

REQUEST FOR CEO APPROVAL

PROJECT TYPE: Medium-sized Project TYPE OF TRUST FUND: GEF Trust Fund

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PART I: PROJECT INFORMATION

Project Title: Implementation of the National Biosafety Framework in Venezuela in accordance to the				
Cartagena Protocol on Biosat	fety			
Country(ies):	Venezuela	GEF Project ID: ¹	5290	
GEF Agency(ies):	UNEP	GEF Agency Project ID:	01068	
Other Executing Partner(s):	General Direction of Biological	Submission Date:	May 27,	
	Diversity, Ministry of Popular Power		2016	
	for Ecosocialism and Water			
	(MINEA), UNDP			
GEF Focal Area (s):	Biodiversity	Project Duration(Months)	48	
Name of Parent Program (if	Biosafety	Project Agency Fee (\$):	176,700	
applicable):				
➤ For SFM/REDD+				
➤ For SGP				
For PPP				

A. FOCAL AREA STRATEGY FRAMEWORK²

Focal Area Objectives	Expected FA Outcomes	Expected FA Outputs	Trust Fund	Grant Amount (\$)	Cofinancing (\$)
BD-3: Build	Outcome 3.1 Potential	All remaining eligible	GEFTF	1,860,000	2,072,000
capacity for the	risks of living modified	countries (about 60-70			
implementation	organisms to biodiversity	depending on			
of the Cartagena	are identified and	programming for rest of			
Protocol on	evaluated in a	GEF-4) have national			
Biosafety (CPB)	scientifically sound and	biosafety decision-			
	transparent manner.	making systems in place.			
		Total project costs		1,860,000	2,072,000

B. PROJECT FRAMEWORK

Project Objective: Establish a platform of legislative, regulatory, social and infrastructure to implement the Cartagena Protocol on Biosafety of biotechnology in the Bolivarian Republic of Venezuela, in order to contribute to the global conservation and sustainable use of biodiversity.

Project Component	Gra nt Type	Expected Outcomes	Expected Outputs	Trust Fund	Grant Amount (\$)	Confirmed Cofinancing (\$)
1. Completion and operation of biosafety legal framework.	TA	1.1. Regulatory biosafety framework is completed, adopted and integrated within the National	1.1.1 National Policy Document on Biosafety. 1.1.2 National Biosafety regulations produced, in connection with existing laws.	GEFTF	234,000	500,000

¹ Project ID number will be assigned by GEFSEC.

Refer to the Focal Area Results Framework and LDCF/SCCF Framework when completing Table A.
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		Strategy for the Conservation of Biodiversity 2010- 2020 and its National Action Plan in alignment to the Cartagena protocol.	1.1.3 National competent authorities defined and appointed. 1.1.4 Sectorial rules/ resolutions and guidelines for the management of GMOs and associated information, by the competent national authorities. 1.1.5 Guidelines and procedural manuals for GMO users, including importers / exporters, producers, processing industry and researchers. 1.1.6 Administrative and technical forms for GMO applications.			
2. Development of appropriate institutional and human capacity for decision-making and regulatory compliance in biosafety.	TA	2.1 The institutional and administrative framework is reinforced to provide effective responses to GMO applications and communicate decisions in line with the CPB.	2.1.1 Centralized administrative system to handle applications with GMOs including a "single-centralized window" designed and approved by NCA's. 2.1.2 Technical Secretariat of the National Biosafety Committee created with specialized technical personnel.	GEFTF	369,500	400,000
		2.2. There is greater human capacity, clarity, scientific and technological bases to make decisions regarding GMOs.	2.2.1 Evaluation processes of environmental and health risks validated by the national authorities responsible for different uses of GMOs.			
		2.3. There is greater human capacity, clarity, scientific and technology to control / monitor	2.3.1 Specialized personnel trained to perform the tasks of monitoring and detection			

		activities with	of GMOs at sea ports,			
		GMOs in the	airports and customs			
		country.	checkpoints.			
			2.3.2 Mechanisms established for risk control and management, including technology and methods for GMO traceability/ detection, and contingency protocols for emergency response in case of accidents involving GMOs.			
3. Development of appropriate capacities for	TA	3.1. Increase the level of public understanding of	3.1.1 Surveys and trend analysis on the level of information, awareness	GEFTF	153,686	400,000
public		biosafety through	and changes in public			
participation in decision-making.		operations based on participatory	opinion about			
		diagnosis.	biotechnology, biosafety and GMOs.			
			3.1.2. Communication			
			strategy in biosafety			
			developed. (including Information on GMOs			
			and biotechnology, and			
			other public awareness			
			materials)			
		3.2. Public	3.2.1 Participation			
		participation in decision-making	structures and mechanisms as part of			
		processes on	authorization process of			
		GMOs is promoted and systematized.	GMOs, including a			
		and systematized.	Claims Desk and Question and Answers			
			system.			
			3.2.2 Discussion forums with the private sector to			
			exchange views and			
			queries.			
		3.3. A coordinated	3.3.1 Public, up to date			
		governmental system for public	sectorial information regarding GMOs			
		access to	present and/or			
		information on	authorized by the			

		biosafety is supported in accordance with Article 20 of the CPB.	country.			
4. Strengthening of infrastructure for the detection and management of GMOs.	ΤΑ	4.1. Equip and operate the Reference Laboratory for Detection of GMOs of the Ministry of Popular Power for the Environment, the lead agency for Biosafety in Venezuela, responsible for supervision and control of GMO's in the country.	4.1.1 An operational laboratory that has the necessary infrastructure to carry out analysis and detection of GMOs, which allows Venezuela to meet its obligations under the CPB.	GEFTF	849,814	700,000
5. Monitoring and Evaluation	ГА	5.1 Project executed in a timely manner, achieving outcomes and producing high quality outputs.	5.1.1 Project inception and closure workshops.5.1.2 SC meetings.5.1.3 MTE and TE.	GEFTF	98,000	
	Subtotal					2,000,000
		Project 1	Total project costs		155,000 1,860,000	72,000 2,072,000

C. SOURCES OF CONFIRMED COFINANCING FOR THE PROJECT BY SOURCE AND BY NAME (\$)

Please include letters confirming cofinancing for the projeSct with this form

Sources of Co-financing	Name of Co-financier (source)	Type of Cofinancing	Cofinancing Amount (\$)
National Government	Ministry of Popular Power for the Ecosocialism and Water (MINEA)	In-kind	2,072,000
Total Co-financing			2,072,000

D. TRUST FUND RESOURCES REQUESTED BY AGENCY, FOCAL AREA AND $\mathbf{COUNTRY}^1$

	Type of	Type of Country Name/	(in \$)			
GEF Agency	Trust Fund	Focal Area	Global	Grant	Agency Fee	Total
	11 ust 1 una		Global	Amount (a)	$(b)^2$	c=a+b
UNEP	GEF TF	Biodiversity	Venezuela	1,860,000	176,700	2,036,700
Total Grant Resources			1,860,000	176,700	2,036,700	

³ PMC should be charged proportionately to focal areas based on focal area project grant amount in Table D below.

F. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:

Component	Grant Amount (\$)	Cofinancing (\$)	Project Total (\$)
International Consultants			0
National/Local Consultants	235,000	0	235,000

G. DOES THE PROJECT INCLUDE A "NON-GRANT" INSTRUMENT? N/A

(If non-grant instruments are used, provide in Annex D an indicative calendar of expected reflows to your Agency and to the GEF/LDCF/SCCF/NPIF Trust Fund).

PART II: PROJECT JUSTIFICATION

A. DESCRIBE ANY CHANGES IN ALIGNMENT WITH THE PROJECT DESIGN OF THE ORIGINAL PIF⁴

A.1 <u>National strategies and plans</u> or reports and assessments under relevant conventions, if applicable, i.e. NBSAPs, national communications, TNAs, NCSA, NIPs, PRSPs, NPFE, Biennial Update Reports, etc.

No changes from PIF.

A.2. GEF focal area and/or fund(s) strategies, eligibility criteria and priorities.

No changes from PIF

A.3 The GEF Agency's comparative advantage:

No changes from PIF

A.4. The baseline project and the problem that it seeks to address:

Information from PIF is valid. However it has been strengthened with the following tables:

Table 1. Threats, root causes and barrier

THREATS	CAUSES OF THREATS	BARRIER ANALYSIS
1. Use of GMOs that have not	Risk assessments for the introduction of	Law for Management of Biological
been assessed for their safety in the	GMOs in the country have not been	Diversity (GORBV 39070 of 01/12/2008)
country.	undertaken, and risk management	waiting for its corresponding regulations.
	measures are not applied (biosafety).	
2. Infrastructure and equipment	Current research facilities are lacking in	Infrastructure (existing lab facilities) is
unfit for GMO research and	biosafety measures. There is	inadequately equipped for GMO detection
detection.	infrastructure, but there is a lack of	purposes.
	equipment, reagents and supplies to	
	follow sampling protocols and GMO	
	detection.	
3. Lack of expertise about	No clear procedures for risk assessment	There is not biosafety policy or law that

For questions A.1 –A.7 in Part II, if there are no changes since PIF and if not specifically requested in the review sheet at PIF stage, then no need to respond, please enter "NA" after the respective question. GEF5 CEO Endorsement Template-February 2013.doc

¹ In case of a single focal area, single country, single GEF Agency project, and single trust fund project, no need to provide information for this table. PMC amount from Table B should be included proportionately to the focal area amount in this table.

