. Was financial information and communication between financial and project management staff complete and transparent?					X	X				
25. Were GEF financial resources disbursed by UNEP in a timely manner? If not, what were the obstacles faced? (financial, administrative, managerial)					X	X				
26. Were administrative processes (procurements, cooperation agreements, etc.) conducted efficiently and in a timely manner by MATE and/or IICA-Country Office?					X	X				
27. Were co-financing commitments met as programmed and made available in a timely manner?					X	X				
28. Were communications with the UNEP Fund Management Officer (in Nairobi) fluid and timely? Was the FMO involved in adaptive management decisions?					X	X				
29. Did any irregularities arise in procurements, use of financial resources and human resource management? If yes, describe these irregularities, together with any measures taken to correct/prevent them.					X	X				
F. EFFICIENCY										
30. How was the operational execution vs. original planning (budget wise)? Was the project implemented cost effective? (were the results achieved at the lowest possible cost					X	X				
31. How was the operational execution vs. original planning (time wise)?					X	X				
32. If present, what have been the main reasons for delay/changes in implementation? Have these affected project execution, costs and effectiveness?	X	X	X	X	X	X				
33. Was adaptive management applied adequately? Were any cost- or timesaving measures put in place in attempting to bring the project as far as possible in achieving its results within its secured budget and time?					X	X				

34. Did the project build adequately (create complementariness) on existing institutions, lessons of other initiatives, data sources, partnerships with third parties and ongoing projects?	X	X	X	X	X	X				
G. MONITORING AND REPORTING										
i. Monitoring Design and Budgeting										
35. To what extent was the project M&E plan viable, Outcome-based and included SMART indicators?					X	X				
36. Were M&E responsibilities clearly defined across project teams? Did the project include an M&E budget? Were project stakeholders involved in monitoring?					X	X				
ii. Monitoring of Project Implementation										
37. Was the M&E system operational and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period?					X	X				
38. How did project teams monitor the participation of disaggregated groups (gendered, marginalised or vulnerable groups, including those with disabilities) in project activities?					X	X				
39. Did monitoring lead to adaptive management and contribute to resolving implementation problems?					X	X				
iii. Project Reporting										
40. Were the required progress, expenditure and terminal reports prepared satisfactorily by the national project team and submitted on time? Were all reporting requirements met?						X				
H. SUSTAINABILITY										
i. Socio-political sustainability										

41. In the absence of external support from UNEP and GEF, is there sufficient government and stakeholder commitment to continue using, enforcing and improving the developed NBF to guide management decisions?	X	X	X	X	X	X				
42. How likely are the government and other stakeholders to continue with individual capacity development efforts for implementing NBF activities?	X	X	X	X	X	X				
43. What are the key factors that contributed to the sustainability of project results and impacts?	X	X	X	X	X	X				
ii. Financial sustainability										
44. To what extent is the continuity of project results and their impact dependent on continued financial support?	X	X	X	X	X	X				
45. What is the likelihood that adequate financial resources will be or will become available to continue implementation the programs, plans, agreements, monitoring systems etc. prepared and agreed upon under the project?	X	X	X	X	X	X				
iii. Institutional sustainability										
46. How likely are the plans, programmes, structures, capacities or collaborations strengthened by the project (either at the site or national level) to remain in place over time for continued support to NBF efforts?	X	X	X	X	X	X				
47. How likely are the government and other stakeholders to continue with institutional capacity development efforts for NBF?	X	X	X	X	X	X				
48. Are there complementary frameworks, mechanisms or processes that already exist that could contribute to the sustainability of NBF efforts?	X	X	X	X	X	X				
I. FACTORS AFFECTING PROJECT PERFORMANCE										
i. Preparation and Readiness										

49. Was the project ready for implementation reasonably soon after project approval? Were appropriate measures 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?					X	X					
ii. Quality of Project Management and Supervision											
50. How effective and efficient was project management by MATE and IICA? How well did they adapt to changes during the project lifetime?						X					
51. To what extent did the National Steering Committee (NSC) provide guidance and oversight, and contribute to effective project implementation?	X	X	X	X	X	X					
52. To what extent did the project team respond to the guidance/recommendations provided by: (a) the National Sterring Committee (NSC)? (b) the UNEP GEF Task Manager?	X	X	X	X		X					
53. Did the project face any operational or institutional constraints that influenced its implementation? If yes, please explain. Were these identified, communicated and overcome opportunely?	X	X	X	X	X	X					
54. How effective and efficient was UNE's project supervision as GEF Agency? (includes monitoring, reporting, risk management, and participation in Steering Committee meetings)					X						
55. Did UNEP provide technical support? If so, what kind? Was it timely and effective?					X						
iii. Stakeholder Participation and Cooperation											
56. To what extent did the project achieve effective stakeholder participation and/or collaboration?	X	X	X	X	X	X					

57. To what extent were stakeholders (local or national) involved in: (a) project design; (b) the sharing of lessons learnt from the project; or (c) the sharing of expertise and technical knowledge, or the pooling of resources?	X	X	X	X	X	X					
iv. Responsiveness to Human Rights and Gender Equity											
58. To what extent were gender issues and the inclusion of minority groups considered in the project's activities and results? (especially in intervention areas)	X	X	X	X	X	X					
59. To what extent did the project address human rights and human wellbeing (e.g. access to land and resources, human health, rights to healthy environment)?	X	X	X	X	X	X					
v. Environmental and Social Safeguards											
60. To what extent the Project management reviewed risk ratings, monitored project implementation for possible safeguard issues and responded (when corresponded) to safeguard issues through risk avoidance, minimization, and reported on implementation of measures taken.						X					
vi. Country Ownership and Driven-ness											
61. In how far have the national partners assumed responsibility for the project and provided adequate support to project execution, including the degree of cooperation received from the various public institutions involved in the project?	X	X	X	X	X	X					
62. How and how well did the project stimulate country ownership of project outputs and outcomes? Is this different by gendered and marginalised groups?	X	X	X	X	X						
vii. Communications and Public Awareness											
63. To what extent did the project achieve effective communications (a) internally, amongst Project team and key stakeholders, and (b) externally, through public awareness and dissemination activities?	X	X	X	X	X						

64. How successful was the project in its knowledge management approach? (exchange of learning among /with project partners and beneficiaries). What were the main challenges and successes relating to knowledge management?	X	X	X	X	X						
65. Was UNEP involved in sharing or communicating on innovations and best practices coming from the project? Was the project connected to any networks or knowledge management platforms for sharing?	X	X	X	X	X						

ANNEX IV - KEY DOCUMENTS CONSULTED

- GEF NBF country endorsement letter
- Approved CEO Endorsement Request for Medium-Sized Project proposal (GEF ID: 3405)
- Approved UNEP Project Document and Appendices, specifically:
    - Appendix 1: Budget by project components and UNEP budget lines
    - Appendix 2: Co-financing by source and UNEP budget lines
    - Appendix 3: Incremental Cost Matrix
    - Appendix 4: Results Framework
    - Appendix 5: Workplan and timetable
    - Appendix 6: Key deliverables and benchmarks
    - Appendix 7: Costed M&E plan
    - Appendix 8: Summary of reporting requirements and responsibilities
    - Appendix 9: Standard Terminal Evaluation TOR
    - Appendix 10: Decision-making flowchart and organizational chart
    - Appendix 11: Terms of Reference for the Post of National Coordinator
    - Appendix 12: Co-financing commitment letters from project partners
    - Appendix 13: Endorsement letter of GEF National Focal Point
    - Appendix 14: Draft procurement plan
    - Appendix 15: Tracking Tool
    - Appendix 16: Stakeholders characterization
    - Appendix 17: National needs assessment in biosafety
- 5-26-10 GEFID 3405 Ecuador-Project Review Sheet
- UNEP response to GEF review
- GEF approval letter
- 1st PCA Amendment (2014)
- 2nd PCA Agreement between UNEP, MAATE and IICA, 2018
- 1ST Amendment to 2nd PCA (2020)
- Minutes /notes of National Steering Committee meetings and / NBC
- ANUBIS – all technical and management reported Project Outputs

- Mid Term Evaluation C.5 Act. 6.2 (E1-5303) 2013
- Progress reports – PIRs (from 2010-2021) and other Periodic documents (Periods 1 – 37)

- Expenditure reports, Budget Reports, Budget reviews
- Consolidated co-finance report
- Audit reports for years 2010, 2011, 2012, , 2013, , 2014, , 2015, , 2016, 2017, 2018, 2019, 2020, 2021
- Cash advance requests and approvals – ANUBIS -
- Annual workplans
- Annual inventories, Final Inventory
- UNEP terminal reporting (Final Report, financial report, budget revision)

- IICA Collaboration Agreement products (received from IICA)

Reference documents

- Ecuador 2008 Constitution
- Ecuador Environmental Code and Rulebook
- AGREGAR CONSTITUCION, REGLAMENTOS, LEYERS, PNBV, CODA, REG CODA
-

- Institutional websites: www.bioseguridad.gob.ec , MAATE, MAG, MIPRO, MSP, AGROCALIDAD, INIAP, UFSQ institutional portals.
- BCH (Ecuador country profile, records on Competent National Authorities and Focal Points, Laws and regulations, Decisions, Risk Assessments, national websites, news)

ANNEX V: PORTAL INPUTS

Table 13 GEF portal inputs

Question: What was the performance at the project's completion against Core Indicator Targets? (For projects approved prior to GEF-7[22], these indicators will be identified retrospectively and comments on performance provided[23]).
Response: *The original Project design was aligned with GEF's Strategy for Financing Biosafety (Doc GEF/C.30/8/Rev.1) approved in December 2006, and was in line with the Focal Area Strategies and Strategic Programming for GEF-4 (Doc GEF/C.31/10) approved in July 2007. It responded directly to Biodiversity Strategic Objective 3: To safeguard biodiversity - Strategic Programme 6 Building Capacity for the Implementation of the Cartagena Protocol on Biosafety. It is also fully aligned with the key elements emphasized in the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol: (i) The need to develop a functional political, legal and regulatory biosafety framework.(ii) The need to strengthen technical and institutional capacity in biosafety, and establish a system for handling requests, carrying out risk assessments, decision-making on LMOs, communicating decisions, monitoring and enforcement. (iii) The need for awareness raising activities, education on biosafety, access to information and public participation on decision-making for LMOs* *The Project has been successful in building capacity for the Implementation of the CPB, and has also successfully helped to strengthen technical and institutional capacity in biosafety. It has been highly successful in creating the technical capacities for LMOs detection, risk assessment, management and communication, although moderately successful to establish the system for handling requests. Public awareness, access to information and participation on decision – making for LMOs has not improved significantly as a result of the Project.*
Question: What were the progress, challenges and outcomes regarding engagement of stakeholders in the project/program as evolved from the time of the MTR? *(This should be based on the description included in the Stakeholder Engagement Plan or equivalent documentation submitted at CEO Endorsement/Approval)*
Response: *The MTR was performed in April 2013, when the planned Project finalization date was December 2014. The Project was extended to December 2015, then it was closed in 2016. A second PCA was signed in July 2018 in order to develop the pending activities and execute the remaining funds. Stakeholders had active participation until the end of the 1st Phase. During 2nd phase the stakeholders participation was mostly related to training and technical activities, with limited active Project steering role.*
Question: What were the completed gender-responsive measures and, if applicable, actual 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)*
Response: *The Project was designed in 2008-2010, and no explicit mention about gender was included in the Project Document. However, due to the very nature of this project, gender balance is implicit, both regarding the target public for the expected outcomes (the whole population of Ecuador) and because all technical and capacity building were attended by a balanced audience. Ecuador laws that are applicable as framework for the Project design explicitly address gender equality and human rights.* *The n*

[22] The GEF is currently operating under the seventh replenishment period of the GEF Trust Fund covering the period July 1, 2018 to June 30, 2022. The GEF Portal Reporting Guide for FY20 Reporting Process indicates that GEF-6 projects that have yet to map existing indicators to GEF-7 Core Indicators need to do so at MTR stage or (if already there) at the time of the TE. .(i.e. not GEF projects approved before GEF-6)

[23] This is not applicable for Enabling Activities

Question: What was the progress made in the implementation of the management measures against the Safeguards Plan submitted at CEO Approval? The risk classifications reported in the latest PIR report should be verified and the findings of the effectiveness of any measures or lessons learned 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)*
Response: *The project envisaged the development of mechanisms for citizen participation during its execution that would balance cultural and gender factors, as needed. The reviewer could not find any evidence of these mechanisms being in place. Socio-economic analyses as part of the LMO risk assessment and risk management processes were considered in the Project design and were developed in project activities.*
Question: What were the challenges and outcomes regarding the project's completed 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)*
Response: *The Project Knowledge Management relied on the development of several technical manuals, guidelines, protocols and procedures related to the LMOs decision – making process, and also on building updated databases of biosafety / biotechnology experts, institutions and projects, along with up-to-date national information on biosafety matters. An important channel for making all this knowledge is the National BCH Portal, or National Biosafety website www.bioseguridadecuador.gob.ec, part of MAATE website. This portal has been upgraded and maintained for many years, but during this review it has not been available publicly.*

ANNEX VI. BRIEF CV OF THE REVIEWER

Name

Profession	Engineer
Nationality	Uruguayan
Country experience	• Americas: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, United States, Uruguay, Venezuela • Europe: Spain, Germany, Switzerland, Italy • Asia: India, Malaysia, Thailand, Japan, Sri Lanka, Viet Nam, Cambodia, China, India • Africa: Egypt • Oceania: Australia
Education	Ph.D. in Computer Science, Universidad de Alcalá, Spain, 2010 M.Sc. in Informatics Engineering, Universidad Pontificia de Salamanca, Spain, 2004 Informatics Engineer, Universidad Católica del Uruguay, 1994 Naval Engineer, Naval Academy, Uruguay, 1979

Biosafety professional experience summary

2017 – 2021 UNEP-GEF PROJECT "Sustainable Capacity Building for Effective Participation in the Biosafety Clearing House (BCH III)".

- BCH Regional Specialist, coordinated project development for the Caribbean and Latin-America regions.
- Planned, managed, and developed BCH training activities in participating countries.
- Planned, organized and deployed national, regional and global BCH workshops.
- Developed and implemented Cartagena Protocol and Biosafety Clearing House Education Materials. Developed, managed and supported the BCH Virtual Learning Environment.
- Coordinated and supported Project Regional Advisors' assistance to participating countries training activities.
- Liaised with all assigned participating countries' government officers in charge of executing the National Project.

2016 – 2017 UNEP-GEF "Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region" – Caribbean Biosafety Regional Portal partial development and Roster Guidelines.

Regional Biosafety Project Website Improvement: experts request process review and posting system implementation. Added sections on biosafety education, capacity building, and network of Caribbean laboratories. Implemented a complete system for participating countries to submit and track/review technical issues to be addressed by the technical resource group.

Developed "Guidelines for the Caribbean Biosafety Network **T**echnical **W**orking **G**roup System ", an implemented functionality of the Caribbean Biosafety Portal.

2016 - 2018 UNEP-GEF "Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region" – Participating countries training & BCH development Consultancy.

Developed online seminars, on-site workshops, BCH consultancy, and National BCH systems/websites design & implementation for Antigua & Barbuda, Bahamas, Barbados, Grenada, St. Kitts & Nevis and Suriname.

2015 "Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region" – Regional workshop Consultancy.

UNEP Caribbean Biosafety Implementation Project - executing agency: University of West Indies. Developed online seminar, on-site workshop and mentoring for project participant countries delegates on Biosafety Clearing House (Port of Spain, Trinidad y Tobago, Nov. 2015.

2015 UNEP-DELC Consultancy – BCH-III Training of Trainers

Designed, developed and facilitated the BCH Training of Trainers workshop for UNEP-GEF BCH-III Capacity Building Project Regional Advisors, Secretariat of the Convention on Biological Diversity; May 2015, Montreal, Canada.

2014 – 2015 UNEP-DELC Consultancy – BCH Training and Certification program

Designed and developed a complete training and certification program & curricula for BCH Capacity Building Projects Regional Advisors

2014 – SCBD (Convention on Biological Diversity) Consultancy – BCH NFP & NAU Training Curricula

Developed complete curricula and contents for online courses on *"Effective usage of the Biosafety Clearing House"* for BCH National Focal Points, Competent National Authorities and Organizations and the public.