² Indicate fees related to this project.

biosafety procedures and requirements, regarding both users and regulators.	exist at the moment.	could boost these processes.
4. Lack of documentation for verification and identification of GMOs imported into the country.	There are no monitoring measures in place to assess the entry of GMOs into the country.	No legal framework to address these issues.
5. Lack of knowledge in consumers and decision makers regarding GMO matters.	Scarce dissemination and sensitizing of the general public on the subject of GMOs. Little information regarding GMOs for decision makers.	A public communications strategy covering the risks of release and use of GMOs does not exist. Lack of sound information about the possible impacts related to use of GMOs.
6. Lack of sufficient mechanisms for interinstitutional and interesectoral coordination.	Lack of coordination, at a national competent authority level, to implement biosafety measures.	Need to enforce national laws and to have technical and administrative guidelines.
7. Lack of technical guidelines to regulate the current GMO importation process.	Lack of technical guidelines to regulate the import of GMOs: seeds, vaccines, medicines in general.	Law for Management of Biological Diversity (GORBV 39070 of 01/12/2008) waiting for its corresponding regulations.
8. Lack of qualified personnel to handle biosafety matters.	Limited technical capacity to undertake the assessment of environmental risks, food safety of GMOs and evaluation of medications obtained from GMOs. Limited availability of information.	Insufficient availability of personnel in biosafety matters. Need to increase the pool of qualified staff. (risk assessment, monitoring and detection)

Table 2. Baseline for the implementation of a biosafety framework

Baseline elements	Current status	Gaps	Project actions
Legal instruments:	 ■ Constitution of the Bolivarian Republic of Venezuela includes the following articles regarding environmental law: 127, 128 and 129. ■ Law of Lands and Agricultural Development (GORBV N° 37.323 from November 13 2001), aimed at establishing the base for integral and sustainable rural development, understood as a fundamental means for human development and economic growth of the agricultural sector, ensuring biodiversity and food safety as well as effective validity of rights of environmental protection and food and agriculture of present and future generations". ■ Organic Law of Science, Technology and (GORBV N° 38.242 from August 03 2005), aimed at the development of orienting principles for science, technology and innovation defined in the Constitution of the Bolivarian Republic of Venezuela, organizing the National Science, Technology and Innovation System, defining guidelines that will shape scientific, technological and innovation activities, with the goal of fostering the generation, use and circulation of knowledge and boosting 	Creation of specific decrees and rules for GMO regulation, based on previously proposed projects such as the proposal for partial regulations to the Law for Management of Biological Diversity regarding safety of biotechnology in activities with GMOs, byproducts and products that may contain them.	A national biosafety policy will be drafted and it will be the overarching tool for the biosafety system. In addition, a proposal of a biosafety act will be created to condense biosafety measures in a single document, but it will use existing legislation as a base.

development of the nation.

- Law for Management of Biological Diversity (GORBV N° 39.070 from December 01 2008), defines the measures related to biosafety in articles: 2, 47, 48, 49, 54 and 55.
- Law for Integral Agricultural Health (GORBV N° 5.890 from June 03 2008). Chapter IX contains articles 46 and 47 that contemplate regulations related to the environment, production, distribution, exchange and commercialization of GMOs in the country, as well as the sworn declaration that must be presented by persons and corporations involved in importing foods, inputs, or raw materials in which GMOs have been used.
- Law for Plan of the Land (GORBV N° 6.118 from December 4 2013), defines the National Strategy for Conservation of Biological Diversity 2010-2020 and its national action plan, which contemplates methodological and communication tools to propel a national biosafety program with an endogenous focus.
- Regulations regarding Environmental Assessment of activities likely to cause environment degradation (GORBV N° 35.946 from April 25 1996) state that environmental assessment will be executed as part of the decision making process in the formulation of policies, programs and development plans, with the aim of incorporating environmental variables in all stages, and states just like Article 129 of the Constitution that interested parties must present corresponding environmental and sociocultural impact studies.
- Regulations on Coordination of Competencies in processing of contracts for access to genetic resources (Resolution N° 95 from August 23 2001; published in GORBV N° 37.268, from August 24 2001). These regulations outline the mechanisms for coordination of activities related to genetic resources, undertaken by various components of the Ministry of People's Power for Ecosocialism and Water.
- Decree for creation of the National Biosafety Commission (GORBV N°

	38.392, Decree N° 4.334, from March 07 2006).		
	■ Joint resolution that dictates the internal regulations of the National Biosafety Commission. (GORBV N° 372.501 from October 27 2009).		
	 Project for complementary regulations to the Law of Management of Biological Diversity regarding the safety of biotechnology in activities with GMOs, their sub products and products that contain them. (Annex MNB-2005). Seeds Law. (GORBV N° 6207 from 		
	December 28 2015), covering national position towards GMOs.		
Technical guidelines:	The country does not currently possess guides for the risk analysis, monitoring and evaluation of GMOs.	Need to have administrative, technological and methodological processes for the analysis and communication of risks.	Technical guidelines for various purposes will be created in support of the operation of NCA's
Administrative guidelines:	The country does not currently have administrative guides, but the MPPAT, through its National Institute of Integral Agricultural Health (INSAI) certifies the entry of agricultural products to the country requesting the following information: - Information of the product's exporter and their representative(s).	Need to have administrative, technological and methodological processes for the certification of food products entering the country.	Administrative procedures will be drafted based on an update of the current NBF, the policy and legal instruments related to Biosafety. Authorities will have more clarity on how to proceed.
	- Authorized signature.		
	- Characteristics of the product to be imported.		
	- Transport means that will be used.		
	- "No transgenic" certification.		
Advisory bodies:	CTNBio was created.	CTNBio is not operational. There is a need to provide technical guidelines and training for the commission to be operative.	The project will review the conformation of the CTNBio during the process of revision of the NBF and will promote its operation providing technical tools and institutional support.
Research and Development in Biotechnology and Biosafety:	There is a laboratory part of the MINEA with equipment and infrastructure to carry out biotechnology research and development. This laboratory also supports process of access to genetic	There is no operational biosafety framework able to process possible applications from	The project will establish a functional biosafety system that will have the capacity to process applications. In addition, the project will offer training opportunities for personnel involved in biosafety and biotechnology.

	resources. The laboratory was implemented with resources from the MEUCT. • IDEA has set the basis in the country in terms of training on GMO detection and traceability. • The Venezuelan Institute of Scientific Research in Biotechnology, the Simon Bolivar University, Central Venezuelan University, National Institute of Agricultural Research, amongst others, are currently developing molecular characterization of species, as well as basic research activities in biotechnology. These institutions have potential to become research and science poles, and thus there is a need to have a functional biosafety system that could process applications that may come (amongst others) from these institutions.	local development.	
Decision making capacity:	MPPEA and CNBio are the main bodies for decision making.	There is limited internal capacity within these bodies to actually take actions towards GMO decisions. A more robust biosafety system should be in place to provide technical advice to decision-makers.	Decision-making capacity will be improved through a more articulated biosafety system, which will include technical instruments, guidelines and trained personnel, which will support the process.
Monitoring and evaluation capacity:	Same as above.	The country las limited monitoring capacity and therefore one of the prevailing gaps is the establishment of GMO detection and monitoring mechanisms.	Monitoring and detection system will be implemented through a national detection lab and equipment and strategies for field monitoring, protocols and guidelines.

-Public awareness level:	Projects such as: - Completion of the second National Report on the application of the Cartagena Protocol on Biosafety. Capacity building for an effective participation in the Center for Interchange of Safety in Biotechnology (CIISB) in the Bolivarian Republic of Venezuela. Aimed at Universities, research institutions, customs officers, people in charge of drafting phytosanitary regulations, inspectors, media, civil society and high ranking decision-makers. Capacity building for an effective participation in the Center for Interchange of Safety in Biotechnology (CIISB - Phase II).	Biosafety is a discipline that changes constantly according to new biotechnology developments, and therefore, there is a great need to continue public awareness and sensitization campaigns in order to support decision-making process.	Surveys and mechanisms to better understand the public awareness level will be used as a base to develop sensitization and awareness strategy. Informative materials.
-Public engagement in Biosafety:	National Strategy for Conservation of Biological Diversity 2010-2020 and its corresponding action plan (GORBV N° 6.118 December 4, 2013), specifically through strategic lines 1 and 6, Information Management, and Control and Supervision of GMOs respectively.	Same as above.	Establishment of public participation mechanisms through the NCA's website.
International cooperation:	Venezuela's United Nations Development Assistance Framework (UNDAF) is focused on two main areas in relation to environmental issues: 1) sustainable development and poverty, and 2) Environment, Energy and Risk Management. The project has impact in these two areas, and thus UNDAF related work will also be part of the project's baseline.	To highlight the importance of biosafety for the priority areas of the UNDAF.	Project will through capacity building and public awareness activities liaise with the UNDAF team to ensure synergies.

A. 5. <u>Incremental</u> /<u>Additional cost reasoning</u>: describe the incremental (GEF Trust Fund/NPIF) or additional (LDCF/SCCF) activities requested for GEF/LDCF/SCCF/NPIF financing and the associated <u>global</u> <u>environmental benefits</u> (GEF Trust Fund) or associated adaptation benefits (LDCF/SCCF) to be delivered by the project:

Biosafety is gaining relevance in Venezuela as the biotechnological activity in the country increases. For this reason, the design and construction of a Laboratory of Reference for Detection of LMOs has been covered with local financing; nonetheless, it is not operational due to the need of specific equipment and trained personnel. Moreover, although these achievements are significant for creating scientific and technological capacity, they are not linked to policies or norms that frame them in an effort leading to correct handling of LMOs, or to mechanisms for inter-institutional cooperation that devote their contribution to the implementation of the CPB. In absence of GEF support, the central government, through the Ministry of Popular Power for Ecosocialism and Water the Ministry of the Popular Power for the Science and Technology will continue developing institutional and human capacity in biosafety, albeit not hand in hand with training of customs personnel or professionals in charge of evaluation of LMOs, or sensitizing decision makers and the general public. Without GEF support the creation of biosafety capacities in Venezuela will be slower. This could have a negative impact for the country in assessing the possibilities (either positive or negative) that the use of modern biotechnology could have. At present, the country follows a precautionary approach towards the use of GMOs since the institutional and technical capacity in biosafety are not enough to provide the country the necessary elements to recognize whether or not under a particular circumstance the use of a GMO could implicate a benefit or a risk.

Likewise, because Venezuela imports a great amount of commodities from other countries in the region, and transboundary movements are expected; this highlights the necessity of the country to have monitoring and detection systems in place. The government has therefore the challenge to create more capacity in the country and provide its competent authorities with the necessary instruments to allow a fair and safe use of these new developments.

The Government of Venezuela will continue to invest in building capacity in biosafety through the already existing organizational structures, such as the activities of the General Direction of Biological Diversity within the Ministry of Popular Power for Ecosocialism and Water; were the focal point for the Cartagena protocol is located and biosafety issues are currently addressed. In parallel, activities of the National Biosafety Commission, which is a multidisciplinary and multi sectorial entity, will continue to advise the Executive regarding the use, management, transport and safe practices of GMOs in diverse fronts such as health, environment, science and technology, security and national defense, agricultural and food self- sufficiency and others. Likewise, the needed actions towards having an operational laboratory for GMO detection will continue with government investment, nonetheless, in absence of GEF support the country's capacity to do that in the immediate future is low due to the need of additional resources to equip and finish the existing laboratory. The laboratory was built with resources from the National Fund for Science and technology (FONACYT); which covered the establishment of 5 rooms, 2 of which are completed. Finally, local institutions such as universities will also continue to provide technical support to the local authorities on biosafety and risk assessment matters such as the Central University of Venezuela, who provides support to the Government in undertaking procedures such as analysis of electrophoresis gels. In absence of GEF support, Venezuela's ability to assess the possible benefits either positive or negative will continue to be limited.

GEF support is sought amongst other things, to complement government efforts to equip the LMO detection facility, as well as to train the personnel that will eventually handle LMO detection. If the detection laboratory is expected to provide services up to the standards of a truly functional and reliable facility it will require more than what the government can provide. This need will be covered under Component 4, through which the local laboratory will be strengthened with the purchase and installation of GMO detection equipment. Likewise, GEF support is seek to increase Venezuela's technical knowledge and capacity on biosafety. This will be achieved through actions under Component 2, such as training courses and programs (risk assessment, monitoring, and detection), and through networking with other biosafety initiatives in the region with UNEP's support; which will at the same time assist in the country's ability to provide more and accurate information to the BCH. In addition, component 2 will seek to reinforce the institutional and administrative framework through the development of a centralized administrative system to handle applications with GMOs including a "single-centralized window". Moreover, to ensure operation of the system, the project will also generate procedures for the evaluation of health and environmental risks for the use of the National Competent Authorities (NCAs). In support of the area of GMO's monitoring, mechanisms will be established for risk control and management, including methods for GMO traceability/ detection, and contingency protocols for emergency response in case of accidents involving GMOs. The development of regulations would be another task for the Central Government that would likely occur at a slow pace and without the establishment of associated administrative systems that are necessary. The combined actions between the Venezuelan Government and the UNEP-GEF project will allow the implementation of the National Biosafety Framework to be based on a collective construction by the society, including public debate with different parties interested in the application of biotechnology. It would allow decisions making to be based on scientific knowledge, human values and bioethics principles, since without GEF support it would be difficult to engage enough sectors and to achieve joint actions to assure an appropriate protection level in the safe use of biotechnology. In this respect, project components 1 and 3 contemplate strategic actions that will support the implementation of the biosafety framework in a participatory manner. For instance, component one will produce a National Policy Document on Biosafety, along with National Biosafety regulations produced, in connection with existing laws. In addition, sectorial rules/resolutions and guidelines for the management of GMO and associated information, by the competent national authorities will be produced with the aim of providing all the necessary tools for the operation of the national biosafety system.

Component 3 is aimed at developing appropriate capacities for public participation in decision-making. This will support the system operation by making the public/users and applicants more aware of biosafety related issues. These will be achieved through the development of a biosafety communication strategy and the creation of participation structures and mechanisms as part of the decision-making process (Claims Desk and Question and Answers system) In addition, surveys and trend analysis on the level of information, awareness and changes in public opinion about

biotechnology, biosafety and GMOs; will be applied to generate baseline information that will be useful to guide the intervention and to measure the impact.

In general, GEF support is expected to complement current government efforts (i.e. creation of laboratory, establishment of a national biosafety committee) as well as previous GEF interventions (i.e The projects development of biosafety framework and BCH - Component 1) to provide the necessary tools and capacity for Venezuela to comply with the CPB and to apply biosafety measures.

In terms of global environmental benefits, the project will allow Venezuela to better meet the objectives of the CBD, the CPB, and will in particular contribute to the achievement of the Aichi Target13, by promoting the safeguarding of genetic diversity of valuable resources (pants, animals, wild relatives) from genetic erosion. This will be done by developing operational biosafety systems that will include risk assessment procedures to support GMO decision-making. In addition, the development of GMO detection facilities will also enhance the countries' monitoring capacities, which will also prevent the unsafe use of not approved products.

A.6 Risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved, and measures that address these risks:

Following a more in depth risk assessment made during PPG, the risk table has been updated and improved:

Risk	category	Mitigation measure
Lack of coordination between the various NCAs to effectively participate in the project due to the fact that not all of them have the same capacities (technically, financially and operationally).	Medium	The authorities will be integrated from the design phase of the project to the end to establish the obligations of each one, resulting in their commitment and participation through formal mechanisms
Possibility of rotation of staff participating in the project.	Medium	Participation of technical personnel with fixed position will be guaranteed in the MPPA as executing agency of the project, as well as in other relevant Ministries, with the purpose of maintaining institutional memory and the capacity of executing the project, even in changing political scenarios.
Loss of the qualified human resource	Medium	Different levels of commitment/involvement will be established within the project structure trying to minimize centralization of information on a single person or department. To do this, support structures, advisory groups, work committees, among other, will be created. This will be complemented with the generation training tools and sessions to share the project information. The NEA will staff dedicated to project to support the NPC.
Political situation	High	To mitigate possible risks related to political issues (i.e. changes in high-level personnel on NCAs, changes in priorities, etc) the project will create a steering committee composed of representatives from various institutions, with the expectation that it can provide high-level support in case changes occur. In addition, high-level meetings and sensitization activities are part of the work plan in order to facilitate interaction with the authorities.
Administrative issues	High	Due to the present currency exchange rates in Venezuela, which poses a potential risk to the project, the funds will be managed by a third party (UNDP) that will be in a position

to keep project funds in USD and make payments on behalf
of the project, in particular procurement that has to be paid
to overseas providers in USD. Currently as stated on
Official Gazette N. 40.865, March 9 2016; the exchange
rate that will be applied to the project under the proposed
fund management scheme is the floating rate (exchange
agreement Central Bank, article 13). If the exchange rate as
per the floating system presents minimal variations, the risk
will be substantially reduced. However if major changes
occur increasing the gap between the floating rate and the
market cost, the risk will increase. Based on this, and
considering the floating nature of the exchange rate, after
the first year of implementation the risk category and
appropriated related actions will be revised.

A.7. Coordination with other relevant GEF financed initiatives

This project is related to other ongoing UNEP-GEF projects on Implementation of National Biosafety Framework and creating capacity for the Biosafety Clearing House mechanism. It aims to develop support measures to facilitate decision making and will allow Venezuela to join neighboring countries' efforts to protect global biodiversity by implementing biosafety frameworks and promoting better informed decision-making in the region. Moreover, UNEP is implementing agency of similar projects in the region, fact that is expected to contribute in networking and join efforts with other projects, making the best use of information available and possible collaboration opportunities. In particular synergies will be sought with ongoing biosafety project in: Peru, Ecuador, Panamá and the Caribbean; and with new GEF-6 biosafety projects such as Guatemala, that will be operational during a similar timeframe. Other implementing agencies such as the World Bank have implemented similar projects too. A particular example was the LAC-Biosafety project where countries such as Peru, Costa Rica, Brazil and Colombia participated. This project generated important technical guidelines that can be useful not only for its participating countries but for other neighboring countries too.

Possible coordination mechanisms will include: participation on regional meetings hosted by UNEP, technical meetings or workshops organized by similar projects in the region, and exchange of information and lessons learned with other project teams.

B. ADDITIONAL INFORMATION NOT ADDRESSED AT PIF STAGE:

B.1 Describe how the stakeholders will be engaged in project implementation.

In developing this project numerous stakeholders are involved in various ways. Important support will mainly come from government institutions as described below; however, other stakeholders also have major participation. An example would be universities, with which the project should collaborate in development of teaching materials, strategies, and to give technical talks. Civil society will also have active participation, as the project involves carrying out several surveys in different groups of society, in order to get their opinion and diagnose level of knowledge about biotechnology and biosafety. These strategies are part of the component of public perception and encouragement of citizen participation. Among the various groups of society that could be part of this exercise, we have identified universities, NGOs, industry and the general public.

The following table indicates the various stakeholders involved in the project and their respective roles.