2011- 2013: UNEP-GEF PROJECT "Continued improvement of the Capacity Building for Effective Participation in the Biosafety Clearing House – BCH-II".

- BCH Regional Specialist, coordinating project development for the Caribbean and Latin-America regions.
- Project management, planning and development of BCH training activities in participating countries.
- Planning, organizing and deployment of national, regional and global BCH workshops.
- Continued development and global implementation of Cartagena Protocol and Biosafety Clearing House Education Materials. Development, management and support for the BCH Virtual Learning Environment.
- Project Regional Advisors coordination for supporting participating countries' training activities.
- Planning and development of more than 50 global online seminars about the Cartagena Protocol and all aspects related to the Biosafety Clearing House, in several languages (EN, ES, FR, AR, RU).

2010: UNEP-GEF BCH-II Capacity Building Project design.

Collaborated to develop UNEP-GEF "Continued improvement of the Capacity Building for Effective Participation in the Biosafety Clearing House – BCH-II" project, full cycle with Project Document (PRODOC), GEF CEO / endorsement, reviews, etc.

2005 – 2010: UNEP-GEF PROJECT "Capacity Building for Effective Participation in the Biosafety Clearing House" – "BCH-I".

- BCH Regional Specialist: coordinated project development for the Latin-America region.
- Planned, managed, organized, and deployed BCH capacity-building activities in the participating countries and regional and global BCH events.
- Developed, implemented, and maintained Cartagena Protocol and Biosafety Clearing House Education Materials.
- Developed, managed and supported the BCH Help System (http://bch.cbd.int/help) and the BCH Virtual Learning Environment, in all UN official languages.
- Coordinated BCH Project Regional Advisors for supporting participating countries training activities.

Global Cartagena Protocol and Biosafety Clearing House training activities developed:

Collaborated with the organization and performed as an instructor in the following UNEP-GEF biosafety global events:

CBD Conferences of the Parties / Meetings of the Parties:

Planned, designed and facilitated the following workshops:

- 2018 COP-MOP 8 – Workshop for BCH National Focal Points, Sharm-el-Sheik, Egypt
- 2016 COP-MOP 7 – Workshop for BCH National Focal Points, Cancun, Mexico
- 2012 COP-MOP 6 – Workshop for BCH National Focal Points, Hyderabad, India
- 2010 COP-MOP 5 – Workshop for BCH National Focal Points, Nagoya, Japan
- 2008 COP-MOP 4 – Workshop for BCH National Focal Points, Bonn, Germany
- 2008 COP-MOP 4 – BCH Side Event, Bonn, Germany
- 2006 COP-MOP 3 – Workshop for BCH National Focal Points, Curitiba, Brazil
- 2005 COP-MOP 2 – Workshop for BCH National Focal Points, Montreal, Canada

UNEP - GEF BCH Capacity Building Projects BCH Regional Workshops:

Planned, designed, and facilitated:

- 2019 Caribbean Regional Training of Trainers BCH- III Workshop, Port of Spain, Trinidad and Tobago
- 2018 Latin America BCH-III Regional Workshop, Montevideo Uruguay
- 2017 Caribbean Regional Training Workshop on Biosafety Clearing House September, Port of Spain, Trinidad and Tobago
- 2015 CAR Biosafety Regional Workshop, Port Of Spain, Trinidad And Tobago
- 2012 BCH CAR Regional Workshop, St. John's, Antigua & Barbuda
- 2011 BCH LAM Regional Workshop, Panama, Panama
- 2008 BCH AFR/CEE/AP Regional Workshop, Cairo, Egypt

- 2007 BCH LAM Regional Workshop, Panama City, Panama
- 2006 BCH LAM Regional Workshop, Montevideo, Uruguay
- 2005 BCH CAR Regional Workshop, Bridgetown, Barbados

UNEP - GEF BCH Capacity Building Projects Regional Advisors Training of Trainers

Recruiting, selecting and training new Regional Advisors for Biosafety Clearing House Capacity Building Projects.

- 2015 BCH-III Regional Advisors Meeting – Training of Trainers, Montreal, Canada
- 2011 BCH-II Regional Advisors Meeting – Training of Trainers, Montreal, Canada
- 2007 BCH Regional Advisors Meeting – Training of Trainers, New Delhi, India
- 2007 BCH Regional Advisors Meeting – Training of Trainers, Geneva, Switzerland
- 2006 BCH Regional Advisors Meeting – Training of Trainers, Bangkok, Thailand

SCBD – BCH-IAC "Informal Advisory Committee"

Participated in all meetings and collaborated with the Biosafety Clearing House Informal Advisory Committee from 2006 to 2020.

National Cartagena Protocol and Biosafety Clearing House training activities developed:

Planned, organized and facilitated several dozen National Biosafety Clearing House Training Workshops, in more than 25 countries, including Antigua & Barbuda, Barbados, Belize, Bolivia, Brazil, Canada, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Egypt, El Salvador, Guatemala, Guyana, Honduras, India, Nicaragua, Panama, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Switzerland, Thailand, Trinidad & Tobago, Uruguay and Venezuela.

CPB and BCH Education Materials Development and Publishing

- Since 2005 managed and produced training materials for BCH Capacity Building Projects I and II, and for several training materials for SCBD development projects.
- Managed development, translations, and publishing of all the existing BCH education materials (more than 80 different learning objects, amounting to more than 180,000 words in each of 5 UN languages – AR, EN, ES, FR AND RU, including more than 50 online – real-time seminars) up to 2001.
- Developed the former full BCH help system (http://bch.cbd.int/help), in 6 UN official languages.
- Setup and maintained the Biosafety Clearing House Virtual Learning Environment (VLE), since 2006 and up to 2021, holding 5 public global courses containing all CPB and BCH learning objects, and more than 50 specifically – targeted courses (countries' national workshops support online courses, regional BCH workshops, global – COP-MOP workshops support online courses and 52 online seminars video recordings, in AR, EN, ES, FR and RU). More than 3700 different users used the BCH VLE and its BCH education materials, from more than **137** countries.
- Organized, developed and managed more than 50 CPB and BCH global webinars, available both from the BCH

(https://bch.cbd.int/help/UNEPGEFBCHII_material.shtml) and the BCH Virtual Learning Environment.

- Developed complete curricula and contents for online courses on “Effective usage of the BCH” for BCH National Focal Points, Competent National Authorities and Organizations and the general public. **(**SCBD**).**
- Designed and developed a complete training and certification program for BCH Capacity Building Projects Regional Advisors (UNEP-DELC).

ANNEX VII. REVIEW TORS

TERMS OF REFERENCE

Terminal Review of the UNEP/GEF projects "Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program (GEF ID Number – 3405)'

Section 1: PROJECT BACKGROUND AND OVERVIEW

Project General Information

Table 1. Project summary - Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program (GEF ID Number – 3405)

UNEP Sub-programme:	Ecosystem Management	**UNEP Division/Branch:**	UN Environment Programme Ecosystems Division GEF Biodiversity and Land Degradation Unit Biodiversity and Land Branch
Expected Accomplishment(s):	The main objective of the project is to help Ecuador to implement the national biosafety framework and implementation of the Cartagena Protocol on biosafety. Specific objectives of each project activity are: Component 1: Finalizing the policy and regulatory biosafety framework. Component 2: Putting in place a fully functional system for decision making and control of LMOs Component 3: Building human and institutional capacity for biosafety Component 4: Improving public awareness and participation in biosafety.	**Programme of Work Output(s):**	PoW 2018/2019 Subprogram 3 – Healthy & Productive Ecosystems
SDG(s) and indicator(s)	Ecuador UNDAF 2019-2022, Strategic Priority 2: Planet 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		

	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[24])	Subprogramme 3: EA(a), Indicator (iii) Subprogramme 4: EA(b), Indicator (i)		
Dates of previous project phases:	Extensions: April 2016 – July 2018 (Inactivity period) July 2018 – April 2020 (Current PCA) April 2020 – January 2022	**Status of future project phases:**	-

FROM THE PROJECT'S PIR REPORT (use latest version) :

Project Title:	Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program

Executing Agency:	Ministry of Environment and Water Inter-American Institute for Cooperation on Agriculture (IICA)

Project partners:	SENESCYT: Secretariat of Higher Education, Science, Technology and Innovation MAGAP: Ministry of Agriculture and Livestock AGROCALIDAD: Agency for Phytosanitary Control, INIAP: National Institute of Agricultural Research, MIPRO: Ministry of Production, International Trade, Investment and Fishing, MSP: Ministry of Public Health SENAE: customs, MRECI: Ministry of Foreign Affairs SENPLADES: Secretariat of Planning

Geographical Scope:	Latin America and Caribbean

Participating Countries:	Ecuador

GEF project ID:	3405	**IMIS number*[25]:**	GLF-2238-2716-4B77-SB-000780.70
Focal Area(s):	Biodiversity	**GEF OP #:**	Programme of Work for the Biennium 2020–2021 Subprogramme 3 – Healthy and productive ecosystems Subprogramme 4 – Environmental governance
GEF Strategic Priority/Objective:	BD 1, 2	**GEF approval date*:**	26 May 2010
UNEP approval date:		**Date of first disbursement*:**	10 March 2011 (original PCA) 22 October 2018 (current PCA)

[24] This does not apply to Enabling Activities

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

Actual start date[26]:	16 December 2010 (original PCA) 4 July 2018 (current PCA)	**Planned duration:**	December 2010 – April 2016 (original PCA)
Intended completion date*:	June 2020	**Actual or Expected completion date:**	31 March 2022
Project Type:	Full Size Project	**GEF Allocation*:**	USD 665,818 $442,384.51 disbursed under original PCA; $223,433.49 to be disbursed under current PCA
PPG GEF cost*:		**PPG co-financing*:**	
Expected MSP/FSP Co-financing*:	USD 2,922,653.60	**Total Cost*:**	USD 39,696,628.27
Mid-term Review/eval. (planned date):	April 2013	**Terminal Evaluation (planned date):**	4th quarter 2021
Mid-term Review/eval. (actual date):		**No. of revisions*:**	
Date of last Steering Committee meeting:		**Date of last Revision*:**	
Disbursement as of 30 June 2021:	USD 627,285.51	**Date of planned financial closure*:**	30 April 2022
Date of planned completion[27]*:	Actual - August 2021, Planned - June 2021 and December 2015	**Actual expenditures reported as of 30 June 2021:**	
Total co-financing realized as of 31 December 2021:	USD 3,215,375.85	**Actual expenditures entered in IMIS as of 31 December 2021*:**	USD 3,881,193.85
Leveraged financing:[28]			

Project Rationale[29]

Ecuador ratified the CP in 2003, being also Party to the CBD. With funding from the Global Environment Facility (GEF) and the support of the United Nations Environment Program (UNEP) the Global Project on "Development of National Biosafety Frameworks" was implemented, aiming to preparing countries for the entry into force of the CP through the development of national regulations on the subject and designing of a National Biosafety System. In Ecuador, the Project "Development of National Biosafety Framework" was launched in June 2003 and ended in June 2006; the result was a proposal for a framework or system including National Biosafety Regulations for LMOs. In 2008 Ecuador voted in favor of a new Constitution, which sets limits on the use of genetically modified organisms, including the import and cultivation of seeds and crops. However, this declaration requires to be translated into a system or national biosafety framework to meet effectively
the provisions of the Constitutional Principle.

With this background, Ecuador has requested the support of GEF through UNEP to finance the project to implement the National Biosafety Framework. The project objective is to assist Ecuador to have a workable and transparent national biosafety framework in place, to fulfill its obligations as a Party to the CP and thus contribute to ensuring an adequate level of protection of biodiversity and human.

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

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

[28] See above note on co-financing

[29] Grey =Info to be added

Project Results Framework

Project Objective: To assist Ecuador to have a workable and transparent national biosafety framework in place, to fulfill its obligations as a Party to the CP and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology.

Components:
1. Finalizing the policy and regulatory biosafety framework
Component 1 aims to complete the policy and regulatory framework on biosafety and promote the formal adoption of biosafety policy and regulations.

2. Putting in place a fully functional system for decision making and control of LMOs
Component 2 seeks to develop the technical and administrative tools and instruments needed to enable the country to have an effective national biosafety system.

3. Building human and institutional capacity for biosafety
Component 3 aims to strengthen the capacity to implement the NBF from the standpoint of human resources, and availability of information, infrastructure and equipment.

4. Improving public awareness and participation in biosafety
Component 4 is aimed at changing perceptions of the public on GM organisms and enhancing their participation in decision-making processes related to these.

5. Biosafety management by the state; monitoring and evaluation, project risk management
Component 5 focuses on project implementation and progress monitoring.

Executing Agency: the Ministry of Environment and Water is the National Executing Authority and leads on all substantive aspects and directs operational decisions. The Inter-American Institute for Cooperation on Agriculture (IICA) acts as the **Executing Agency**, but its role is mostly related to fund management and operational support.

Executing Arrangements

The Project was executed by MAE through the National Division of Biodiversity and Natural Protected Areas (of the Natural Heritage Under-secretariat), and had UNEP as its GEF Implementing Agency. Even though there were no formal agreements with other public or private entities to support technical and logistical aspects of the project, there is support from the public institutions mentioned in the prodoc for their active participation in the project, as well as a participation plan for the engagement of other non-governmental sectors. The National Biosafety Commission (NBC) presided by MAE was an important agent for the project. As a multisectoral body, its main purpose is to advise the NCA (MAE) on biosafety matters. It incorporates representatives of key sectors in the field, from both public and private organizations; its member institutions are: the Ministry Environment, the Ministry of Agriculture, the Ministry of Health, the Ministry of Industries, a representative of the Chambers of production from the Sierra Region and one from de Costa, a delegate from CEDENMA and a delegate from SENACYT. The project coordination unit included a National Coordinator, a technical assistant and an administrative and financial assistant. The coordination unit worked in close relationship with the Biosafety Unit of MAE. The project was supported by the Steering Committee (the NBC itself) as an inter-institutional coordination and advisory body.

Project Cost and Financing

Total Budget as indicated in the Final Report (US$):

Cost to the GEF Trust Fund:	665,818.00
Co-financing total:	3,215,375.85
Total project cost:	3,881,193.85

Co-finance summary:

Cost to the GEF Trust Fund: 665,818.00

Co-financing:

In-kind

Ministry of Agriculture (MAG)	11.283,20
Ministry of Environment	439.532,54
Ministry of Public Health (MSP)	23.104,00
Agency of Agriculture Quality Insurance (AGROCALIDAD - MAG)	104.126,00
National Institute of Agriculture Search (INIAP)	14.459,40
Ministry of Production (MIPRO)	13.131,88
Coordinator Ministries	13.648,00
National Secretariats	22.394,88
Custom (SENAE)	14.674,00
Academic Sector	135.297,00
IICA	63.905,55
TOTAL	**855.556,45**

Implementation Issues

To be added from MTE.

Section 2. OBJECTIVE AND SCOPE OF THE REVIEW

Objective of the Review

In line with the UNEP Evaluation Policy[30] and the UNEP Programme Manual[31], the Terminal Review (TR) is undertaken at operational completion of the project to assess project performance (in terms of relevance, effectiveness and efficiency), and determine outcomes and impacts (actual and potential) stemming from the project, including their sustainability. The Review has two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote operational improvement, learning and knowledge sharing through results and lessons learned among UNEP and Ministry of Environment and Water of Ecuador, Inter-American Institute for Cooperation on Agriculture (IICA). Therefore, the Review will identify lessons of operational relevance for future project formulation and implementation, especially for future phases of the project, where applicable.

Key Review principles

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.

The "Why?" Question. As this is a Terminal Review and a follow-up project is likely or similar interventions are envisaged for the future, particular attention will be given to learning from the experience. Therefore, the "why?" question should be at the front of the consultant(s)' minds all through the review exercise and is supported by the use of a theory of change approach. This means that the consultant(s) need to go beyond the assessment of "what" the project performance was and make a serious effort to provide a deeper understanding of "why" the performance was as it was (i.e. what contributed to the achievement of the project's results). This should provide the basis for the lessons that can be drawn from the project.

Attribution, Contribution and Credible Association: In order 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 reviews. 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.