Stakeholder	Roles and responsibilities	Potential participation/Involvement in project
Ministry for Popular	Formulation, coordination and execution of the	Will be the coordination center for
Power for Ecosocialism	policies related to natural resources and the	CBD and CPB. Will drive, facilitate

and Water	environment.	and coordinate implementation of the
	Regulation and control of access and use of genetic resources in general, as well as establishing, approving and auditing compliance with regulations and procedures related to the analysis and assessment of risks, mitigation of impacts on biological diversity and the environment.	project with the involved entities. Will also serve as the main coordination center for the project with UNEP. Is the host of the laboratory for GMO detection that will be improved under this project (reference laboratory for GMO detection in MINEA)
General Direction of Biological Diversity	Formulation, coordination and execution of policies related to biosafety.	National coordination center for this GEF project. Will be directly responsible for the formulation and execution of the project. This directorate is part of the Ministry for Ecosocialism and Water. This entity hosts the Cartagena
		Protocol Focal Point.
Ministry for Popular Power for Agricultural Production and Lands	National competent authority to undertake coordination and harmonization of agricultural production chains, with the aim of fostering development of a strong and diverse agricultural sector with high efficiency levels. To that extent, we are working hard on the strengthening of specific systems for technological information and dissemination that will provide the necessary tools for the parts to optimize their productive work and guarantee the food security for the Venezuelan people, in a frame of respect for biodiversity and incentive for ecologically sustainable development.	Will serve as national authority in the reach of its competences.
Ministry for Popular Power for Health	National competent authority responsible for the promotion, prevention, surveillance, control, regulation, rehabilitation and safe and secure reinstatement of integral health, guaranteeing opportune access to service networks and ensuring a healthy environment; fostering research, scientific, technological and human development as well as well as production of health products with universality, equality, solidarity, honesty, responsibility and celerity, to ensure quality of life for the Venezuelan people in an articulate, co-responsible and participative manner.	Will serve as national authority in the reach of its competences.
Ministry for Popular Power for Industry and Trade	National competent authority in charge of regulating on behalf of the Executive Branch in the development of basic, intermediate and light industries in the country, through social inclusion in the production process, promoting technology transfer and local innovation for the installation, reactivation and drive of national industries, aiming at the satisfaction of national and local needs of the population, substituting imports, in a frame of socialist values and	Will serve as national authority in the reach of its competences.

	principles that will result in strengthening of the productive economy.	
Ministry for Popular Power for Food	National competent authority responsible for guaranteeing population's access to food through regulation, formulation, follow up and evaluation of policies regarding trade, industry, marketing and distribution of food products, storage, conservation, transport, delivery, positioning, quality and consumption; inspection, security, enforcement and penalties on agricultural storage activities, operation and exploitation of silos, cold rooms, warehouses and other related state properties; regulation and granting of permits, authorizations, licenses, certificates and other formalities regarding export and import in the food sector.	Will serve as national authority in the reach of its competences.
Ministry for Popular Power for Education, Science and Technology	National competent authority responsible for formulating, promoting, adopting and following of public policies, plans, programs, projects, mechanisms and instruments aimed at strengthening science, technology and innovation and their applications, thus contributing to the construction of the socialist productive model.	Will serve as national authority in the reach of its competences.
Ministry for Popular Power for Fisheries and Aquaculture	National competent authority in charge of driving the fisheries sector, increasing production, national supply and development of aquaculture.	Will serve as national authority in the reach of its competences.
National Biosafety Commission (CNBio)	Multidisciplinary and multi sectorial entity, advisor to the Executive regarding the use, management, transport and safe practices in diverse fronts (among those that stand out: health, environment, science and technology, security and national defense, agricultural and food self- sufficiency and others).	Contribute in its areas of competency to complement the applicability of the CPB.
Public/private Universities and Research Institutions	Support in the execution of specific project components.	Provide support in the execution of certain training and sensitizing activities in universities and public institutions, and be a source of experts for capacity building activities.
Social groups	Exchange of information, generation of communication strategies, public awareness and lessons learned.	Provide technical input to the project and aiding in undertaking of awareness activities.

B.2 Describe the socioeconomic benefits to be delivered by the Project at the national and local levels, including consideration of gender dimensions, and how these will support the achievement of global environment benefits (GEF Trust Fund/NPIF) or adaptation benefits (LDCF/SCCF):

The Cartagena protocol on its Article 26, highlights the importance of socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. In this sense, the actions proposed through this project will deliver a stronger and operative biosafety system for Venezuela, which will allow the country to better assess the possible consequences associated with the use of GMOs. Socio-economic benefits will be delivered

in consequence since the country will be in a better position and with enhance capacities to analyze the impacts of GMO on various sectors. For instance, trained personnel on biosafety issues in the NCAs will be able to prevent risks and ensure safe use of biotechnology, which has an impact in areas such as agriculture, health, and the general public. Also, GMO detection capacities in the country will allow the monitoring of imports that may contain GMOs and support the authorities in accept only products that have been approved by the country.

In relation to gender as a key issue in socio-economic considerations, gender awareness and capacity should be created among the Parties under the CP to recognize the gender differences in relation to the use of biological biodiversity. These differences should be considered when implementing the Protocol and evaluating the socio-economic impacts that can arise from GMO introduction on the conservation and sustainable use of biodiversity. In this sense the project will promote the participation of both, men and women in project related activities such as trainings, meetings, decision-making and the implementation of technical and decision-making bodies.

Women's involvement in the biotechnological field is crucial given their different needs and concerns about GMOs. Encouraging women to become scientists would be key in the assessment and possible production and/or introduction of GMOs. Unfortunately, women are not encouraged to do so; a smaller proportion of girls receive training in science and technology (Huyer, 2006); college-educated women are less than half as likely to be employed in science and technology; and women employed in these fields earn 20% less than men (Graham and Smith, 2005). The project will support the development of women in science by providing support through components 2 and 3, which are expected to create technical capacities in biosafety /biotechnology and raise awareness of the subject.

Also, women are more prone to nutritional deficiencies because of their unique nutritional needs, especially when they are pregnant or breastfeeding. GMOs could potentially help reduce their malnutrition problems, and thus women involvement in the various biosafety scenarios is paramount to ensure that these possibilities are analyzed.

Finally, gender considerations will also be taken into account in the process of recruitment of project personnel and consultants, trying whenever possible to balance the number of beneficiaries between male and female. Likewise gender balance will be considered when selecting trainees and beneficiaries of opportunities derived from the project.

Finally, this project will support the achievement of global environment benefits since Venezuela as mega diverse country will be assessing the use of GMOs under a functional biosafety system with clear regulations and technical tools; and which is based in the Cartagena Protocol. Therefore, preventing the possible risks to the environment and to the population associated with the use of GMOs.

From the socio-environment point of view, the safe use of new technological products could open new opportunities for development. However, before adopting the use of such products it is necessary to have in place a robust regulatory system that allow the country to assess the possible benefits and/or risks related to their use. Likewise, if the country is better prepared for decision-making through a more robust biosafety system, local people and institutions will benefit from the possibilities of the safe use of biotechnology, and in particular local developments could be supported. This discipline could bring along employment opportunities that could open new possibilities for local people. Moreover, a science-based risk assessment will also bring benefits to the environment and the population by ensuring that products that could be available have gone through a rigorous analysis that will safeguard biodiversity and food security.

B.3. Explain how cost-effectiveness is reflected in the project design:

This Project builds on previous work by following on directly from the UNEP-GEF NBF project and BCH project, whereby the bases for the current project's goals were already set through these initiatives. Therefore, the project does not start from scratch, and instead, will consolidate actions that will complement previous efforts.

The chosen structure for the results framework and the national implementation arrangements for the project respond directly to the main topics defined and discussed under the prior UNEPGEF projects, to the scheme of the Cartagena Protocol, to the experience already gained in executing this type of project in the past, and to the national legislation scheme.

The Ministry of Popular Power for Ecosocialism and Water (MINEA) will act as Executing Agency, having a strong link with the CPB and BCH Focal Points, who are hosted by that institution. It will also involve an array of relevant stakeholders in the Project for the consolidation of a strong and collegiate biosafety system; which is a cost-effective approach in the sense that the lead institution for the project is also a well-connected organization with well-established synergies with other governmental organization, which will facilitate the creation of partnerships and cooperation agreements.

The project will also foster a collaborative relationship in favour of biosafety with the academic sector, by engaging educational centers such as universities in the project's training activities. In particular, Universities will play a key role in supporting the creation of technical capacities through the participation of professors in workshops and activities coordinated by the project In Venezuela majority of the universities, research laboratories and educational centers are of a public nature. These institutions lead biotechnology process in the country, and through the "Ley Orgánica de Ciencia, Tecnología e Innovación (LOCTI)" the Ministry of Popular Power for University Education, Science and Technology (MPPEUCT) offers grants for research in this area. The MPPEUCT play an important role for this project, since its main objective is to direct and guide science and technology activities in Venezuela, amongst which are biotechnology and biosafety. Synergies between the project and MPPEUT will result in cooperation at a technical and strategic level in aspects such as public awareness, information dissemination, and technical analysis.

Therefore, project's cost effectiveness is based in a design that foresees both, sustainability and integration factors, so that biosafety is managed in a de-centralized way that complements the country's biotechnology initiatives, involving institutions who have direct responsibilities in biosafety, in generating biodiversity information, and in forming scientific know-how, and through structures that allow access to scientific expertise and technological capacity when these is not available in-house. The project's sustainability is also adding to its cost-effectiveness. For instance, the project will upgrade an existing laboratory which has been built and has been set within the competency of the Ministry of Ecosocialism and Waters. This means that this laboratory will have an allocation of national funds for its operation, ensuring that the same and ergo the GEF investment, will be sustainable over time and complemented with national efforts.

Another important contribution to the project's cost-effectiveness is the experience gained by the National Executing Agency, in project management, since this is only one of the various projects managed by MINEA, who has also acted as EA of other GEF projects such as Support for the Preparation of the First National Communication on Climate Change, Strengthening the Marine and Coastal Protected Areas System,. In addition the Ministry of Ecosocialism and Waters has been executing agency of other initiatives amongst with the following can be cited: Strengthening of capacities of the office of management and international cooperation, Institutional Capacity Building for the Ministry of Popular Power for Ecosocialism and Water to enhance participation and International Technical Cooperation.

C. DESCRIBE THE BUDGETED M &E PLAN:

The project will follow UNEP standard monitoring, reporting and evaluation processes and procedures. Substantive and financial project reporting requirements are summarized in Appendix 4. Reporting requirements and templates are an integral part of the UNEP legal instrument to be signed by the executing agency and UNEP.

The project M&E plan is consistent with the GEF Monitoring and Evaluation policy. The Project Results Framework presented in Annex A includes SMART indicators for each expected outcome. These indicators along with the key deliverables and benchmarks included in Annex I will be the main tools for assessing project implementation progress

and whether project expected results are being achieved. The means of verification of these elements are summarized in the Project Result Framework, Annex A.

A costed first draft of project M&E Plan is presented here below. Costs mentioned in this tool are fully integrated in the project budget, presented in Annex G.

An inception workshop will be held at the onset of project implementation to ensure all actors understand their roles and responsibilities vis-à-vis project monitoring and evaluation. Indicators and their means of verification may be fine-tuned at the inception workshop. Day-to-day project monitoring is the responsibility of the project management team. It is the responsibility of the PM to inform UNEP of any delays or difficulties faced during project implementation so that the appropriate support or corrective measures can be adopted in a timely fashion.