Communicating Review Results. A key aim of the Review is to encourage reflection and learning by UNEP staff and key project stakeholders. The consultant should consider how reflection and learning can be promoted, both through the review process and in the communication of review findings and key lessons. Clear and concise writing is required on all review deliverables. Draft

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

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

and final versions of the main Review Report will be shared with key stakeholders by the Task Manager. There may, however, be several intended audiences, each with different interests and needs regarding the report. The consultant will plan with the Task Manager which audiences to target and the easiest and clearest 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.

Key Strategic Questions

In addition to the review criteria outlined in Section 10 below, the Review will address the **strategic questions**[32] 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 TR:

Q1: To what extent has the project achieved an effective application of the Cartagena Protocol on Biosafety, implemented the national biosafety regulatory framework and developed national capacities to properly handle LMO to safeguard biodiversity?
Q2: What impact has been achieved by actors engaged in the project moving on and deploying their knowledge in novel areas? How were the lessons learned used in applying agile and adaptive management of the project?
Q3: What changes were made to adapt to the effects of COVID-19 and how might any changes affect the project's performance?
Q4: How effectively has the project addressed MTR recommendations?

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 was the performance at the project's–completion against Core Indicator Targets? *(For projects approved prior to GEF-7, these indicators will be identified retrospectively and comments on performance provided*[33]*).*
b) Under Factors Affecting Performance/Stakeholder Participation and Cooperation:
What were the progress, challenges and outcomes regarding engagement of stakeholders in the project/program as evolved from the time of the MTR? *(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 were the completed gender-responsive measures and, if applicable, actual 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 was the progress made in the implementation of the management measures against the Safeguards Plan submitted at CEO Approval? The risk classifications reported in the latest PIR report should be verified and the findings of the effectiveness of any measures or lessons learned 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:

[32] The strategic questions should not duplicate questions that will be addressed under the standard review criteria described in section 10.

[33] This does not apply to Enabling Activities

What were the challenges and outcomes regarding the project's completed 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)*

Review Criteria

All review criteria will be rated on a six-point scale. Sections A-I below, outline the scope of the review criteria. The set of review criteria are grouped in nine categories: (A) Strategic Relevance; (B) Quality of Project Design; (C) Nature of External Context; (D) Effectiveness, which comprises assessments of the availability of outputs, achievement of outcomes and likelihood of impact; (E) Financial Management; (F) Efficiency; (G) Monitoring and Reporting; (H) Sustainability; and (I) Factors Affecting Project Performance.
Annex 1 of these Terms of Reference provides a table with a list of various tools, templates and guidelines that can help Review Consultant(s) to follow a thorough review process that meets all of UNEP's needs.

A. Strategic Relevance

The Review will assess the extent to which the activity is suited to the priorities and policies of the donors, implementing regions/countries and the target beneficiaries. 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. 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's Medium-Term Strategy[34] (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[35] (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/GEF/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.

[34] UNEP's Medium Term Strategy (MTS) is a document that guides UNEP's programme planning over a four-year period. It identifies UNEP's thematic priorities, known as 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

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

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

The Review will assess the alignment of the project with global priorities such as the SDGs and Agenda 2030. 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 also 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 Relevant Existing Interventions/Coherence*[36]

An assessment will be made of how well the project, either at design stage or during the project inception or mobilization[37], took account of ongoing and planned initiatives (under the same sub-programme, other UNEP sub-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.

Factors affecting this criterion may include:

- Stakeholders' participation and cooperation.
- Responsiveness to human rights and gender equity.
- Country ownership and driven-ness.

B. Quality of Project Design

The quality of project design is assessed using an agreed template during the review inception phase. Ratings are attributed to identified criteria and an overall Project Design Quality rating is established. The complete Project Design Quality template should be annexed in the Review Inception Report. Later, the overall Project Design Quality rating[38] should be entered in the final review ratings table (as item B) in the Main Review Report and a summary of the project's strengths and weaknesses at design stage should be included within the body of the Main Review Report.

Factors affecting this criterion may include (at the design stage):

- Stakeholders participation and cooperation.
- Responsiveness to human rights and gender equity.

C. Nature of External Context

At review inception stage a rating is established for the project's external operating context (considering the prevalence of conflict, natural disasters and political upheaval[39]). This rating is

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

[37] 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.

[38] In some instances, based on data collected during the review process, the assessment of the project's design quality may change from Inception Report to Main Review Report.

[39] Note that 'political upheaval' does not include regular national election cycles, but unanticipated unrest or prolonged disruption. The potential delays or changes in political support that are often associated with the regular national election

entered in the final review ratings table as item C. Where a project has been rated as facing either an *Unfavourable* or *Highly Unfavourable* external operating context, and/or a negative external event has occurred during project implementation, the ratings for Effectiveness, Efficiency and/or Sustainability may be increased at the discretion of the Review Consultant and Task Manager together. A justification for such an increase must be given.

D. Effectiveness

i. Availability of Outputs[40]

The Review will assess the project's success in producing the programmed outputs and making them available to the intended beneficiaries as well as its success in achieving milestones as per the project design document (ProDoc). Any formal modifications/revisions made during project implementation will be considered part of the project design. Where the project outputs are inappropriately or inaccurately stated in the ProDoc, reformulations may be necessary in the reconstruction of the Theory of Change (TOC). In such cases a table should be provided showing the original and the reformulation of the outputs for transparency. The availability of outputs will be assessed in terms of both quantity and quality, and the assessment will consider their ownership by, and usefulness to, intended beneficiaries 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 available and meeting expected quality standards.

Factors affecting this criterion may include:

- Preparation and readiness.
- Quality of project management and supervision.[41]

ii. Achievement of Project Outcomes[42]

The achievement of project outcomes is assessed as performance against the outcomes as defined in the reconstructed[43] Theory of Change. These are outcomes that are intended to be achieved by 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 to show where substantive amendments to the formulation of project outcomes is necessary to allow for an assessment of performance. The Review should report evidence of attribution between UNEP's intervention and the project outcomes. In cases of normative work or where several actors are collaborating to achieve common outcomes, evidence of the nature and magnitude of UNEP's 'substantive

cycle should be part of the project's design and addressed through adaptive management of the project team. From March 2020 this should include the effects of COVID-19.

[40] 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).

[41] For GEF funded projects 'project management and supervision' will refer to the project management performance of the Executing Agency and the technical backstopping provided by UNEP, as Implementing Agency.

[42] 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)

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

contribution' should be included and/or 'credible association' established between project efforts and the project outcomes realised.

Factors affecting this criterion may include:

- Quality of project management and supervision.
- Stakeholders' participation and cooperation.
- Responsiveness to human rights and gender equity.
- Communication and public awareness.

iii. Likelihood of Impact

Based on the articulation of long-lasting effects in the reconstructed TOC *(i.e. from project outcomes, via intermediate states, to impact)*, the Review will assess the likelihood of the intended, positive impacts becoming a reality. Project objectives or goals should be incorporated in the TOC, possibly as intermediate states or long-lasting impacts. The Evaluation Office's approach to the use of TOC in project reviews is outlined in a guidance note and is supported by an excel-based flow chart, 'Likelihood of Impact Assessment Decision Tree'. Essentially the approach follows a 'likelihood tree' from project outcomes to impacts, taking account of whether the assumptions and drivers identified in the reconstructed TOC held. Any unintended positive effects should also be identified and their causal linkages to the intended impact described.
The 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 and Social Safeguards.
The Review will consider the extent to which the project has played a catalytic role[44] or has promoted scaling up and/or replication as part of its Theory of Change (either explicitly as in a project with a demonstration component or implicitly as expressed in the drivers required to move to outcome levels) and as factors that are likely to contribute to greater or long lasting impact.

Ultimately UNEP and all its partners aim to bring about benefits to the environment and human well-being. Few projects are likely to have impact statements that reflect such long-lasting or broad-based changes. However, the Review will assess the likelihood of the project to make a substantive contribution to the long-lasting changes represented by the Sustainable Development Goals, and/or the intermediate-level results reflected in UNEP's Expected Accomplishments and the strategic priorities of funding partner(s).

Factors affecting this criterion may include:

- Quality of Project Management and Supervision (including adaptive management).
- Stakeholders participation and cooperation.
- Responsiveness to human rights and gender equity.
- Country ownership and driven-ness.
- Communication and public awareness.

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[44] The terms catalytic effect, scaling up and replication are inter-related and generally refer to extending the coverage or magnitude of the effects of a project. Catalytic effect is associated with triggering additional actions that are not directly funded by the project – these effects can be both concrete or less tangible, can be intentionally caused by the project or implied in the design and reflected in the TOC drivers, or can be unintentional and can rely on funding from another source or have no financial requirements. Scaling up and Replication require more intentionality for projects, or individual components and approaches, to be reproduced in other similar contexts. Scaling up suggests a substantive increase in the number of new beneficiaries reached/involved and may require adapted delivery mechanisms while Replication suggests the repetition of an approach or component at a similar scale but among different beneficiaries. Even with highly technical work, where scaling up or replication involves working with a new community, some consideration of the new context should take place and adjustments made as necessary.

E. Financial Management

Financial management will be assessed under three themes: *adherence* to UNEP's financial policies and procedures, *completeness* of financial information and *communication* between financial and project management staff. The Review will establish the actual spend across the life of the project of funds secured from all donors. This expenditure will be reported, where possible, at output/component level and will be compared with the approved budget. The Review will verify the application of proper financial management standards and adherence to UNEP's financial management policies. Any financial management issues that have affected the timely delivery of the project or the quality of its performance will be highlighted. The Review will record where standard financial documentation is missing, inaccurate, incomplete or unavailable in a timely manner. The Review will assess the level of communication between the Project Manager and the Fund Management Officer as it relates to the effective delivery of the planned project and the needs of a responsive, adaptive management approach.

Factors affecting this criterion may include:

- Preparation and readiness.
- Quality of project management and supervision.

F. Efficiency

Under the efficiency criterion the Review will assess the extent to which the project delivered maximum results from the given resources. This will include an assessment of 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 also assess to what extent any project extension could have been avoided through stronger project management and identify any negative impacts caused by project delays or extensions. The Review will describe any cost or time-saving measures put in place to maximise results within the secured budget and agreed project timeframe and consider whether the project was implemented in the most efficient way compared to alternative interventions or approaches.

The Review will give special attention to efforts made by the project teams during project implementation to make use of/build upon pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities [45] with other initiatives, programmes and projects etc. to increase project efficiency.
The factors underpinning the need for any project extensions will also be explored and discussed. Consultants should note that as management or project support costs cannot be increased in cases of 'no cost extensions', such extensions represent an increase in unstated costs to UNEP and Executing Agencies.

Factors affecting this criterion may include:

- Preparation and readiness (e.g. timeliness).
- Quality of project management and supervision.
- Stakeholders participation and cooperation.

G. Monitoring and Reporting

[45] Complementarity with other interventions during project design, inception or mobilization is considered under Strategic Relevance above.

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

i. Monitoring Design and Budgeting

Each project should be supported by a sound monitoring plan that is designed to track progress against SMART[46] 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. In particular, the Review 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. The Review will assess the quality of the design of the monitoring plan as well as the funds allocated for its implementation. The adequacy of resources for Mid-Term and Terminal Evaluation/Review should be discussed, where applicable.

ii. Monitoring of Project Implementation

The Review will assess whether the monitoring system was operational and facilitated the timely tracking of results and progress towards project objectives throughout the project implementation period. This assessment will include consideration of whether the project gathered relevant and good quality baseline data that is accurately and appropriately documented. This should include monitoring the representation and participation of disaggregated groups, including gendered, marginalised or vulnerable groups, such as those living with disabilities, in project activities. 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 were used to support this activity.

The performance at project completion 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.

iii. Project Reporting

UNEP has a centralised project information management system (Anubis) in which project managers upload six-monthly progress reports against agreed project milestones. This information will be provided to the Review Consultant(s) by the Task Manager. Some projects have additional requirements to report regularly to funding partners, which will be supplied by the project team (e.g. the Project Implementation Reviews and Tracking Tool for GEF-funded projects). The Review will assess the extent to which both UNEP and GEF reporting commitments have been fulfilled. Consideration will be given as to whether reporting has been carried out with respect to the effects of the initiative on disaggregated groups.

Factors affecting this criterion may include:

- Quality of project management and supervision.
- Responsiveness to human rights and gender equity (e.g disaggregated indicators and data).

H. Sustainability

Sustainability[47] is understood as the probability of the benefits derived from the achievement of project outcomes being maintained and developed after the close of the intervention. The Review will identify and assess the key conditions or factors that are likely to undermine or contribute to the endurance of achieved project outcomes (i.e. 'assumptions' and 'drivers'). Some factors of

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

[47] 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)

sustainability may be embedded in the project design and implementation approaches while others may be contextual circumstances or conditions that evolve over the life of the intervention. Where applicable an assessment of bio-physical factors that may affect the sustainability of direct outcomes may also be included.

i. Socio-political Sustainability

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

ii. Financial Sustainability

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

iii. Institutional Sustainability

The Review will assess the extent to which the sustainability of project outcomes (especially those relating to policies and laws) 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. In particular, the Review will consider whether institutional capacity development efforts are likely to be sustained.

Factors affecting this criterion may include:

- Stakeholders participation and cooperation.
- Responsiveness to human rights and gender equity (e.g. where interventions are not inclusive, their sustainability may be undermined).
- Communication and public awareness.
- Country ownership and driven-ness.

I. Factors Affecting Project Performance and Cross-Cutting Issues

(These factors are rated in the ratings table but are discussed within the Main Review Report as cross-cutting themes as appropriate under the other review criteria, above. If these issues have not been addressed under the Review Criteria above, then independent summaries of their status within the reviewed project should be given in this section)

i. Preparation and Readiness

This criterion focuses on the inception or mobilisation stage of the project (i.e. the time between project approval and first disbursement). 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. *(Project preparation is included in the template for the assessment of Project Design Quality).*

ii. Quality of Project Management and Supervision

For GEF funded projects 'project management and supervision' may refer to the project management performance of the Executing Agency and the technical backstopping and supervision provided by UNEP as Implementing Agency. The performance of parties playing different roles should be discussed and a rating provided for both types of supervision (UNEP/Implementing Agency; Partner/Executing Agency) and the overall rating for this sub-category established as a simple average of the two.

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 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, target users of project outputs and any other collaborating agents external to UNEP and the executing partner(s). 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 occurring since the MTR 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 Equality

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[48].

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 Equality and Human Rights are adequately taken into account. In particular the Review will consider to what extent project, implementation and monitoring have taken into consideration: (i) possible inequalities (especially those related to gender) 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; and (iii) the role of disadvantaged groups (especially women, youth and children and those living with disabilities) in mitigating or adapting to environmental changes and engaging in environmental protection and rehabilitation.

The completed gender-responsive measures and, if applicable, actual 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.

[48]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

v. Environmental and Social Safeguards

UNEP projects address environmental and social safeguards primarily through the process of environmental and social screening at the project approval stage, risk assessment and management (avoidance, minimization, mitigation or, in exceptional cases, offsetting) of potential environmental and social risks and impacts associated with project and programme activities. The Review will confirm whether UNEP requirements[49] were met to: *review* risk ratings on a regular basis; *monitor* project implementation for possible safeguard issues; *respond* (where relevant) to safeguard issues through risk avoidance, minimization, mitigation or offsetting and r*eport* on the implementation of safeguard management measures taken. UNEP requirements for proposed projects to be screened for any safeguarding issues; for sound environmental and social risk assessments to be conducted and initial risk ratings to be assigned are reviewed above under Quality of Project Design). The Review will also consider the extent to which the management of the project minimised UNEP's environmental footprint. Implementation of the management measures against the Safeguards Plan submitted at CEO Approval should be reviewed, the risk classifications verified and the findings of the effectiveness of any measures or lessons learned 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. While there is some overlap between Country Ownership and Institutional Sustainability, this criterion focuses primarily on the forward momentum of the intended projects results, i.e. either: a) moving forwards from outputs to project outcomes or b) moving forward from project outcomes towards intermediate states. 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 (e.g. representatives from multiple sectors or relevant ministries beyond Ministry of Environment). 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 gendered 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 project's completed 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.

[49] 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.

Section 3. REVIEW APPROACH, METHODS AND DELIVERABLES

The Terminal Review will be an in-depth review using a participatory approach whereby key stakeholders are kept informed and consulted throughout the review process. Both quantitative and qualitative review methods will be used as appropriate to determine project achievements against the expected outputs, outcomes and impacts. It is highly recommended that the consultant(s) maintains close communication with the project team and promotes information exchange throughout the review implementation phase in order to increase their (and other stakeholder) ownership of the review findings. Where applicable, the consultant(s) 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 biodiversity and natural resource management strategies, other substantive documents prepared by the projects and others;

Project design documents (including minutes of the project design review meeting at approval); Annual Work Plans and Budgets or equivalent, revisions to the project (Project Document Supplement), the logical framework and its budget;

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

Project deliverables (e.g. publications, reports, assessments, surveys);

Mid-Term Review or Mid-Term Evaluation of the project;

Evaluations/Reviews of similar projects.

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

UNEP Task Manager (TM);

Project Manager (PM)

Project management team;

UNEP Fund Management Officer (FMO);

Portfolio Manager and Sub-Programme Coordinator, where appropriate;

Project partners based on stakeholder analyses;

Relevant resource persons;

Representatives from civil society and specialist groups (such as women's, farmers and trade associations etc).

Surveys

Field visits

Other data collection tools, all as appropriate for the terminal review and elaborated in the inception report.

Review Deliverables and Review Procedures

The Review Consultant will prepare:

- **Inception Report:** (see Annex 1 for a list of all templates, tables and guidance notes) containing an assessment of project design quality, a draft reconstructed 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 Report:** containing an executive summary that can act as a stand-alone document; detailed analysis of the review findings organised by review criteria and supported with evidence; lessons learned and recommendations and an annotated ratings table.

A **Review Brief** (a 2-page overview of the evaluand and review findings) for wider dissemination through the UNEP website may be required. This will be discussed with the Task Manager no later than during the finalization of the Inception Report.

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. The Task Manager will then forward the revised draft report to other project stakeholders, for their review and comments. Stakeholders may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions as well as providing feedback on the proposed recommendations and lessons. Any comments or responses to draft reports will be sent to the 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.
The final version of the Terminal Review report will be assessed for its quality by the UNEP Evaluation Office using a standard template and this assessment will be annexed to the final Terminal Review report.

At the end of the review process, 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 the **Lessons Learned**.

The Review Consultant

The Review Consultant will work under the overall responsibility of the Task Manager in consultation with the Fund Management Officer, the Head of Unit/Branch, the Portfolio Manager and the Sub-programme Coordinators of the relevant UNEP Sub-programmes as appropriate.

The Review Consultant will liaise with the Task Manager on any procedural and methodological matters related to the Review. It is, however, the consultant's individual responsibility (where applicable) to arrange for their visas and immunizations as well as to plan meetings with stakeholders, organize online surveys, obtain documentary evidence and any other logistical matters related to the assignment. The UNEP Task Manager and project team will, where possible, provide logistical support (introductions, meetings etc.) allowing the consultants to conduct the Review as efficiently and independently as possible.

The Review Consultant will be hired for 40 days over the period of 4 months (1 June 2023 to 30 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 7 years of technical / evaluation experience is required, preferably including evaluating large, regional or global programmes and using a Theory of Change approach; and a good/broad understanding of biodiversity and biosafety issues is desired. For this consultancy, fluency in oral and written English and Spanish is a requirement. Working knowledge of the UN system and specifically the work of UNEP is an added advantage. The work will be home-based with possible field visits.

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

Schedule of the Review

The table below presents the tentative schedule for the Review over 4 months since start of the assignment.

Table 3. Tentative schedule for the Review

Milestone	Tentative Dates
Inception Report	3 weeks from starting date
Review Mission	6 weeks from starting date
E-based data collection through interviews, surveys and other approaches.	8 weeks from staring date
PowerPoint/presentation on preliminary findings and recommendations	8 weeks from starting date
Draft Review Report to Task Manager (and Project Manager)	12 weeks from starting date
Draft Review Report shared with wider group of stakeholders	13 weeks from starting date
Final Review Report	16 weeks from starting date
Final Review Report shared with all respondents	16 weeks from starting date

Contractual Arrangements

The Review Consultant(s) will be selected and recruited by the Task Manager under an individual Special Service Agreement (SSA) on a "fees only" basis (see below). By signing the service contract with UNEP/UNON, the consultant certifies that they have not been associated with the design and implementation of the project in any way which may jeopardize their independence and impartiality towards project achievements and project partner performance. In addition, 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 sigh the Code of Conduct Agreement Form.

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

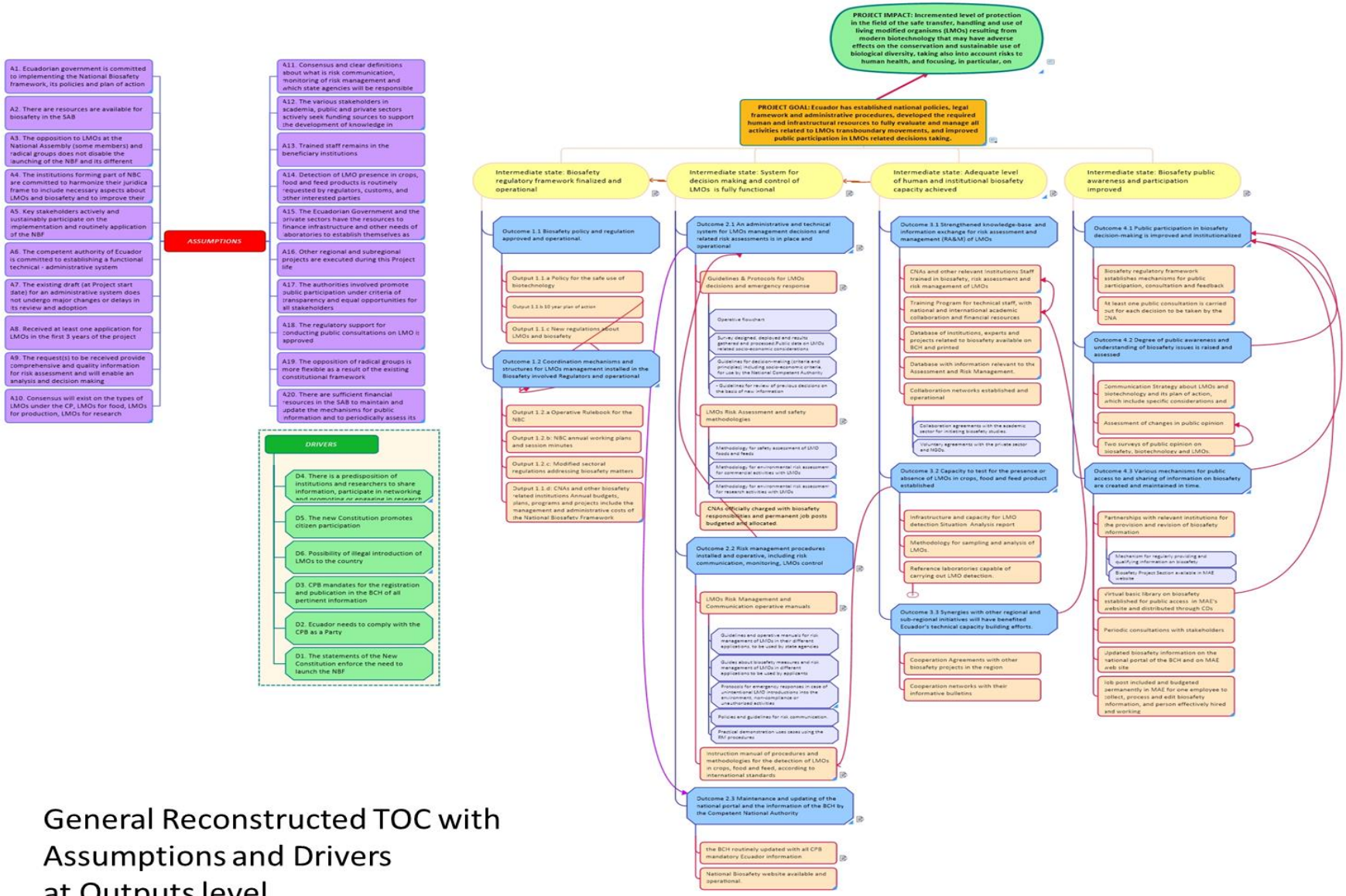
Deliverable	Percentage Payment
Approved Inception Reports (*as per Annex I document #9)*	30%
Approved Draft Main Review Reports *(as per Annex I document #10)*	30%
Approved Final Main Review Reports	40%

Fees only contracts: Where applicable, air tickets will be purchased by UNEP and 75% of the Daily Subsistence Allowance for each authorised travel mission will be paid up front. Local in-country travel will only be reimbursed where agreed in advance with the Task Manager and on the production of acceptable receipts. Terminal expenses and residual DSA entitlements (25%) will be paid after mission completion.

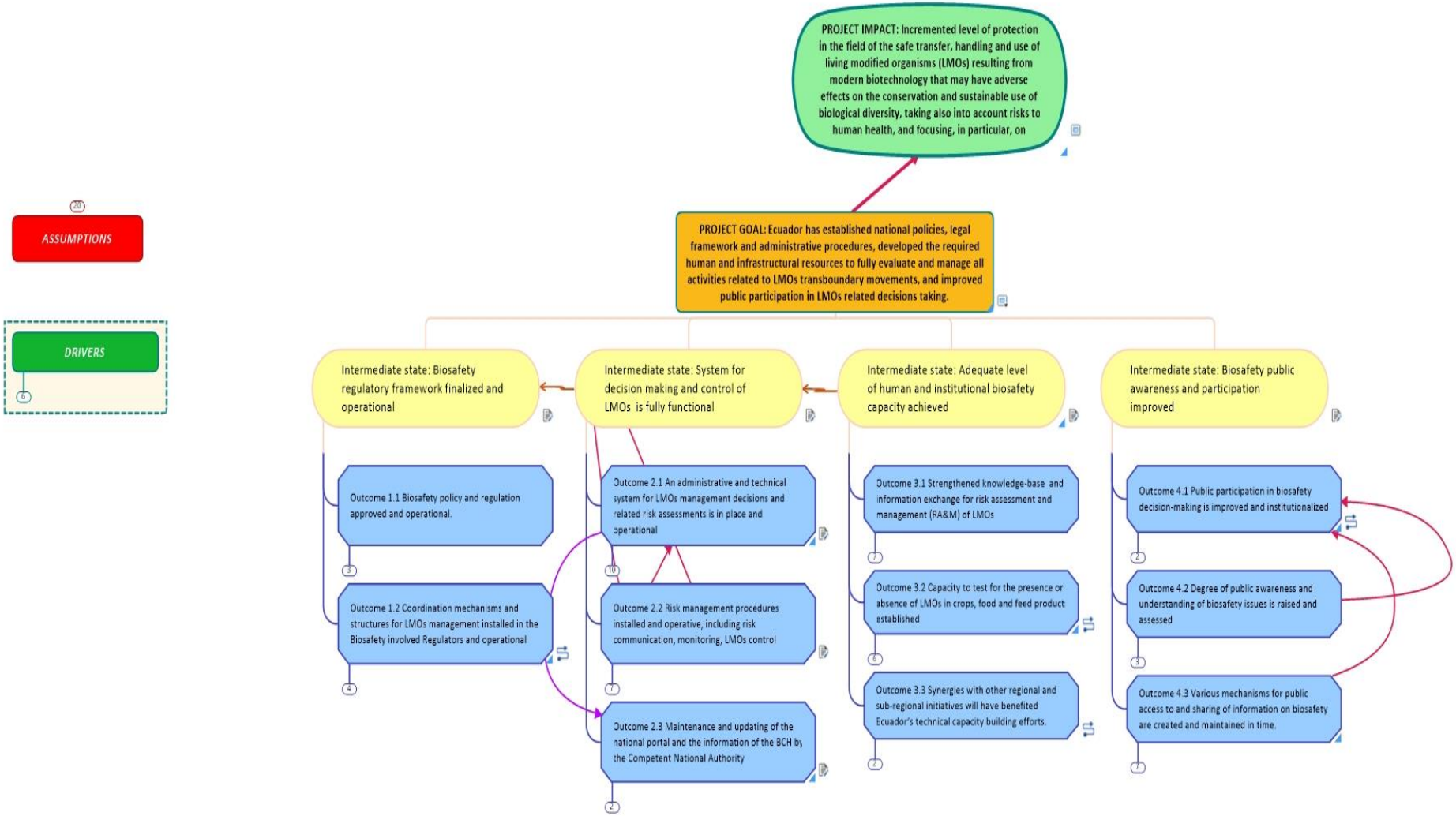
The consultant may be provided with access to UNEP's information management systems (e.g. PIMS, Anubis, SharePoint, etc.) and, if such access is granted, the consultants agree not to disclose information from that system to third parties beyond information required for, and included in, the Review Report.

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 UNEP, payment may be withheld at the discretion of the Head of Branch or Portfolio Manager until the consultants have improved the deliverables to meet UNEP's quality standards.
If the consultant fails to submit a satisfactory final product to the Project Manager in a timely manner, i.e. before the end date of their contract, UNEP reserves the right to employ additional human resources to finalize the report, and to reduce the consultant's fees by an amount equal to the additional costs borne by the project team to bring the report up to standard or completion.