The PSC will issue reports every 6 months on progress by the project and make recommendations concerning the need to revise any aspects of the Project Results Framework, or the M&E plan. Supervision to ensure that the project meets UNEP and GEF policies and procedures is the responsibility to the UNEP-GEF Task Manager. The Task Manager will also review the quality of draft project outputs, provide feedback to the project partners, and establish peer review procedures to ensure adequate quality of project outputs in close collaboration with the PM.

The Task Manager will develop an initial supervision plan that will be communicated to the project partners during the inception workshop for comments. The emphasis of the Task Manager supervision will be on outcome monitoring but without neglecting project financial management and implementation monitoring. Progress vis-à-vis delivering the agreed project global environmental benefits will be assessed by the RSC. Project risks and assumptions will be regularly monitored both by project partners and UNEP. Risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR. Key financial parameters will be monitored quarterly to ensure cost-effective use of financial resources.

UNEP will be responsible for managing the mid-term review/evaluation and the terminal evaluation. The Project Manager and partners will participate actively in the process. The project will be reviewed or evaluated at mid-term. The purpose of the Mid-Term Review (MTR) or Mid-Term Evaluation (MTE) is to provide an independent assessment of project performance at mid-term, to analyze whether the project is on track, what problems and challenges the project is encountering, and which corrective actions are required so that the project can achieve its intended outcomes by project completion in the most efficient and sustainable way.

The project Steering Committee will participate in the MTR or MTE and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented. An MTR is managed by the UNEP Task Manager. An MTE is managed by the Evaluation Office (EO) of UNEP. The EO will determine whether an MTE is required or an MTR is sufficient.

An independent terminal evaluation (TE) will take place at the end of project implementation. The EO will be responsible for the TE and liaise with the UNEP Task Manager throughout the process. The TE will provide an independent assessment of project performance (in terms of relevance, effectiveness and efficiency), and determine the likelihood of impact and sustainability. It will have two primary purposes:

- (i) to provide evidence of results to meet accountability requirements, and
- (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP and executing partners.

While a TE should review use of project funds against budget, it would be the role of a financial audit to assess probity (i.e. correctness, integrity etc.) of expenditure and transactions.

The TE report will be sent to project stakeholders for comments. Formal comments on the report will be shared by the EO in an open and transparent manner. The project performance will be assessed against standard evaluation criteria using a six point rating scale. The final determination of project ratings will be made by the EO when the report is finalized. The evaluation report will be publically disclosed and will be followed by a recommendation compliance process. The direct costs of reviews and evaluations will be charged against the project evaluation budget.

M&E activity	Responsible Parties	Aprox. Budget from GEF (US\$)	Budget co- finance	Time Frame
Inception Workshop & closure workshop	Project Management Unit (PMU) UNEP	20,000	3,000	Within 2 months of project start-up
Inception Report	PMU	500	3,000	1 month after project inception meeting
Measurement of project indicators (outcome, progress and performance indicators, GEF tracking tools) including baseline data collection (communications, others, computer)	Project CoordinatorPMU/ Project team	9,000	10,000	Outcome indicators: start, mid and end of project Progress/perform. Indicators: Within 1 month of the end of reporting period i.e. on or before 31 January and 31 July (through progress reports) Baseline data collection: within the 1st year.
Project Steering Committee (SC) meetings	Project Coordinator PMU UNEP	16,000	3,000	Twice a year Minimum
Reports of SC meetings	Project Coordinator with inputs from partners	500	3,000	
PIR	Project Coordinator PMU UNEP	2,000	2,000	annually
Monitoring visits to field sites and areas where project is active	Project Coordinator PMU UNEP	5,000	5,000	
Mid Term Evaluation Due to the risks identified during the preparatory phase of this proposal, the mid-term evaluation will be done after the first year of implementation, in order to provide useful recommendations if needed after all the executing mechanisms have been operational in order to better assess possible challenges and or	UNEP TM/ UNEP Evaluation Office PMU	20,000	3,000	At mid-point of project

M&E activity	Responsible Parties	Aprox. Budget from GEF (US\$)	Budget co- finance	Time Frame
assets.				
Terminal Evaluation	UNEP TM/ UNEP Evaluation Office PMU	25,000	3,000	At project end
Total M&E Plan Budget		98,000	35,000	

PART III: APPROVAL/ENDORSEMENT BY GEF OPERATIONAL FOCAL POINT(S) AND GEF AGENCY(IES)

A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT(S) ON BEHALF OF THE GOVERNMENT(S):): (Please attach the Operational Focal Point endorsement letter(s) with this form. For SGP, use this OFP endorsement letter).

NAME	POSITION	MINISTRY	DATE (MM/dd/yyyy)
Ms. Lissett Hernández	Director, International	Ministry of Environment/	25-01-13
	Cooperation	Ministerio del Poder Popular	
		Para Ambiente	

B. GEF AGENCY(IES) CERTIFICATION

This request has been prepared in accordance with GEF/LDCF/SCCF/NPIF policies and procedures and meets the GEF/LDCF/SCCF/NPIF criteria for CEO endorsement/approval of project.

Agency Coordinator, Agency Name	Signature	Date (Month, day, year)	Project Contact Person	Telephone	Email Address
Brennan Van Dyke Director, GEF Coordination Office, UNEP	Brenon Van Dyla	August 25, 2016	Marianela Araya Quesada	305-3169	Marianela.Araya@unep.org

ANNEXES:

ANNEX A: Logical framework

ANNEX B: Responses to GEF reviews (GEF STAP)

ANNEX C: Status of implementation of project preparation activities and the use of funds.

ANNEX D: Calendar of expected reflows

ANNEX E: Consultants to be hired ANNEX F -1: Detailed GEF Budget

ANNEX F-2: Detailed Co-finance budget

ANNEX G: Monitoring and Evaluation budget or workplan

ANNEX H: Project implementation arrangements

ANNEX I: Detailed project workplan ANNEX J: Focal Area Tracking Tools ANNEX K: OFP Endorsement letters

ANNEX L: Co-finance letters

ANNEX M: Environmental and social safeguards checklist

ANNEX N: Acronyms and abbreviations

APPENDICES:

Appendix 1: Supervision plan

Appendix 2: Procurement plan

Appendix 3: TORs for key personnel Appendix 4: Reporting requirements

ANNEX A: Logical framework

Project Objective: Implementation of the national biosafety framework in Venezuela in accordance to the Cartagena Protocol on Biosafety.

Alignment with UNEP's PoW: Sub-programme Environmental Governance, EA (b) The capacity of countries to develop and enforce laws and strengthen institutions to achieve internationally agreed environmental objectives and goals and comply with related obligations is enhanced.

Output 2: Legal technical assistance provided to support initiatives by countries to implement, monitor and achieve compliance with, and enforcement of, international environmental obligations, including those set out in multilateral environmental agreements.

Indicator: Increased number of legal and institutional measures taken by countries to enforce the rule of law and improve the implementation of internationally agreed environmental objectives and goals, with the assistance of UNEP.

OBJECTIVES,			dia godis, with t		(EI)				
OUTCOMES AND OUTPUTS INDICATORS	BASELINE CONDITIONS	MID TERM TARGETS	END OF PROJECT TARGETS	MEANS OF VERIFICATION	ASSUMPTIONS				
Component 1: Completion and operation of biosafety legal framework.									
1.1 Regulatory biosafety framework is completed, adopted and integrated within the National Strategy for the Conservation of Biodiversity 2010-2020 and its National Action Plan in alignment to the Cartagena Protocol. Biosafety framework integrated and supported by binding documents (Policy, NCAs). Biosafety framework integrated and supported by binding documents (Policy, NCAs). Biosafety framework integrated and supported by binding documents (Policy, NCAs).	- PC was ratified on 2003 CNBio is not currently operative There are 7 national competent authorities in Venezuela There is a diagnosis on the legal framework that needs updating Need to generate national laws (e.g. executive orders or administrative rulings) of a more specific nature Guidelines for analysis of requests must be generated.	1.1.1 First draft of the biosafety policy must be finished and ready for socialization with main stakeholders, and eventual presentation to competent authorities. 1.1.2 National biosafety regulations drafted 1.1.3 Appointment of national competent authorities in biosafety matters. 1.1.4-6 50% progress in the development of guidelines, protocols, sectorial and technical regulations for handling of GMOs.	1.1.1 Socialization of the biosafety policy with stakeholders and subject to national approval. 1.1.2 Final document biosafety regulations submitted to authorities. 1.1.3 National authorities in biosafety have the necessary personnel to handle matters related to CPB and biosafety. 1.1.4-6 Guidelines, protocols, sectorial and technical regulations for handling of GMOs in the country (GMO in transit, confined trials, emergency measures risk assessment) finished and available for NCAs.	- Review of drafts of proposed regulations. - Official notice of personnel appointment in the NCA for matters related to CPB and biosafety. - Policy document. - Technical guidelines and protocols documents.	- Key actors are involved in matters related to CPB and biosafety and actively participate in the review process for the new legal framework Local authorities support the project's activities NCAs start the process of approving the project's products.				

Component 1: OUTPUTS

- 1.1.1 National Policy Document on Biosafety.
- 1.1.2 National Biosafety regulations produced, in connection with existing laws.
- 1.1.3 National competent authorities defined and appointed.
- 1.1.4 Sectorial rules/resolutions and guidelines for the management of GMO and associated information, by the competent national authorities.
- $1.1.5 \ Guidelines \ and \ procedural \ manuals \ for \ GMO \ users, including \ importers/exporters, producers, processing industry \ and \ researchers.$

1.1.6 Administrative and technical forms for GMO applications.

Component 2. Development of appropriate institutional and human capacity for decision-making and regulatory compliance in biosafety.

compliance in biosafety.								
2.1 The institutional and administrative	If any during the project life, GMO applications	Currently there is no system in place to process GMO related	Administrative system to handle applications with GMOs designed	Administrative system to handle applications approved by	-Admin system design documentSubmission of documents for	NCAs are willing to cooperate in the design of a common		
framework is reinforced to provide effective responses to GMO applications and communicate decisions in line with the CPB.	processed according to the CPB provisions and timeframe. Participation of at least 1 person from all the competent authorities in the analysis of GMO applications.	applications. NCAs are those related to biosafety issues, but there is a lack of a clear structure or system for biosafety issues.	and socialized with main stakeholders and NCAs. National Biosafety Committee is operational	NCAs and under implementation. National Biosafety Committee is operational.	approvalMemos of communication with stakeholders and other NCAsApproval of the administrative system from NCA's	biosafety system, designate personnel to interact with project team, and revise project documents for further approval.		
2.2. There is greater human	NCA can process applications and	Currently there is limited capacity	Personnel from NCAs trained in	Personnel from NCAs trained in	Courses attended or offered.	Governmental institutions and in		
capacity,	fulfil CPB	in NCA	biosafety matters	biosafety matters	01 01101001	particular NCAs,		
clarity,	requirements	personnel in	(risk assessment	(risk assessment	Hands on training	will take into		
scientific and	through	terms of	and decision-	and decision-	exercises.	account technical		
technological	technically	technical	making).	making).		advice and		
bases to make	qualified	biosafety			Biosafety	analysis for		
decisions	personnel.	knowledge,	At least 1	At least 2	committee	decision-making.		
regarding	Diala assassant	which is an	training activities	training activities	established and			
GMOs.	Risk assessment	obstacle to review possible	have allowed discussion of	have allowed discussion of	operational.			
	can take place.	applications and	biosafety gender	biosafety gender				
	Technical	issue	related issues.	related issues				
	recommendations	recommendations	Totaled Issues.	Totaled Issues				
	from biosafety	for decision-	Proposal on how					
	committee	making. Few	to issue technical					
	support decision-	personnel have	recommendations					
	making.	been trained	for decision-					
	Normals and C	formally on	making	Duamanal t.				
	Number of women and men	biosafety and there is a need	developed.	Proposal on how to issue technical				
	trained in	for hands-on		recommendations				
	biosafety	training		for decision-				
	workshops.	experiences.		making				
	r ···	There are no		socialized and				
	Number of	personnel		approved by				

	Training	technically		authorities.		
	activities in	trained to				
	which gender	conform the				
	considerations	biosafety				
	related to	committee.				
	biosafety have					
	been					
	raised/discussed.					
2.3. There is	GMO monitoring	Monitoring	Identification of	Mechanisms	Analysis of main	Customs officers,
greater human	activities take	capacity is very	mechanisms for	established for	gaps to cover.	as well as other
capacity,	place at various	limited or null.	risk control and	risk control and		entities' (sea
clarity,	points (sea ports,	The country	management,	management,	Memos and	ports, airports)
scientific and	airports and	imports goods	including	including	minutes of	personnel
technology to	customs	that may contain	technology and	technology and	meetings with	available to
control /	checkpoints).	GMOs for food,	methods for	methods for	customs	participate on
monitor		feed and	GMO	GMO	authorities and	project activities
activities with	There is capacity	processing but	traceability/	traceability/	representatives of	and be trained.
GMOs in the	to react on	nowadays there	detection.	detection.	other control	
country.	biosafety	is no mechanism			points.	Interest from
	emergency cases.	to confirm what	Contingency			custom
		is coming in as	protocols for		Purchase of	authorities in
		an import.	emergency		equipment	undertakes
		Customs	response drafted.			biosafety
		personnel are not	Personnel from	Personnel from	Training	measures.
		aware of	control points	control points	activities.	
		biosafety, not of	sensitized about	sensitized about		
		possible	biosafety and	biosafety and		
		monitoring	trained in the use	trained in the use		
		measures in this	of the monitoring	of the monitoring		
		respect. There is	techniques and	techniques and		
		a need for	protocols.	protocols.		
		technical				
		capacity as well				
		as for				
		sensitization of				
		involved actors.				

Component 2: OUTPUTS

- 2.1.1 Centralized administrative system to handle applications with GMOs including a "single-centralized window" designed and approved by NCA's.
- 2.1.2 Technical Secretariat of the National Biosafety Committee created with specialized technical personnel.
- 2.2.1 Evaluation processes for environmental and health risks validated by the national authorities responsible for different uses of GMOs
- 2.3.1 Specialized personnel trained to perform the tasks of monitoring and detection of GMOs at sea ports, airports and customs checkpoints.
- 2.3.2 Mechanisms established for risk control and management, including technology and methods for GMO traceability/ detection, and contingency protocols for emergency response in case of accidents involving GMOs.

Component 3: Development of appropriate capacities for public participation in decision-making.								
3.1. Increase the	Better	Biosafety is not a	Surveys for	Surveys for	Survey forms and	General public		
level of public	understanding of	subject included	various actors	various actors	analysis of the	and personnel		
understanding	biosafety at	in technical or	designed and	applied to at least	information.	from competent		
of biosafety	various levels	formal training	applied to at least	4 target groups.		authorities is		
through	(general public,	programs, and	2 of the target		BCH and project	willing to		
operations	NCA's	there are	groups	National BCH	website.	participate in		
based on	personnel, related	currently no		updated.		biosafety		
participatory	institutions).	official	Biosafety and		Informative	sensitization		
diagnosis.		campaigns to	biotechnology	Development of	materials	activities.		
		sensitize the	communication	informative	designed.			
		general public	strategy drafted	materials		Local authorities,		
		and /or other	and approved by		Communication	in particular the		

3.2. Public	Public	actors on biosafety related issues. There is no formal study on the actual knowledge of biosafety on various society groups; and there is no communication strategy for biosafety or biotechnology related matters. However there is a need to socialize the issue in order to obtain support for the operation of the biosafety system Currently there	the EA. Discussion forums have taken place National BCH updated Project website developed and online by PY1 Development of informative materials	Discussion forums have taken place	Strategy document	EA supports the biosafety communication strategy and public awareness actions.
participation in decision-making processes on GMOs is promoted and systematized.	participation mechanisms in place. Better understanding of biosafety.	are no public participation mechanisms in place since there is actually no biosafety operation system established.	Participation structures and mechanisms as part of authorization process of GMOs, including a Claims Desk and Question and Answers system designed and socialized for NCA's feedback.	Participation structures and mechanisms as part of authorization process of GMOs, including a Claims Desk and Question and Answers system established.	Consultancy document. Socialization of the proposal to NCAs. Inclusion of public participation measures in the NCA website.	and with capacity to address public comments and queries. Public with interest to participate in biosafety decision-making.
3.3. A coordinated governmental system for public access to information on biosafety is supported in accordance with Article 20 of the CPB.	National BCH website is updated and shares important biosafety information.	The BCH needs to be updated.	BCH is revised and information is updated, including the new outputs of the project, country decisions and news, as well as any other relevant information.	BCH is re- revised and updated to include new project products.	BCH portal updates.	The BCH is recognized as a portal where Biosafety information can be found. There is interest from the public and authorities to use the site.

Component 3: OUTPUTS

- 3.1.1 Surveys and trend analysis on the level of information, awareness and changes in public opinion about biotechnology, biosafety and GMOs.
- 3.1.2. Communication strategy in biosafety developed. (including Information on GMOs and biotechnology, and other public awareness materials)
- 3.2.1 Participation structures and mechanisms as part of authorization process of GMOs, including a Claims Desk and Question and Answers system.
- 3.2.2 Discussion forums with the private sector to exchange views and queries.
- 3.3.1 Public, up to date sectorial information regarding GMOs present and/or authorized by the country.

Component 4: Strengthening of infrastructure for the detection and management of GMOs.								
4.1. Equip and	GMO detection	Nowadays the	List of laboratory	Laboratory	Equipment	The identified		
operate the	capacity	country has no	equipment	equipment	quotations and	laboratory will		

Reference	improved and	GMO detection	revised and	received and	invoices.	continue to be in
Laboratory for	supports	capacity that	updated (by	installed.		conditions to be
Detection of	countries'	could serve as a	PY1).		Laboratory tests	upgraded.
GMOs of the	fulfilment of	national		Equipment test	performed.	
Ministry of	CPB	reference	Purchase of	and setup.		The purchase of
Popular Power	requirements.	laboratory. The	equipment	_	Protocols used.	equipment can
for the	_	infrastructure of	commence (by	Laboratory		take place.
Environment,		existing labs that	PY2).	improved and		_
the lead agency		are link to the		ready to operate.		The cooperation
for Biosafety in		NCAs is basic	Laboratory			agreements with
Venezuela,		and requires	improvements			the laboratory can
responsible for		improvements to	for operations			be signed on
supervision and		undertake on	begin (by PY2).			time.
control of		regular basis				
GMO's in the		GMO detection.				
country.						

Component 4: OUTPUTS

ANEEX B: responses to GEF reviews (GEF STAP)

Separate document

ANNEX C: STATUS OF IMPLEMENTATION OF PROJECT PREPARATION ACTIVITIES AND THE USE OF FUNDS⁵

A. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES FINANCING STATUS IN THE TABLE BELOW:

PPG Grant Approved at PIF: \$54,714					
Project Preparation Activities Implemented	GEF/LDCF/SCCF/NPIF Amount (\$)				
	Budgeted	Amount Spent	Amount		
	Amount	Todate	Committed		
Drafting of Project Proposal	44,714	0	44,714		
Consultation meetings	10,000	0	10,000		
Total	54,714	0	54,714		

Note: Project proposal was drafted with co-finance funds. PPG funds will be used to support project activities during the first year, in particular: project inception meeting, and lobbying with other NCAs to secure support to the project, in particular to minimize potential risks associated to political changes. In addition, activities to strengthen the mapping of actors in biosafety will be undertaken with these funds.

^{4.1.1} An operational laboratory that has the necessary infrastructure to carry out analysis and detection of GMOs, which allows Venezuela to meet its obligations under the CPB.