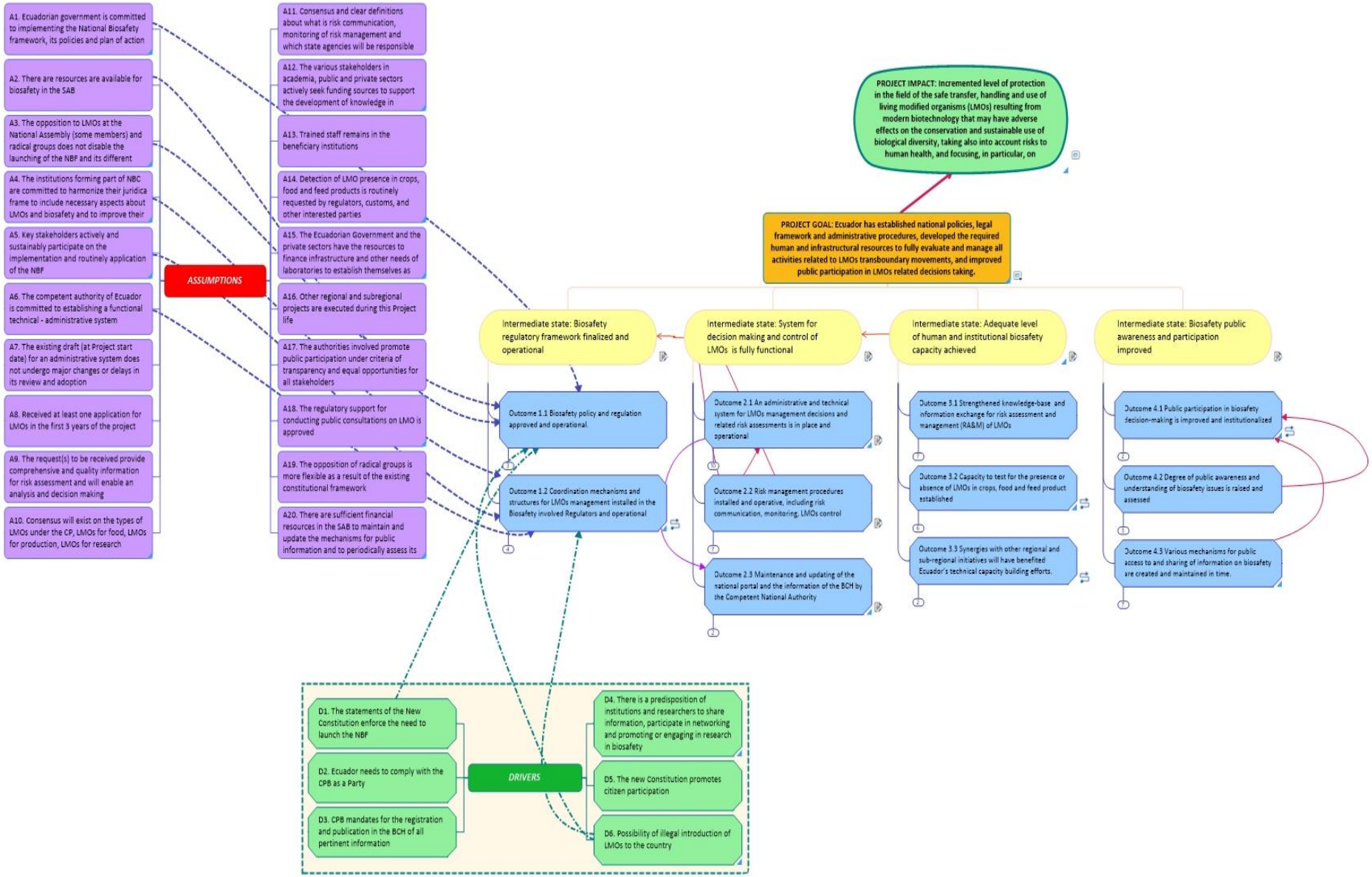
ANNEX VIII – RECONSTRUCTED THEORY OF CHANGE



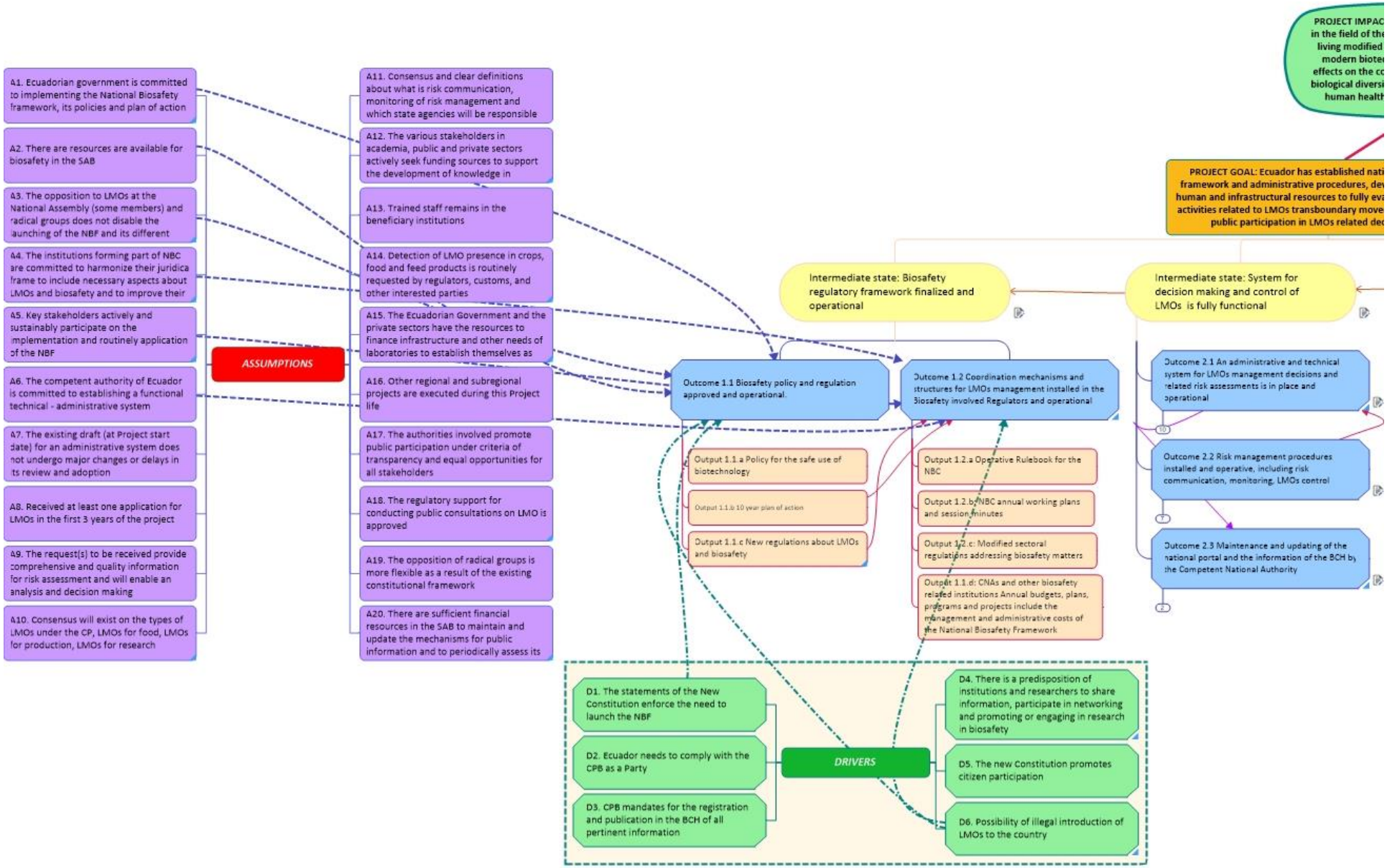
General Reconstructed TOC with Assumptions and Drivers at Outputs level



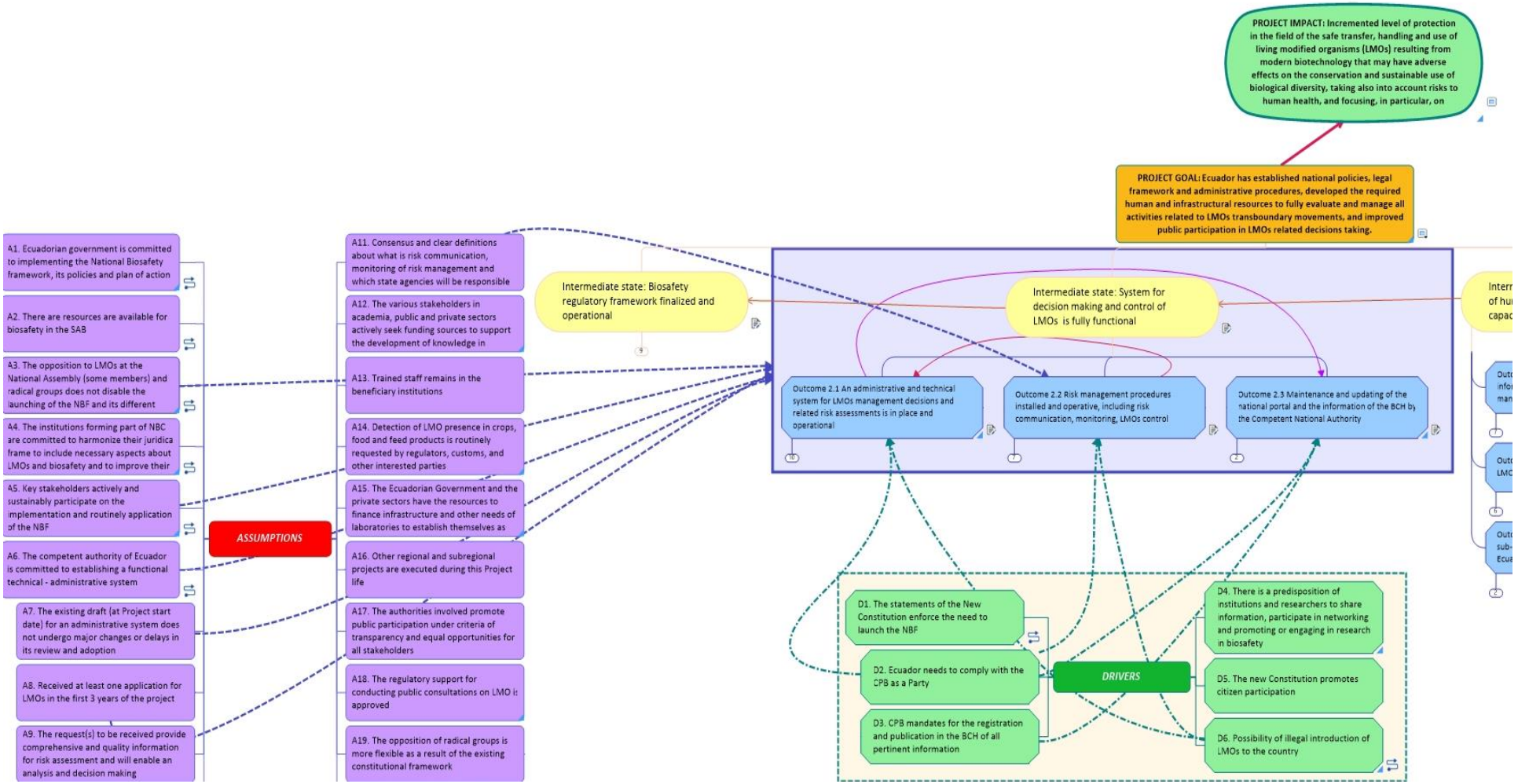
Collapsed TOC at Outcomes level



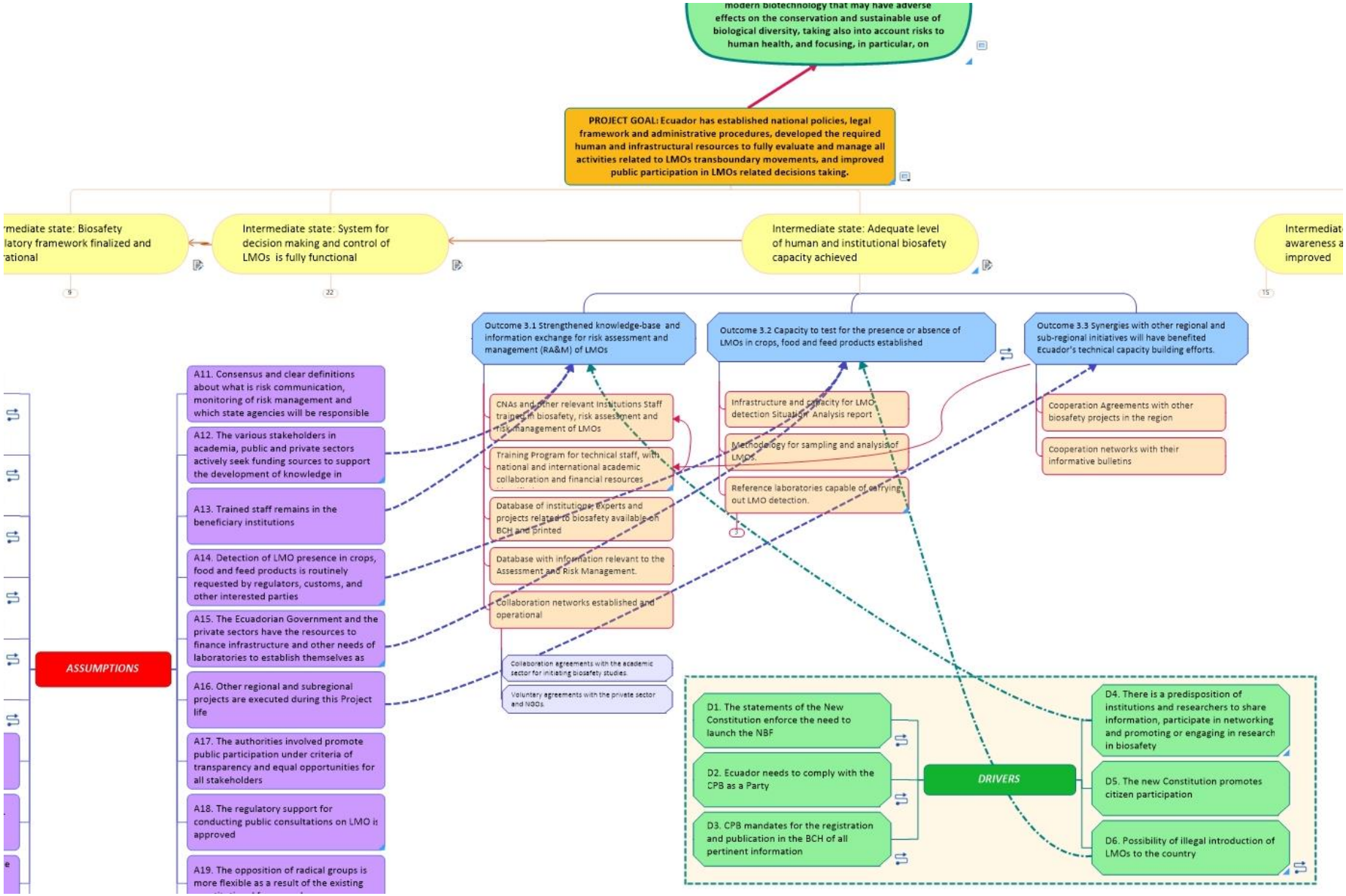
Assumptions and Drivers for Outcome 1



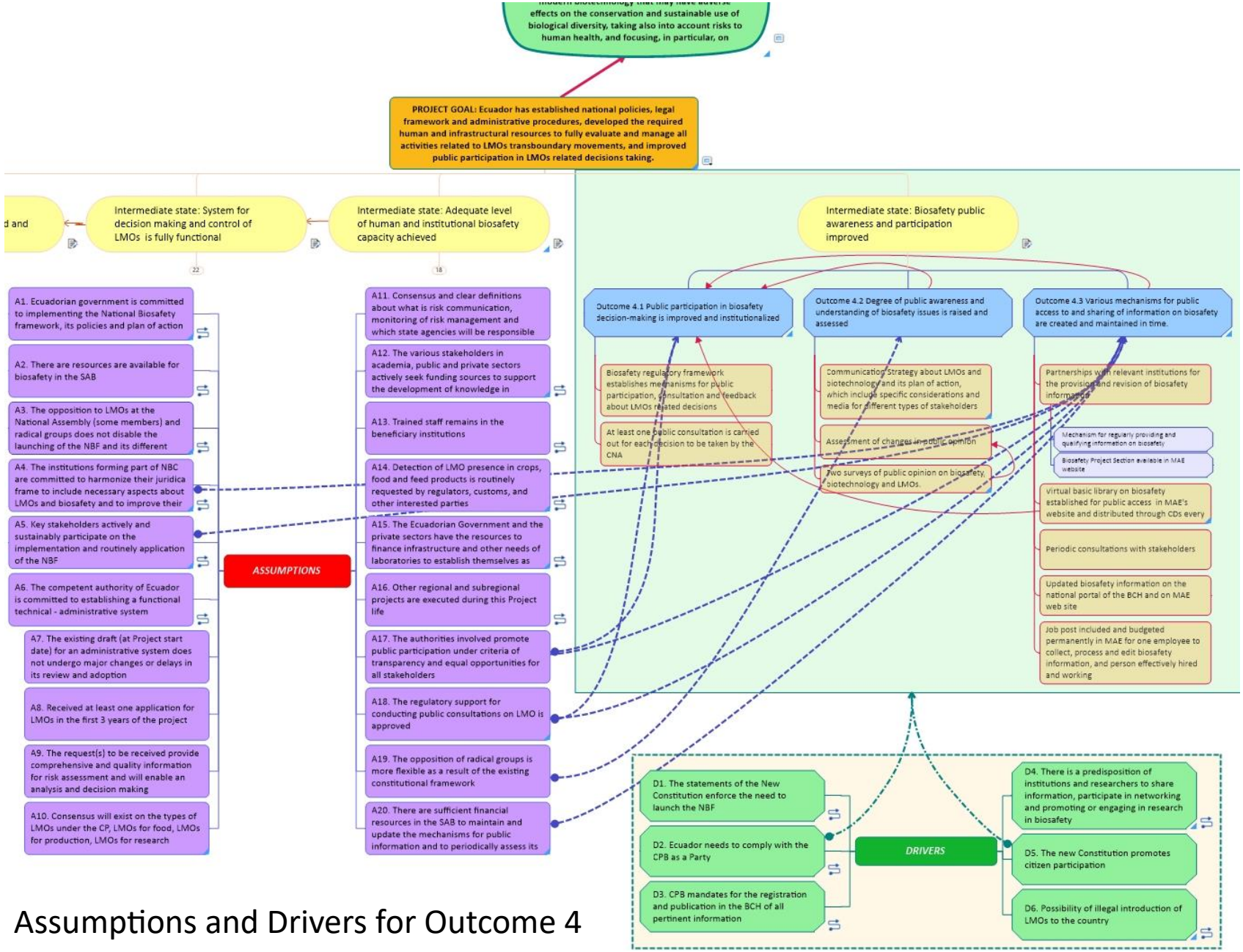
Assumptions and Drivers for Outcome 1



Assumptions and Drivers for Outcome 2



Assumptions and Drivers for Outcome 3



Assumptions and Drivers for Outcome 4

ANNEX IX – STAKEHOLDER ANALYSIS

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
GLOBAL / REGIONAL				
UNEP	YES	UNEP is the GEF Implementing Agency for this project. As a UN agency, it has a direct influence and interest over the project's success.	UNEP will be the GEF Implementing. It will participate on the project's NSC and provide project oversight and technical support.	Different task managers during the project life, need to interview all
IICA	NO	IICA is an important institution in LAC, part of OEA, supporting Ecuador in the agriculture field. IICA was a strategic ally because through this institution the Biosafety Project could run many activities and received a valuable technical support. IICA provided 7% of the country in-kind contribution to the Project.	In 2018 a collaboration agreement was made between MAE and IICA and an amendment to the original PCA was done. IICA took charge of several project remaining activities and procurement tasks. Since 2018: budget management, technical support (writing ToR for external consultancies, providing consultants products to MAE, planning and helping to coordinate different capacity building activities, contracting and managing project audit reports).	

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
CENTRAL GOVERNMENT				
POLICY, REGULATORY & RESEARCH				
MINISTRY OF ENVIRONMENT – MAE	YES	MAE is the institution in charge of executing CBD and CPB agreements and its purpose is to manage natural resources in a sustainable way. It is the focal point of CBD and CPB, executing some environmental projects with GEF funds. MAE provided 25% of the country cash contribution, and 51% of the in-kind co-finance	Project Executing Agency. Under the provisions of the Environmental Management Law, MAE is responsible for implementing the National Biosafety System	Different NPC during the project.
MINISTRY OF AGRICULTURE, LIVESTOCK, ACUACULTURE AND FISHERIES - MAGAP	YES	Direct beneficiary of the project, its participation is mandatory and it is a member of the NCB. MAG is the institution in charge of executing all the agriculture policies in Ecuador. Identified in the PRODOC as KEY stakeholder. Provided 1% of the country in-kind co-finance.	Roles: To collaborate for developing national policies and regulations. To provide technical and political support to the Project. To provide technical justification for the introduction of GM seeds and crops. This Ministry is also mandated to regulate biosafety under the new Organic Law on Food Sovereignty. Its main participation was in discussions around the project technical and regulatory proposals	Authorities and delegates have changed during the project

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
			of Biosafety and training activities as a member of NBC	
MINISTRY OF PUBLIC HEALTH - MSP	YES	The MSP is mandated to exercise stewardship of the national health system through the promotion and protection of health, food safety, and environmental health. This institution is also part of the NBC and has participated actively in previous UNEP-GEF biosafety projects. Direct beneficiary of the project, its participation is mandatory in the NBF and in the project's Steering Committee. Identified in the PRODOC as KEY stakeholder. Provided 3% of the country in-kind co-finance.	Roles: To provide technical support about human health issues related to LMOs and biosafety in general. To participate in biosafety training events. To provide support for training on LMOs for food processing detection methodologies, through these institutions: • Sanitary Regulation and Control Agency (**ARCSA**) • Littoral Polytechnic School (**ESPOL**).	Did MSP participate in the project design? How? How is MSP using / applying the products developed during the Project?

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
SENESCYT: SECRETARIAT OF HIGHER EDUCATION, SCIENCE, TECHNOLOGY AND INNOVATION	YES	This Institution is responsible for planning and managing the national strategy for improving high-level education in Science and Technology. Under this objective, one of the strategic lines is to foster the development of national capacity in Biotechnology and Biosafety.	SENESCYT contributed to many activities in the Biosafety Project especially in fourth level fellowships. Provided 75% of the in-cash national co-finance, and 2% of the in-kind contribution.	No document certifying how this co-finance was implemented is available in ANUBIS (no details are provided in the Final report either) Its actual role in the project needs to be clarified. Did this Institution participate in Project design? How?

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
Ministry of Production, International Trade, Investment and Fishing, MIPRO	YES?	Direct participant and beneficiary of the project; part of the NBC; its participation is mandatory. Identified in the PRODOC as KEY stakeholder. Provided 2% of the country in-kind co-finance.	To provide technical and political support	Did MIPRO participate in the project design? How? How is MIPRO using / applying the products developed during the Project?
AGROCALIDAD: Agency for Phytosanitary Control	??	AGROCALIDAD, being the national control agency for phytosanitary matters and depending from MAG, is responsible for technical and human capacities for LMO detection. Identified in the PRODOC as KEY stakeholder. This agency benefited with methodologies, protocols and specific training activities from the Biosafety project consultancies. Provided 12% of the country in-kind co-finance.	Role: To support the implementation of LMO detection laboratories.	Did AGROCALIDAD participate in the project design? How? How is AGROCALIDAD using / applying the products developed during the Project?

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
INIAP: National Institute of Agricultural Research	YES	INIAP as a part of MAG is the main Government institution related to agricultural research. Identified in the PRODOC as KEY stakeholder. Provided 2% of the country in-kind co-finance.	Role: To support the Project with technical issues, to develop normative proposals with a sound scientific background.	Did INIAP participate in the project design? How? How is INIAP using / applying the products developed during the Project?
SENAE: customs	NO?	A direct beneficiary of the project, SENAE is the institution in charge control and monitoring at borders (particularly ports). SENAE participated in many Biosafety Project activities especially in training activities. Identified in the PRODOC as KEY stakeholder. Provided 2% of the country in-kind co-finance.	To participate in training activities.	IDEM ABOVE
MRECI: Ministry of Foreign Affairs	NO?	International Agreements (CPB)	Participated in some trainings	Role to be clarified, this institute is not listed in the original PRODOC
SENPLADES: Secretariat of Planning	YES?	General support on national planning alignment. Provided 1% of the country in-kind co-finance.	To provide support about national planning guidelines	Did SENPLADES participate in the project design? How?

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
NATIONAL BIOSAFETY COMMISSION	YES?	the NBC and its individual delegates are direct beneficiaries of the project; its participation is mandatory and,	To centrally support the Project in all its components.	
LEGISLATORS	NO	As decision makers for legislative purposes, they are directly responsible for national biosafety policies approval. Their participation in the project should be very active and will be sustained through lobbying and communication. Identified in the PRODOC as KEY stakeholder.	Consideration and approval of national laws, protocols and guidelines related to biosafety.	Research when and how they were involved
ACADEMIA				
UNIVERSITIES AND ACADEMIA	??	Important actors and direct beneficiaries of the project, as biotechnology is part of the institution's curricula and research interests. Identified in the PRODOC as KEY stakeholder. Provided 2% of the country in-kind co-finance.	Roles: to promote the development of tertiary courses and research on national biotechnology and biosafety. To provide technical advice on biotech and biosafety matters. To develop LMOs detection and risk assessment training activities.	What universities were involved during project design and later implementation?
CIVIL SOCIETY & PRODUCER GROUPS				

Stakeholder	Took part in project design?	Interests and/or Influence	Potential responsibility /role in project implementation	Comment for evaluation
INDUSTRY	??	Direct beneficiary of the project and an important stakeholder; the safety of LMOs is part of industrial sector agenda, especially for those involved in food, feed and medicine production.	they participate in the NBC through chamber representatives	
CONSUMERS	NO	Intended to be direct and final beneficiaries of the project.	Public awareness, training and education on modern biotechnology and biosafety matters, participation in decision making regarding LMOs management.	
FARMERS ASSOCIATIONS	NO	Direct beneficiaries of the project, particularly the small farmers	Roles?	
NON GOVERNMENTAL ORGANIZATIONS	NO	Interested in environment and biosafety matters. CEDENMA represents a large group of environmental NGOs and is part of the NBC.	Roles?	
COMMUNICATIONS MEDIA	NO	Broadly interested in biosafety, the media is an important actor.	Role: to inform the general public on novel science and technology issues.	

ANNEX X - ADJUSTMENT OF THE PROJECT RESULTS STATEMENTS

Columns in white are from the original approved Results Framework. **Blue-shaded columns** show the revisions or additions proposed for evaluation purposes.

Intended Impact: Incremented level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and focusing, in particular, on transboundary movements			
Project Goal: Ecuador has established national policies, legal framework and administrative procedures, developed the required human and infrastructural resources to fully evaluate and manage all activities related to LMOs transboundary movements, and improved public participation in LMOs related decisions taking.			
Project Objective	**Indicators**	**Revised Objective**	**Revised /Additional Indicators**
To assist Ecuador to have a workable and transparent national biosafety framework in place, to fulfil its obligations as a Party to the Cartagena Protocol on Biosafety and thus contribute to ensuring an adequate level of protection of biodiversity and human health from modern biotechnology.	Biosafety Policy and Regulatory Framework finalized, aligned with Cartagena Protocol for Biosafety	To implement and operationalize a workable and transparent biosafety framework	unchanged

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
Component 1: Finalizing the Policy and Regulatory Biosafety Framework					
1.1 Biosafety policy and regulations formally approved, sustainably funded and their application initiated	Availability of: a) Inter-ministerial agreement approving policy on biosafety b) Biosafety regulations c) Plan of action for the Biosafety policy and NBF implementation with a 10 years scope d) State annual budget (SAB) includes resources for biosafety	a) Policy for the safe use of biotechnology	1.1 Biosafety policy and regulation approved and operational.	a) Inter-ministerial agreement approving policy on biosafety available	unchanged
		b) 10 year plan of action		b) Biosafety regulations approved and operational.	unchanged
		c) New regulations about LMOs and biosafety		c) 10 years Plan of action for the Biosafety policy and NBF implementation developed	unchanged
		d) Annual budgets and/or plans, programs and projects of the NCA and of the entities involved include the management and administrative costs of the national system of security of biotechnology		d) Required resources for Biosafety framework are included y n the State annual budget (SAB)	CNAs and other biosafety related institutions Annual budgets, plans, programs and projects include the management and administrative costs of the National Biosafety Framework

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
1.2 The management of LMOs is improved through permanent coordination mechanisms and structures	Availability of: a) Rulebook for NBC functioning	a) Operative Rulebook for the NBC	1.2 Coordination mechanisms and structures for LMOs management installed in the Biosafety involved Regulators and operational	a) Rulebook for NBC installed and operational	unchanged
					NBC annual working plans and session minutes
	b) NBC is well conformed, operating and includes delegates from key stakeholders.	c) Sectoral regulations and technical norms harmonized, including trade and LMO products		b) NBC is established and operational, integrated by delegates from all key stakeholders.	Modified sectoral regulations addressing biosafety matters
	c) Biosafety is mainstreamed into sectoral regulations through harmonization			c) Sectoral regulations contain the required specific clauses for Biosafety management, focused on LMOs and aligned with national	

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
				Constitution, Laws and the CPB	
Component 2: Putting in place a fully functional system for decision making and control of LMOs					
2.1A fully functional administrative-technical system for handling requests and for risk assessment of LMOs is in place, based on technical, scientific and socio-economic criteria and the precautionary principle	a) Operative flowchart for handling applications and risk assessments of LMOs with requisites, benchmarks and due dates is conceptualized	a) operative flowchart	2.1 An administrative and technical system for LMOs management decisions and related risk assessments is in place and operational	a) Operative flowchart for handling applications and risk assessments of LMOs is designed and approved by related regulators and stakeholders b) unchanged	a) Approved Operative flowchart b), c) Guidelines for LMOs decision – making for CNAs

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
	b) Guidelines, methodologies, manual, guides and protocols are established as tools for risk assessment and decision taking	b) Guidelines for decision-making, including criteria and principles, for use by the National Competent Authority c) Guidelines for review of previous decisions on the basis of new information d) Methodology for safety assessment of LMO foods and feeds e) Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for commercial activities with LMOs		c) unchanged d) unchanged	d) unchanged e) unchanged f) unchanged g) CNAs officially charged with biosafety responsibilities and permanent job posts budgeted and allocated

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
		f) Methodology for environmental risk assessment including scientific, technical and socioeconomic criteria for research activities with LMOs			h) Survey designed, deployed and results gathered and processed.Public data on LMOs related socio-economic considerations
		g) Institutions and personnel responsible of the different aspects related to biosafety			
	c) Practical cases demonstrate the functionality and improvements to the system				

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
	d) Personnel is assigned from each competent entities	h) Survey to collect data for socio-economic considerations			
2.2 Risk management includes risk communication, monitoring, LMOs control and enforcement of regulations; and it is consistent with the CP and the Constitution	a) Guidelines, manuals and protocols for risk management developed	a) Guidelines and operative manuals for risk management of LMOs in their different applications, to be used by state agencies b) Guides about biosafety measures and risk management of LMOs in different applications to be used by petitioners c) Instruction manual of procedures and	2.2 Risk management procedures installed and operative, including risk communication, monitoring, LMOs control	a) unchanged b) Procedures, deadlines, personnel and institutions in charge of risk management and its	a) unchanged b) Guides about biosafety measures and risk management of LMOs in different applications to be used by applicants c) unchanged

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
		methodologies for the detection of LMOs in crops, food and feed, according to international standards		monitoring are installed and operative	d) unchanged
	b) Procedures, deadlines, personnel and institutions in charge of risk management and its monitoring	d) Policies and guidelines for risk communication			e) unchanged
		e) Protocols for emergency responses in case of unintentional LMO introductions into the environment, non-compliance or unauthorized activities		c) Practical cases that demonstrate the cost-effectiveness of the risk management system are available and published	f)Practical demonstration uses cases using the RM procedures

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
	c) Practical cases demonstrate the cost-effectiveness of the risk management system				
2.3 Maintenance and updating of the national portal and the information of the BCH by the Competent National Authority	a) Information available at the national portal of the BCH.	a) Biosafety Clearing House has all the communication of decisions and other relevant information from Ecuador	2.3 unchanged .	a) Ecuador CPB mandatory information is available in the Biosafety Clearing House b) Ecuador National Biosafety Portal is operational and shows (among other national information) all Ecuador BCH registered information	a) the BCH routinely updated with all CPB mandatory Ecuador information b) National Biosafety website available and operational.