If at CEO Endorsement, the PPG activities have not been completed and there is a balance of unspent fund, Agencies can continue undertake the activities up to one year of project start. No later than one year from start of project implementation, Agencies should report this table to the GEF Secretariat on the completion of PPG activities and the amount spent for the activities.

GEF5 CEO Endorsement Template-February 2013.doc

ANNEX D: CALENDAR OF EXPECTED REFLOWS (if non-grant instrument is used)

Provide a calendar of expected reflows to the GEF/LDCF/SCCF/NPIF Trust Fund or to your Agency (and/or revolving fund that will be set up)

N/A

ANNEX E: CONSULTANTS TO BE HIRED FOR THE PROJECT USING GEF/LDCF/SCCF RESOURCES

Position Titles	\$/ Person	Estimated	Tasks To Be Performed
	Week*	Person	
		Weeks**	
For Project Management			
Local	T		
National Project Coordinator (admin	12,750	4 years	See TORs for National Project
tasks)			Coordinator
Project assistant	5,000	4 years	To support project admin duties in coordination with NPC
Justification for travel, if any:			
For Technical Assistance			
Local			
Consultancy for drafting a national BS policy	833.33	36	Develop the document of the National Biosafety Policy in consultation with local authorities and stakeholders, and the project unit. Includes drafting of the document, technical consultations and presentation of the same to authorities.
Consultancy for drafting BS regulation act	833.33	36	Develop the document of the National Biosafety Act in consultation with local authorities and stakeholders, and the project unit. Includes drafting of the document, technical consultations and presentation of the same to authorities.
Consultancy to develop sectorial rules and regulations	833.33	24	Development of sectorial regulations for NCAs, in a consultative manner and aligned with the Biosafety Policy and Act. Includes coordination meetings, consultations and technical expertise.
Consultancy to develop technical guidelines and protocols (transit, confined field trial, emergency measures, risk assessment)	555.55	36	Development of guidelines and protocols for NCAs, in a consultative manner and aligned with the Biosafety Policy and Act. Includes coordination meetings, consultations and technical expertise.
Consultancy to develop guidelines and procedures as per output 1.1.4 Consultancy to develop monitoring	555.55 694.44	36	Development of guidelines (output 1.1.4) in a consultative manner and aligned with the Biosafety Policy and Act. Includes coordination meetings, consultations and technical expertise. Development of monitoring and

and detection mechanisms including: methods for GMO traceability/ detection, and contingency protocols for emergency response in case of accidents involving GMOs			detection system to manage GMOs in the country. Includes the development of traceability and detection procedures and contingency measures. Includes coordination meetings, consultations and technical expertise. Products to be aligned with National Biosafety System, Policy and Act.
Consultancy for the development of the project website	500	24	To develop a project website.
Consultancy for the development of a Q&A system and portal for public opinion on the NCA's website. (could be link with the development of the digital system on component 2)	500	24	To develop portal for Q&A to enhance public participation in the GMO decision making. To be developed in close consultation with the project unit, NCA and in alignment with the CPB.
Consultancy for assessing the real need in terms of equipment at the moment of project implementation	625.00	24	To undertake assessment of the laboratory facility that will be strengthen through the project, and propose amendment (if necessary) to the procurement plan based on status quo and local possibilities for purchasing. Consultancy also includes development of a layout for the installation of equipment in the lab.
Consultancy validation of detection protocols developed under component 2.	729.17	48	To test protocols developed under component 2. Includes amendments of the same, if necessary.
Justification for travel, if any:			

ANNEX F -1: Detailed GEF Budget

Separate document

ANNEX F-2: Detailed Co-finance budget

Separate document

ANNEX G: Monitoring and Evaluation budget or workplan

M&E activity	Responsible Parties	Aprox. Budget from GEF (US\$)	Budget co- finance	Time Frame
Inception Workshop & closure workshop	Project Management Unit (PMU) UNEP	20,000	3000	Within 2 months of project start-up
Inception Report	PMU	500	3,000	1 month after project inception meeting
Measurement of project indicators (outcome,	Project Coordinator	9,000	10,000	Outcome indicators: start, mid and end of

M&E activity	Responsible Parties	Aprox. Budget from GEF (US\$)	Budget co- finance	Time Frame
progress and performance indicators, GEF tracking tools) including baseline data collection (communications, others, computer)	· PMU/ Project team			project Progress/perform. Indicators: Within 1 month of the end of reporting period i.e. on or before 31 January and 31 July (through progress reports) Baseline data collection: within the 1 st year.
Project Steering Committee (SC) meetings	Project Coordinator PMU UNEP	16,000	3,000	Twice a year Minimum
Reports of SC meetings	Project Coordinator with inputs from partners	500	3,000	
PIR	Project Coordinator PMU UNEP	2,000	2,000	annually
Monitoring visits to field sites and areas where project is active	Project Coordinator PMU UNEP	5,000	5,000	
Mid Term Review. Due to the risks identified during the preparatory phase of this proposal, the mid-term evaluation will be done after the first year of implementation, in order to provide useful recommendations if needed after all the executing mechanisms have been operational in order to better asses possible challenges and or assets.	UNEP TM/ UNEP Evaluation Office PMU	20,000	3,000	At mid-point of project
Terminal Evaluation	UNEP TM/ UNEP Evaluation Office PMU	25,000	3,000	At project end
Total M&E Plan Budget		98,000	35,000	

ANNEX H: Project implementation arrangements

• DESCRIBE THE DIVISION OF RESPONSIBILITIES

UNEP's Division of Environmental Policy Implementation (DEPI) is the GEF Agency (or Implementing Agency, IA) for the Project on behalf of the GEF Secretariat, with the following roles:

- Provide consistent and regular Project oversight to ensure the achievement of Project objectives
- Liaise between the Project and the GEF Secretariat,
- Ensure that both GEF and UNEP policy requirements and standards are applied to and are met (reporting obligations, technical, fiduciary, M&E)
- Ensure timely disbursement/sub-allotment of funds to the executing agency (EA), based on the agreed legal documents
- Approve budget revision, certify fund availability and transfer funds
- Organize mid- and end-term evaluations and audit
- Provide technical support and assessment of the execution of the Project
- Provide guidance if requested to main TORs/MOUs and subcontracts issued by the Project
- Follow-up with EA for progress, equipment, financial and audit reports
- Certify project operational completion
- Member of the Project Steering Committee (PSC)

The Ministry of Popular Power for Ecosocialism and Water is the Executing Agency (EA) of the Project. Its main responsibilities include:

- Oversee Project execution in accordance with the project results framework and budget, the agreed work plan and reporting tasks.
- Support the Project Management Unit (PMU) in coordinating project activities at national and local levels.
- Provide technical expertise through its personnel and networks.
- Ensure technical quality of products, outputs and deliverables, including reports to UNEP.
- Provide guidance and coordination to the PMU and Venezuelan stakeholders.
- Facilitate access to sites and locations.
- Support logistical issues, e.g. through organization of meetings and provision of relevant facilities.
- Support the PMU in regular Project reporting, incl. progress, financial and audit reporting to IA.
- Chair the project steering committee.

If such need arises, the EA will notify the IA, in writing, of its intention to modify the agreed implementation plan and budget, and will seek approval from UNEP, and the Project Steering Committee. It will also rectify any issues raised by IA with respect to project execution in a timely manner.

The **Project Steering Committee** (**PSC**) will provide strategic direction and oversight to project management. The PSC will be a multi-disciplinary and multi-sectoral body covering related environment areas of practice. The PSC will include representatives of relevant government agencies, academic institutions and other stakeholder representatives, including but not limited to: Ministry of Popular Power for the Environment (MINEA), Ministry of Popular Power for Health (MPPS), Ministry of Popular Power for Food (MINPAL), Ministry of Popular Power for Science, Technology and Innovation (MEUCT), Ministry of Popular Power for Agriculture and Land (MAPT), Ministry of Popular Power for Industry and Trade (MIC), UNEP representatives, the executing agency, the fund management agency (UNDP) and the Venezuelan CPB focal point. It will meet at least once a year, or more often according to expressed need, to review the progress, approve the work plan and budget, provide direction and guidance, and assist in project implementation as well as build synergies with other complementing initiatives. The EA will provide support services, as required.

The Project Management Unit (PMU) will be located at MINEA; it will consist of:

■ The Project Coordinator (NPC) Full time.

- The Project Administrative Assistant
- At least one person half-time from the NEA to support project processes.
- Other as required
- Representative from UNDP (as fund management agency)

PMU roles comprise:

- Ensure Project execution, including all technical aspects
- Ensure Project governance and oversight of the financial resources from the GEF investment in collaboration with the third party who will manage the project funds locally (UNDP)
- Provide staff time and expertise in guiding and advancing the project. (at least one person half- time staff dedicated to the project + administrative support)
- Provide Project reporting according to the supervision plan in collaboration with the third party who will manage the project funds locally (UNDP)
- Share all achievements and products of the project with all relevant stakeholders and UNEP
- Ensure that consultants and project partner organizations deliver against their contracts and in time
- Organize the Steering Committee meetings and serve as its secretariat
- Overall management and implementation of the Project M&E framework to evaluate project performance
- Management of the flow of information from the field to the Project collaborators, and producing periodic monitoring reports

Responsibilities of the Fund Management Agency (UNDP):

- Prepare and manage ToR, contracts and MoU with consultants and project partners using appropriate legal instruments. ToR and selection process will be done in consultation with the PMU (clearance), and according with the project's approved work plan and budget. ToRs should be cleared by UNEP.
- Do all payments related to the project as per request and coordination with the EA and the project work plan and approved budget.
- Prepare the periodic expenditure reports as per UNEPs templates and system (Anubis) and revise the same with the PMU to ensure accuracy and signature of the same. NPC should provide data on co-finance for the reports, and support the process getting the reports signed.
- Undertake procurement of goods and services for the project and keep an updated inventory as per UNEP templates
- Ensure that consultants and project partner organizations deliver against their contracts and in time (in collaboration with PMU)
- Provide support to the Project M&E activities.
- Participate on the SC meetings

Project collaborators: Partner organizations, sectoral ministries, scientific institutions, etc. will be involved in the Project to provide expertise in environmental knowledge and information management, regular updates on biosafety activities in the country, staff time and experience in guiding and advancing the activities' implementation, support the Project with robust field data on biosafety issues at stake, linking with stakeholders, including at local level for project implementation and for receiving and transferring stakeholder input and feedback.