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
Component 3: Building human and institutional capacity for biosafety *(outputs listed with the order of appearance in Prodoc, then reordered based in corresponding outcome indicators)*					
3.1 Strengthened knowledge-base and information exchange for risk assessment and management (RA&M) of LMOs	a) Increased availability of data about experts, institutions and projects. b) Increased availability of basic information for RA&M c) Number of people trained on RA&M and in-office, from key institutions, governmental and civilian d) Intersectoral cooperation consolidated to support the NBF	a) Staff trained in biosafety, risk assessment and risk management of LMOs, in the National Competent Authority and other relevant institutions b) Training Program for technical staff, with national and international academic collaboration and financial resources identified f) Database of institutions, experts and projects related to biosafety	3.1 unchanged	a) unchanged b) unchanged c) unchanged	f) Database of institutions, experts and projects related to biosafety available on BCH and printed g) Database with information relevant to Risk Assessment and Management b) Training Program for technical staff, with national and international academic collaboration and financial resources identified

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
		g) Database with information relevant to the Assessment and Risk Management h) Collaboration agreements with the academic sector for initiating biosafety studies i) Voluntary agreements with the private sector and NGOs k) Cooperation networks with their informative bulletins		d) unchanged	a) CNAs and other relevant Instttutions Staff trained in biosafety, risk assessment and risk management of LMOs (Numbers?) h,i,k) Collaboration networks established and operational

3.2 Capacity to test for the presence or absence of LMOs in crops, food and feed products established	a) There is better knowledge on the analytic capacity related to biotechnology b) Number of people trained on LMO detection and in-office, from key institutions c) Availability of reference labs, certified or in process of certification for LMO detection d) It is confirmed and ensured an appropriate methodology for sampling and analysis of LMOs, the availability of supplies and reagents, and the provision of services for the State, for the detection of LMOs	c) Analysis of infrastructure and capacity for LMO detection d) Reference laboratories capable of carrying out LMO detection e) Agreed Methodology for sampling and analysis of LMOs	3.2 unchanged	a) unchanged b) unchanged	c) Infrastructure and capacity for LMO detection Situation Analysis report. d) Reference laboratories capable of carrying out LMO detection d1) State owned certified LMOs detection laboratory, or Agreement with 2 external providers d2) At least 4 technicians trained in LMOs in crops, food and feed detection e) Methodology for sampling and analysis of LMOs e1) Logistics established for LMOs detection Supplies, reagents and services

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
3.3 Synergies with other regional and sub-regional initiatives will have benefited Ecuador's technical capacity building efforts.	a) Number of strategic alliances formed	j) Cooperation Agreements with other biosafety projects in the region k) Cooperation networks with their informative bulletins	3.3 unchanged	a) unchanged, but standards for these indicators have not been stated	j) unchanged k) unchanged
Component 4: Improving public awareness and participation in biosafety *(outputs listed with the order of appearance in Prodoc, then reordered based in corresponding outcome indicators)*					
4.1 Public participation in biosafety decision-making is improved and institutionalized	a) Procedures for public consultation in decision-making with LMOs are applied b) Number of public consultations carried out	a) Mechanisms for public participation, consultation and feedback are established by regulations and use internet media	4.1 unchanged	a) unchanged b) unchanged	a) Biosafety regulatory framework establishes mechanisms for public participation, consultation and feedback about LMOs related decisions a1) At least one public consultation is carried out for each decision to be taken by the CNA

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
4.2 Degree of public awareness and understanding of biosafety issues is raised and assessed	a) Public opinion polls show an increase in the percentage of people who know about biotechnology and biosafety as a result of the communication strategy	b) Communication Strategy about LMOs and biotechnology and its plan of action, which include specific considerations and media for different types of stakeholders g) Two surveys of public opinion on biosafety, biotechnology and LMOs h) Assessment of changes in public opinion	4.2 Unchanged	a1) Communication Strategy is being executed at national level a2) unchanged from a)	b) unchanged g) unchanged h) unchanged

4.3 Various mechanisms for public access to and sharing of information on biosafety are created and maintained in time	a) Number of visits to MAE project' s website, number of opinions and consultations on biosafety received b) Increased availability to the general public of unbiased information on biosafety and biotechnology in MAE website, in digital format and in print c) Generating entities provide information to the public benefit, and its dissemination is institutionalized by the State	e) Ongoing partnerships with relevant institutions for the provision and revision of biosafety information f) Periodic consultations with stakeholders c) Public information on national use of LMOs, through virtual and document libraries d) Updated biosafety information on the national portal of the BCH and on MAE web site i) Personnel (1) assigned to collect, process and edit information	4.3 unchanged	a1) Number of visits to MAE project' s website a2) Number of opinions and consultations on biosafety received	e) Partnerships with relevant biosafety-related institutions, for providing related information add1) Mechanism for regularly providing and qualifying information on biosafety add2) Biosafety Project Section available in MAE website f) unchanged, but no indicator was defined c) Virtual basic library on biosafety established for public access in MAE's website and distributed through CDs every two years d) unchanged

Outcomes	Outcome Indicators	Outputs	Revised Outcomes	Revised /Additional Indicators	Revised / Additional Outputs
					j) Job post included and budgeted permanently in MAE for one employee to collect, process and edit biosafety information, and person effectively hired and working.

ANNEX XI - IMPLEMENTATION PLAN OF RECOMMENDATIONS

Implementation Plan of Recommendations

Project Title and Reference No.: Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program

Contact Person (TM/PM): Robert Erath

	PLANS			
RECOMMENDATIONS	**ACCEPTED (YES/NO/PARTIALLY)**	**WHAT WILL BE DONE?**	**EXPECTED COMPLETION DATE**	**REPONSIBLE OFFICER/ UNIT/ DIVISION/ AGENCY**
Recommendation 1 (to NEA, Government): As the Project has already finished and some final outcomes not fully achieved, the most important immediate recommendation is to continue working for the approval of the complete set of harmonized intersectoral regulations, and make the National Biosafety System operational (complying with the CP), by approving and installing the necessary administrative procedures and coordination among	Partially	The recommendation is for the NEA. The report has been shared and it is up to the NEA to follow through. UNEP will endeavor to contact relevant staff and inquire about progress.	End of 2024	NEA

	PLANS			
RECOMMENDATIONS	**ACCEPTED (YES/NO/PARTIALLY)**	**WHAT WILL BE DONE?**	**EXPECTED COMPLETION DATE**	**REPONSIBLE OFFICER/ UNIT/ DIVISION/ AGENCY**
the involved CNAs and other related Institutions.				
Recommendation 2 (to NEA, Government): Closely linked to the previous recommendation is one of promptly addressing the budget needs to be able to operate this system, considering human resources and infrastructure (including logistics for detection laboratories).	Partially	The recommendation is for the NEA. The report has been shared and it is up to the NEA to follow through. UNEP will endeavor to contact relevant staff and inquire about progress.	End of 2024	NEA
Recommendation 3 (to NEA, Government): As the country faces (and has been demonstrated) the illegal introduction and planting of LMOs, it is imperative to put in place regulations, procedures and measures to be taken to address this reality.	Partially	The recommendation is for the NEA. The report has been shared and it is up to the NEA to follow through. UNEP will endeavor to contact relevant staff and inquire about progress.	End of 2024	NEA
Recommendation 4 (to NEA, Government): In order to promote the research on	Partially	The recommendation is for the NEA. The report has been shared and it is up to the NEA to follow through. UNEP	End of 2024	NEA

	PLANS			
RECOMMENDATIONS	**ACCEPTED (YES/NO/PARTIALLY)**	**WHAT WILL BE DONE?**	**EXPECTED COMPLETION DATE**	**REPONSIBLE OFFICER/ UNIT/ DIVISION/ AGENCY**
LMOs in the country, revise and approve the required regulations that address the introduction of LMOs for research (contained use as specified in the CP). Drafts have been produced by the Project.		will endeavor to contact relevant staff and inquire about progress.		
Recommendation 5 (to NEA, Government): Continue fostering the regular functioning of the recently approved National Biosafety Committee, not only to address LMOs related decisions but also to have installed an expert inter – agencies able to address next generation technologies (e.g. products derived from Synthetic Biology).	Partially	The recommendation is for the NEA. The report has been shared and it is up to the NEA to follow through. UNEP will endeavor to contact relevant staff and inquire about progress.	End of 2024	NEA

The following is a summary of lessons learned from some of the project's experiences and based upon explicit findings of the review. They briefly describe the context from which the lessons are derived, and the potential for wider application:

Lesson Learned #1:	This Project has faced a very challenging context, with strong barriers to achieve some of the outcomes, derived from the current national legislation and adverse public perception of LMOs and lack of high-level support. In all the interviews and conferences maintained by the reviewer, the dedication and professionalism of the NEA appointed officers and particularly the NPC and biosafety officer has been commended. However, due to the previously mentioned barriers, many regulations and harmonized norms that were drafted as Project outputs did not count with the required high-level political authorities support. The lack of governmental decision to approve proposed regulations and implement the system actually acted as a barrier to achieve some high-order Project outcomes.
Context/comment:	Indeed one of the principal challenges despite technical capacities, has been the political will to provide support.

Lesson Learned #2:	The development of all technical outputs and products has been effective and of high quality, and the training activities reached many hundreds of biosafety involved professionals.
Context/comment:	Despite shifting political scenarios, important accomplishments at the technical level were achieved.

Lesson Learned #3:	The collaboration of IICA in several stages of the Project was key for the successful development of many outputs.
Context/comment:	IICA has indeed been a valuable partner in this project (as well as for others).

Lesson Learned #4:	An important result of the Project has been the formal and sustainable creation and operation of the Biosafety Unit inside MAATE, not only for this Project management but for other issues related to

	Biosafety in general. Particularly, this Unit is now working on new biotechnology matters (Synthetic Biology) that need to be addressed at a national level.
Context/comment:	Implementation of the Biosafety Unit inside MAATE is a valuable achievement of this project.

Lesson Learned #5:	Although the Project included a Component specifically addressing Public Awareness, its outcomes have not been enough to overcome the existing general resistance to address and legislate specific norms to deal with LMOs related biosafety decision – making. When the Project was designed using the methodology of logic framework, the risk inherent to the existing pathway that is evident in the RToC from Public Awareness (particularly focused on political awareness and buy-in) to the intermediate state "System for decision making and control of LMOs is fully functional", was not sufficiently valued. During Project implementation this issue proved to be critical.
Context/comment:	Political will continues to be a challenge to the intended outcomes of the project.

ANNEX XII - QUALITY ASSESSMENT OF THE REVIEW REPORT

Review Title: Implementation of the National Biosafety Framework of Ecuador under the Biosafety Program' (GEF ID 3405)

Consultant: Ernesto Ocampo

All UNEP Reviews are subject to a quality assessment by the UNEP Evaluation Office. This is an assessment of the quality of the review product (i.e. Main Review Report).

Substantive Report Quality Criteria	Comments	Final Review Report Rating
Quality of the Executive Summary Purpose: acts as a stand alone and accurate summary of the main review product, especially for senior management. To include: • concise overview of the review object • clear summary of the review objectives and scope • overall review rating of the project and key features of performance (strengths and weaknesses) against exceptional criteria • reference to where the review ratings table can be found within the report • summary response to key strategic review questions • summary of the main findings of the exercise/synthesis of main conclusions summary of lessons learned and recommendations.	Final report *(coverage/omissions)*: The section contains all required information. Final report *(strengths/weaknesses)*: The content presented in this section is informative on the objective of the review object and some of its strengths and weaknesses. It includes responses 'Key Strategic Questions' of the Review.	4
Quality of the 'Introduction' Section Purpose: introduces/situates the evaluand in its institutional context, establishes its main parameters (time, value, results, geography) and the purpose of the review itself. To include: • institutional context of the project (sub-programme, Division, Branch etc) • date of PRC approval, project duration and start/end dates • number of project phases (where appropriate) • results frameworks to which it contributes (e.g. POW Direct Outcome) • coverage of the review (regions/countries where implemented) • implementing and funding partners • total secured budget • whether the project has been evaluated in the past (e.g. mid-term, external agency etc.) concise statement of the purpose of the review and the key intended audience for the findings.	Final report *(coverage/omissions)*: The introduction captures most of the required elements, except for a description of the institutional context of the project (sub-programme, Division, Branch) and the Programme of Work it contributes to. Final report *(strengths/weaknesses)*: The introduction is written, and in clear and concise language. However, it contains information, such as a history of the project and amendments, that is not required. It also contains information on alignment to GEF Strategy at design, but does not include details of the project's institutional context within UNEP.	4
Quality of the 'Review Methods' Section Purpose: provides reader with clear and comprehensive description of review methods, demonstrates the credibility of the findings and performance ratings. To include: • description of review data collection methods and information sources • justification for methods used (e.g. qualitative/ quantitative; electronic/face-to-face)	Final report *(coverage/omissions)*: The section is partially complete; it covers most of the required aspects except for the number and types of respondents to interviews and questionnaires. Final report *(strengths/weaknesses)*: The section presents a description of the review methods, including the data	5

Substantive Report Quality Criteria	Comments	Final Review Report Rating
• number and type of respondents *(see table template)* • selection criteria used to identify respondents, case studies or sites/countries visited • strategies used to increase stakeholder engagement and consultation • methods to include the voices/experiences of different and potentially excluded groups (e.g. vulnerable, gender, marginalised etc) • details of how data were verified (e.g. triangulation, review by stakeholders etc.) • methods used to analyse data (scoring, coding, thematic analysis etc) • review limitations (e.g. low/ imbalanced response rates across different groups; gaps in documentation; language barriers etc) ethics and human rights issues should be highlighted including: how anonymity and confidentiality were protected. Is there an ethics statement? E.g. *'Throughout the* review *process and in the compilation of the Final Review Report efforts have been made to represent the views of both mainstream and more marginalised groups. All efforts to provide respondents with anonymity have been made.*	analysis process, review limitations and the consultant's efforts to overcome them. It also covers aspects such as the treatment of potentially marginalised groups and considerations for ethical issues – although it does not provide explicit details of those efforts.	
Quality of the 'Project' Section Purpose: describes and verifies key dimensions of the evaluand relevant to assessing its performance. To include: • *Context:* overview of the main issue that the project is trying to address, its root causes and consequences on the environment and human well-being (i.e. synopsis of the problem and situational analyses) • *Results framework*: summary of the project's results hierarchy as stated in the ProDoc (or as officially revised) • *Stakeholders:* description of groups of targeted stakeholders organised according to relevant common characteristics • *Project implementation structure and partners:* description of the implementation structure with diagram and a list of key project partners • *Changes in design during implementation:* any key events that affected the project's scope or parameters should be described in brief in chronological order *Project financing:* completed tables of: (a) budget at design and expenditure by components (b) planned and actual sources of funding/co-financing	Final report *(coverage/omissions):* All required sub-categories are addressed Final report *(strengths/weaknesses):* Much of the required information is described comprehensively. Additionally, the section includes a good description of the main issues being addressed by the project and changes in design during implementation. However, the sub-section addressing the *implementation structure* could have benefited from a more detailed definition of the implementation arrangements and roles for the IA, EA, PMU, steering committee, technical support etc. In addition, the *Stakeholders* section could have benefitted from a description of each stakeholder group (listed in Table 3).	5
Quality of the Theory of Change Purpose: to set out the TOC at Review in diagrammatic and narrative forms to support consistent project performance; to articulate the causal pathways with drivers and assumptions and justify any reconstruction necessary to assess the project's performance. To include:	Final report *(coverage/omissions):* The section includes a diagrammatic (Annex VIII) and narrative description of the project's TOC. The process of reconstructing the TOC has also been provided. The table with the reconstruction of results according to UNEP definitions is in Annex X. Final report *(strengths/weaknesses):*	3

Substantive Report Quality Criteria	Comments	Final Review Report Rating
• description of how the *TOC at Review*[50] was designed (who was involved etc) • confirmation/reconstruction of results in accordance with UNEP definitions • articulation of causal pathways • identification of drivers and assumptions • identification of key actors in the change process summary of the reconstruction/results re-formulation in tabular form. *The two results hierarchies (original/formal revision and reconstructed) should be presented as a two-column table to show clearly that, although wording and placement may have changed, the results 'goal posts' have not been 'moved'*. This table may have initially been presented in the Inception Report and should appear somewhere in the Main Review report.	Both the narrative and the diagram provide a description of the project's intervention logic. Drivers and Assumptions are mentioned, and an attempt has been made to identify which outcomes they are expected to influence. Although the text refers to dependencies between results, and the TOC diagram shows various interlinkages, the narrative fails to provide a explicit and detailed discussion on causal relationships between the different results as shown in the TOC. The narrative could also have benefitted from the inclusion of a summary of the reconstruction/results reformulation in tabular form. Intermediate States have been introduced in the reconstructed TOC however there is no clear explanation or justification for their inclusion is weak.	
Quality of Key Findings within the Report Presentation of evidence: nature of evidence should be clear (interview, document, survey, observation, online resources etc) and evidence should be explicitly triangulated unless noted as having a single source. Consistency within the report: all parts of the report should form consistent support for findings and performance ratings, which should be in line with UNEP's Criteria Ratings Matrix. Findings Statements (where applicable): The frame of reference for a finding should be an individual review criterion or a strategic question from the TOR. **A finding should go beyond description and uses analysis to provide insights that aid learning specific to the evaluand.** In some cases a findings statement may articulate a key element that has determined the performance rating of a criterion. Findings will frequently provide insight into 'how' and/or 'why' questions.	Finding statements have been presented explicitly as stand-alone statements under some of the review criteria. Where this is not the case, findings may be inferred from the assessments made under those evaluation criteria, as well as from the performance ratings, recommendations, and lessons learned. Some findings provide insights beyond a description of the evidence. For example, in the *Outcome Section*, the findings are written as bottom-line statements that encapsulate various aspects of the Outcomes. However, many findings simply describe the evidence provided (e.g., the *Output Section* findings), and others do not fully capture the evidence provided.	4
Quality of 'Strategic Relevance' Section Purpose: to present evidence and analysis of project strategic relevance with respect to UNEP, partner and geographic policies and strategies at the time of project approval. To include: Assessment of the evaluand's relevance vis-à-vis: • Alignment to the UNEP Medium Term Strategy (MTS), Programme of Work (POW) and Strategic Priorities • Alignment to Donor/GEF/Partners Strategic Priorities • Relevance to Regional, Sub-regional and National Environmental Priorities	Final report *(coverage/omissions)*: Most the required elements have been included in this section, except for the sub-section *Alignment to Donor/GEF/Partners Strategic Priorities*. Final report *(strengths/weaknesses)*: More detail on the project's alignment with the MTS, PoW and strategic priorities within UNEP would have been helpful; the Review does not discuss the linkage between the project and specific Direct Outcomes or Expected Accomplishments in UNEP's MTS and PoW. It also mentions the GEF Core Indicator Targets to which it	4

[50] During the Inception Phase of the review process a *TOC at Review Inception* is created based on the information contained in the approved project documents (these may include either logical framework or a TOC or narrative descriptions), formal revisions and annual reports etc. During the review process this TOC is revised based on changes made during project intervention and becomes the *TOC at Evaluation*.

Substantive Report Quality Criteria	Comments	Final Review Report Rating
Complementarity with Existing Interventions: complementarity of the project at design (or during inception/mobilisation[51]), with other interventions addressing the needs of the same target groups.	is aligned but does not specify what these indicators are.	
Quality of the 'Quality of Project Design' Section Purpose: to present a summary of the strengths and weaknesses of the project design, on the basis that the detailed assessment was presented in the Inception Report.	Final report *(coverage/omissions):* This section is complete. It presents a summary of strengths and weaknesses observed in the project design, including the project design quality assessment table. Final report *(strengths/weaknesses):* The project design strengths and weakness have been summarised in a clear manner. The section could however have benefited from more detail to help explain the criteria ratings; for example, it lists strengths such as situational analysis and budget, but it does not explain why these were strong areas.	4.5
Quality of the 'Nature of the External Context' Section Purpose: to describe and recognise, when appropriate, key external features of the project's implementing context that limited the project's performance (e.g. conflict, natural disaster, political upheaval[52]), and how they affected performance. While additional details of the implementing context may be informative, this section should clearly record whether or not a major and unexpected disrupting event took place during the project's life in the implementing sites.	The nature of the external context affecting project implementation– and especially regarding the socio-political dimensions of this intervention – has been described in detail. The review notes that, over time, public perception and political priorities support regarding LMOs evolved as a result of the changes introduced in the 2008 Constitution, banning LMOs in the country except only with strong exceptions. While this adversely impacted project implementation (and several TOC assumptions could not hold as a result), this was not as a result of a conflict, natural disaster, or political upheaval.	4
Quality of 'Effectiveness' Section **(i) Availability of Outputs:** Purpose: to present a well-reasoned, complete and evidence-based assessment of the outputs made available to the intended beneficiaries. To include: • a convincing, evidence-supported and clear presentation of the outputs made available by the project compared to its approved plans and budget • assessment of the nature and scale of outputs versus the project indicators and targets • assessment of the timeliness, quality and utility of outputs to intended beneficiaries identification of positive or negative effects of the project on disadvantaged groups, including those with specific needs due to gender, vulnerability or marginalisation (e.g. through	Final report *(coverage/omissions):* The assessment of Outputs is included and addresses all the programmed outputs identified in the Results Framework. It is missing a discussion on the timeliness and utility of outputs to intended beneficiaries, and negative or positive effects on women and marginalized groups. Final report *(strengths/weaknesses):* The review focuses on the status of the programmed outputs and their availability to the intended users; there is less emphasis given to the qualitative aspects of these outputs (quality, utility, timeliness).	4

[51] 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.

[52] Note that 'political upheaval' does not include regular national election cycles, but unanticipated unrest or prolonged disruption. The potential delays or changes in political support that are often associated with the regular national election cycle should be part of the project's design and addressed through adaptive management of the project team.

Substantive Report Quality Criteria	Comments	Final Review Report Rating
disability).	The presentation of Outputs is organized and supported by evidence in Table 8. However, the table is missing output indicator targets to assess the scale of some of outputs (for example, one of the outputs calling for "instruction manuals" was listed as "completed", but there is no information about the targeted number of manuals or how many were produced). The table is complemented by "findings" in the form of paragraphs, but they do not provide much more than a summary of what is in the table. Issues related to potentially marginalised / disadvantaged groups are not discussed.	
ii) Achievement of Project Outcomes: Purpose: to present a well-reasoned, complete and evidence-based assessment of the uptake, adoption and/or implementation of outputs by the intended beneficiaries. This may include behaviour changes at an individual or collective level. To include: • a convincing and evidence-supported analysis of the uptake of outputs by intended beneficiaries • assessment of the nature, depth and scale of outcomes versus the project indicators and targets • discussion of the contribution, credible association and/or attribution of outcome level changes to the work of the project itself • any constraints to attributing effects to the projects' work identification of positive or negative effects of the project on disadvantaged groups, including those with specific needs due to gender, vulnerability or marginalisation (e.g. through disability).	Final report *(coverage/omissions):* The assessment of Outcomes is included and addresses all the expected outcomes identified in the Results Framework Final report *(strengths/weaknesses):* The section provides an evidence-based discussion of each of the Outcomes, and in some cases discusses attribution to the project. Constraints experienced by the project in achieving the expected Outcomes have been described. Cross-referencing to the reconstructed TOC has been used in the analysis of Outcomes. However, it does not provide a full analysis of the scope of all the outcomes because it does not include indicators and targets for all Outcomes. As such it is difficult to ascertain how the project intended to measure Outcome achievement. The section could have benefitted from additional details on the depth of some of the Outcomes (for example, for Outcome 3.3., it mentioned that the project collaborated with other initiatives, but did not elaborate on how Ecuador's technical capacity benefitted as a result). Potentially positive/negative effects of the project on disadvantaged groups have not been identified.	4
(iii) Likelihood of Impact: Purpose: to present an integrated analysis, guided by the causal pathways represented by the TOC, of all evidence relating to likelihood of impact, including an assessment of the extent to which drivers and assumptions necessary for change to happen, were seen to be holding. To include: • an explanation of how causal pathways emerged and change processes can be shown • an explanation of the roles played by key actors and change agents	Final report *(coverage/omissions):* The section presents an assessment of the likelihood of Impact achievement Final report *(strengths/weaknesses):* To some extent, cross-referencing to the reconstructed TOC has been used in the analysis of causality. The section is missing a detailed explanation of how the causal pathways emerged, including a discussion on whether the drivers and assumptions held and the role of key players (these are	3.5

Substantive Report Quality Criteria	Comments	Final Review Report Rating
• explicit discussion of how drivers and assumptions played out identification of any unintended negative effects of the project, especially on disadvantaged groups, including those with specific needs due to gender, vulnerability or marginalisation (e.g. through disability).	however covered to some extent under section C: *Nature of external context*). The section focuses on describing the extent to which the Intermediate States were achieved. However, it could have benefitted from a discussion of how the project Outcomes led to the level of Intermediate States achievement. Potentially positive/negative effects of the project on disadvantaged groups have also not been identified. The rating given (ML) does not appear consistent with the presented evidence, which indicates a less promising situation than the rating implies.	
Quality of 'Financial Management' Section Purpose: to present an integrated analysis of all dimensions evaluated under financial management and include a completed 'financial management' table (may be annexed). Consider how well the report addresses the following: • *adherence* to UNEP's financial policies and procedures • *completeness* of financial information, including the actual project costs (total and per activity) and actual co-financing used *communication* between financial and project management staff	Final report *(coverage/omissions):* The section is partially complete; it covers two of the three aspects of financial management. Final report *(strengths/weaknesses):* The sub-sections on *adherence* and *completeness* contain most of what is required. There is no explicit assessment of the '*communication'* dimension of financial management (rated 'Highly Satisfactory' in Table 13, but without the supporting evidence). Tables 10 and 11 could have been consolidated to provide a better angle of comparison between the co-financing at design and actual co-financing figures.	4
Quality of 'Efficiency' Section Purpose: to present an integrated analysis of all dimensions evaluated under efficiency (i.e. the primary categories of cost-effectiveness and timeliness). To include: • time-saving measures put in place to maximise results within the secured budget and agreed project timeframe • discussion of making use, during project implementation, of/building on pre-existing institutions, agreements and partnerships, data sources, synergies and complementarities with other initiatives, programmes and projects etc. • implications of any delays and no cost extensions the extent to which the management of the project minimised UNEP's environmental footprint.	Final report *(coverage/omissions):* Implications of delays have been described at length. Time- and cost-saving measures taken to improve efficiency, and efforts to minimise the environmental footprint, are not explicitly included. Final report *(strengths/weaknesses):* The assessment of efficiency is evidence-based. The focus of the assessment is primarily on the effects that project delays and extensions have had on the achievement of the project's objective (including loss of momentum and stakeholders' interest). Time- and cost-saving measures that were used to eventually bring the project to completion have not been analysed.	4.5
Quality of 'Monitoring and Reporting' Section Purpose: to present well-reasoned, complete and evidence-based assessment of the evaluand's monitoring and reporting. Consider how well the report addresses the following: • quality of the monitoring design and budgeting *(including SMART results with measurable indicators, resources for MTE/R etc.)*	Final report *(coverage/omissions):* The section is complete; all required sub-criteria are included. Final report *(strengths/weaknesses):* The assessment is mostly well-reasoned and evidence based.	4.5

Substantive Report Quality Criteria	Comments	Final Review Report Rating
• quality of monitoring of project implementation *(including use of monitoring data for adaptive management)* • quality of project reporting *(e.g. PIMS and donor reports)* \	The *monitoring design and budgeting* sub-section does not cover some of the important aspects including data collection methods and whether data was disaggregated by groups. The sub-section on *monitoring of project implementation* is not sufficiently critical of the role of monitoring data in adaptive/ result-based management; instead, emphasis has been placed on the effects of project delays on monitoring activities.	
Quality of 'Sustainability' Section Purpose: to present an integrated analysis of all dimensions evaluated under sustainability (i.e. the endurance of benefits achieved at outcome level). Consider how well the report addresses the following: • socio-political sustainability • financial sustainability institutional sustainability	Final report *(coverage/omissions):* The section is complete; all required sub-criteria are included. Final report *(strengths/weaknesses):* The section provides an integrated analysis of the dimensions of sustainability. The discussions are clear, and evidence based. The rating given for the sub-criteria '*financial sustainability'* and '*institutional sustainability'* are however inconsistent with the findings as presented (both in this section and in other parts of the report); a lower rating would have had a more accurate reflection of the reality. The section could have benefitted from a description of the extent to which the project objective is dependent on each of the dimensions of sustainability.	5
Quality of Factors Affecting Performance Section Purpose: These factors are not always discussed in stand-alone sections and may be integrated in the other performance criteria as appropriate. However, if not addressed substantively in this section, a cross reference must be given to where the topic is addressed and that entry must be sufficient to justify the performance rating for these factors. Consider how well the review report, either in this section or in cross-referenced sections, covers the following cross-cutting themes: • preparation and readiness • quality of project management and supervision[53] • stakeholder participation and co-operation • responsiveness to human rights and gender equality • environmental and social safeguards • country ownership and driven-ness communication and public awareness	Final report *(coverage/omissions):* The section is complete and covers all the required factors affecting project performance. Final report *(strengths/weaknesses):* All elements are discussed to varying levels of detail, but it is possible to get a fair overview of how these factors impacted on project performance. The discussions are relatively consistent with findings presented in other sections of the report. The section could have benefitted from more detail for each factor. In most cases (except for '*communication and public awareness'),* the justification for the ratings given is inadequate.	4
Quality of the Conclusions Section	Final report *(coverage/omissions):*	4

[53] In some cases 'project management and supervision' will refer to the supervision and guidance provided by UNEP to implementing partners and national governments while in others, specifically for GEF funded projects, it will refer to the project management performance of the executing agency and the technical backstopping provided by UNEP. This includes providing the answers to the questions on Core Indicator Targets, stakeholder engagement, gender responsiveness, safeguards and knowledge management, required for the GEF portal.

Substantive Report Quality Criteria	Comments	Final Review Report Rating
(i) Conclusions Narrative: Purpose: to present summative statements reflecting on prominent aspects of the performance of the evaluand as a whole, they should be derived from the synthesized analysis of evidence gathered during the review process. To include: • compelling narrative providing an integrated summary of the strengths and weakness in overall performance (achievements and limitations) of the project • clear and succinct response to the key strategic questions human rights and gender dimensions of the intervention should be discussed explicitly (e.g. how these dimensions were considered, addressed or impacted on)	Conclusions are presented in the report; responses to the key strategic questions are missing here but covered in the Executive Summary Final report *(strengths/weaknesses):* The summary is clear but quite brief. It highlights the main strengths / achievements and weaknesses/ shortcomings of the project that were identified through the review process, but it is a missing an integrated, compelling storyline. The responses to the [four] key strategic questions have not been explicitly covered in the Conclusions, but they have been addressed in the Executive Summary. A table presenting all the evaluation criteria, summaries of their individual assessments, and performance ratings, is included in the conclusion section. There is no discussion on how the project addressed gender and human rights.	
ii) Utility of the Lessons: Purpose: to present both positive and negative lessons that have potential for wider application and use (replication and generalization) Consider how well the lessons achieve the following: • are rooted in real project experiences (i.e. derived from explicit review findings or from problems encountered and mistakes made that should be avoided in the future) • briefly describe the context from which they are derived and those contexts in which they may be useful do not duplicate recommendations	Final report *(coverage/omissions):* Lessons learned are included in the review Final report *(strengths/weaknesses):* The lessons learned statements, while grounded on actual findings presented in the review (based on both positive and negative experiences), have not been formulated in a manner that renders them useful for wider application and use in other similar contexts. The lessons learned provide little more than summaries of different areas of the project (for example, lesson learned #2 simply states that some of the project outputs were delivered successfully). These could be better phrased in a way that generally identifies the context from which they are derived and those contexts in which they may be useful/ replicated. This section could also have benefited from using the template provided by the Evaluation Office for the presentation of lessons learned.	3.5
(iii) Utility and Actionability of the Recommendations: Purpose: to present proposals for specific action to be taken by identified people/position-holders to resolve concrete problems affecting the project or the sustainability of its results. Consider how well the lessons achieve the following: • are feasible to implement within the timeframe and resources available (including local capacities) and specific in terms of who would do what and when	Final report *(coverage/omissions):* Recommendations are included in the review. Final report *(strengths/weaknesses):* The recommendations are grounded on actual findings presented in the review. The remedial action and responsibility for implementation are included.	3.5

Substantive Report Quality Criteria	Comments	Final Review Report Rating
• include at least one recommendation relating to strengthening the human rights and gender dimensions of UNEP interventions • represent a measurable performance target in order that the Evaluation Office can monitor and assess compliance with the recommendations. NOTES: **(i)** In cases where the recommendation is addressed to a third party, compliance can only be monitored and assessed where a contractual/legal agreement remains in place. Without such an agreement, the recommendation should be formulated to say that UNEP project staff should pass on the recommendation to the relevant third party in an effective or substantive manner. The effective transmission by UNEP of the recommendation will then be monitored for compliance. **(ii)** Where a new project phase is already under discussion or in preparation with the same third party, a recommendation can be made to address the issue in the next phase.	To some extent, the contextual background can also be identified, however this is not explained sufficiently enough to clearly address what specifically needs to be done and/or why the proposed actions are important. The recommendations do not have timeframes, and the level of priority for the recommendations are missing. Some of the recommendations seems duplicative (for example, Recommendations 1, 3, and 4 are about ensuring that the regulations and procedures are in place to limit LMOs in the country). There is no recommendation related to strengthening the human rights or gender dimensions of UNEP interventions. This section could have benefited from using the template provided by the Evaluation Office for the presentation of recommendations.	
Quality of Report Structure and Presentation **(i) Structure and completeness of the report:** To what extent does the report follow the Evaluation Office structure and formatting guidelines? Are all requested Annexes included and complete?	Final report *(coverage/omissions):* The report follows the recommended structure for the most part and also includes the required annexes Final report *(strengths/weaknesses):* The report mostly follows the UNEP Evaluation Office guidelines but some areas are not fully compliant. For example, the lessons and learned and recommendation do not have the EOU suggested formats. The report is also missing some of the recommended financial tables.	5
(ii) Writing and formatting: Consider whether the report is well written (clear English language and grammar) with language that is adequate in quality and tone for an official document? Do visual aids, such as maps and graphs convey key information?	The report is written in clear language and is adequate in quality and tone for an official document. However, there are typos and grammatical errors (e.g., lack of punctuations and inconsistent capitalization of findings). Some abbreviations are not defined on first mention. There are inconsistencies with the formatting of dates, currencies, and numbers within the same paragraph	5
		Moderately Satisfactory (4.3)