National consultancy services will be called in as required for specific tasks, such as needs assessments, legal advice, capacity development and training for key stakeholder groups, or modelling.

• DESCRIBE THE INTERNAL STRUCTURE

The PMU is responsible for the daily implementation of the project, including all reporting and monitoring and evaluation duties, as well as the follow-up of all contractual tasks. The PMU liaises with all project partners, and receives their technical advice and support. At the same time, the PMU serves as secretariat to the Project Steering Committee. PMU will liaise with the third party who will manage the funds (UNDP) to ensure timely submission of data to do the expenditures reports, processing of contracts, etc. A representative of UNDP will be part of the PMU to facilitate interaction.

• DESCRIBE THE EXTERNAL STRUCTURE

The Project Steering Committee, chaired by the EA, is in charge of project oversight and overall guidance. It will meet at least on an annual basis or according to the project's needs.

• DESCRIBE THE OVERSIGHT MECHANISM

The main oversight body for the project is its Steering Committee, comprised of the Implementing Agency, the Executing Agency, fund management agency and representatives of all main partners and stakeholder groups. Further monitoring and evaluation procedures of the project, including regular reporting duties, are detailed in Annex G and Appendix 4. The Executing Agency can undertake field visits at any stage and is tasked to support the mid-term review and terminal evaluation and audit of the project.

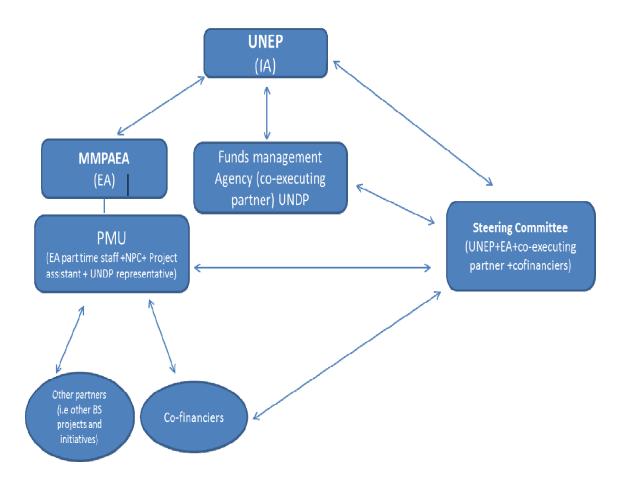


Fig.1. Executing arrangements

ANNEX I: Detailed project workplan Separate document

ANNEX J: Focal Area Tracking Tools

ANNEX K: OFP Endorsement letters

Separate document

ANNEX L: Co-finance letters

Separate document

ANNEX M: Environmental and social safeguards checklist

Checklist for Environmental and Social issues

Please note that as part of the GEFs evolving Fiduciary Standards that Implementing Agencies have to meet is the need to address 'Environmental and Social Safeguards'.

To address this requirement UNEP-GEF have developed this checklist with the following guidance:

- 1. Initially filled in during concept development to help guide in the identification of possible risks and activities that will need to be included in the project design.
- 2. A completed checklist should accompany the PIF
- 3. Check list reviewed during PPG phase and updated as required
- 4. Final check list submitted with Project Package clearly showing what activities are being undertaken to address issues identified

Project Title:	Implementation of the National Biosafety Framework in Venezuela in accordance to the Cartagena Protocol on Biosafety					
GEF project ID and UNEP ID/IMIS Number	UNEP ADDIS: 01068					
Project status (preparation, implementation, MTE/MTR, TE)	CEO-endorsement request Date of this version: 11-03-16					
Checklist prepared by (Name, Title, and Institution)	Marianela Araya, Task Mana	ger UNEP BD Unit				

In completing the checklist both short- and long-term impact shall be considered.

Section A: Project location

If negative impact is identified or anticipated the Comment/Explanation field needs to include: Project stage for addressing the issue; Responsibility for addressing the issue; Budget implications, and other comments.

	Yes/No/N.A.	Comment/explanation
- Is the project area in or close to -		
- densely populated area	N/A	Project mainly in capacity building issues. Project will be executed from Caracas, the capital, with sensitization and public awareness activities taking place in other areas of the county.
- cultural heritage site	N/A	
- protected area	N/A	
- wetland	N/A	
- mangrove	N/A	
- estuarine	N/A	
- buffer zone of protected area	N/A	
- special area for protection of biodiversity	N/A	

- Will project require temporary or permanent support facilities?	No	The project will be executed through the Ministry of Ecosocialism and Water, and the project unit will be hosted there.		
If the project is anticipated to impact any of the above areas an Environmental Survey will be needed to determine if the project is in				
conflict with the protection of the area or if it will cause significant disturbance to the area.				

Section B: Environmental impacts

If negative impact is identified or anticipated the Comment/Explanation field needs to include: Project stage for addressing the issue; Responsibility for addressing the issue; Budget implications, and other comments.

	Yes/No/N.A.	Comment/explanation
- Are ecosystems related to project fragile or degraded?	N/A	Project activities are mainly capacity building
- Will project cause any loss of precious ecology, ecological, and economic functions due to construction of infrastructure?	N/A	The project will not engage in any construction. Only an existing laboratory facility will be enhanced, and it will be mainly through installation of equipment, work tables, etc.
- Will project cause impairment of ecological opportunities?	N/A	
Will project cause increase in peak and flood flows? (including from temporary or permanent waste waters)	N/A	
- Will project cause air, soil or water pollution?	N/A	
- Will project cause soil erosion and siltation?	N/A	
- Will project cause increased waste production?	N/A	
- Will project cause Hazardous Waste production?	N/A	
- Will project cause threat to local ecosystems due to invasive species?	N/A	No, all the contrary the project will implement biosafety measures for the management of GMOs.
- Will project cause Greenhouse Gas Emissions?	N/A	
- Other environmental issues, e.g. noise and traffic	N/A	
Only if it can be carefully justified that any negative both in the short and long-term, can the project go a		roject can be avoided or mitigated satisfactorily

Section C: Social impacts

If negative impact is identified or anticipated the Comment/Explanation field needs to include: Project stage for addressing the issue; Responsibility for addressing the issue; Budget implications, and other comments.

	Yes/No/N.A.	Comment/explanation
- Does the project respect internationally proclaimed human rights including dignity, cultural property and uniqueness and rights of indigenous people?	Yes	The project has taken into account cultural property and socio-economic considerations. This is part of the biosafety framework that will be established, which is expected to safeguard local biodiversity that is also important for various society groups.
- Are property rights on resources such as land tenure recognized by the existing laws in affected countries?	N/A	
- Will the project cause social problems and conflicts related to land tenure and access to resources?	N/A	
- Does the project incorporate measures to allow affected stakeholders' information and consultation?	Yes	The project included informative activities through public awareness and sensitization campaigns, and through the establishment of mechanisms for participation in decision-making. In addition, the project SC will be conform of a variety of stakeholders, amongst which the main entities that will have a role in biosafety activities at a national level.
- Will the project affect the state of the targeted country's (-ies') institutional context?	Yes	The project will enhance and strengthen institutional capacities at the community and national level.
- Will the project cause change to beneficial uses of land or resources? (incl. loss of downstream beneficial uses (water supply or fisheries)?	N/A	
- Will the project cause technology or land use modification that may change present social and	No	The project does not promote the use of any particular technology; it only creates regulatory capacity for the

	Yes/No/N.A.	Comment/explanation
economic activities?		country to take informed decisions. Therefore, the project itself will not cause modifications to social or economic activities. It will however raise awareness and create technical capacity that over time could contribute to the execution of particular activities.
- Will the project cause dislocation or involuntary resettlement of people?	No	
- Will the project cause uncontrolled in-migration (short- and long-term) with opening of roads to areas and possible overloading of social infrastructure?	No	
- Will the project cause increased local or regional unemployment?	No	
- Does the project include measures to avoid forced or child labour?	N/A	
- Does the project include measures to ensure a safe and healthy working environment for workers employed as part of the project?	N/A	
- Will the project cause impairment of recreational opportunities?	No	
- Will the project cause impairment of indigenous people's livelihoods or belief systems?	No	
- Will the project cause disproportionate impact to women or other disadvantaged or vulnerable groups?	No	
- Will the project involve and or be complicit in the alteration, damage or removal of any critical cultural heritage?	No	
- Does the project include measures to avoid corruption?	Yes	UNEP fiduciary standards will be followed as a requirement of UNEP as a GEF IA.
Only if it can be carefully justified that any negative impa and long-term, can the project go ahead.	ct from the project	t can be avoided or mitigated satisfactorily both in the short

Section D: Other considerations

If negative impact is identified or anticipated the Comment/Explanation field needs to include: Project stage for addressing the issue; Responsibility for addressing the issue; Budget implications, and other comments.

i	Yes/No/N.A.	Comment/explanation
- Does national regulation in affected country (-ies) require EIA and/or ESIA for this type of activity?	N/A	
- Is there national capacity to ensure a sound implementation of EIA and/or SIA requirements present in affected country (-ies)?	N/A	
 Is the project addressing issues, which are already addressed by other alternative approaches and projects? 	No	The scope of the project is different from the one of other initiatives. However, the project will look for synergies and avoid duplication.

ANNEX N: Acronyms and abbreviations

ACRONYMS AND ABBREVIATIONS

BCH Biosafety Clearing House

CBD Convention on Biological Diversity
CNBio National Biosafety Commission
CPB Cartagena Protocol on Biosafety
EO Evaluation Office of UNEP
GEF Global Environment Facility
GMO Genetically Modified Organism

INIA National Agricultural Research Institute
IVIC Venezuelan Institute for Scientific Research

LMO Living Modified Organism

M&E Project Monitoring and Evaluation

MAPT Ministry of Popular Power for Agricultural Production and Lands MINEA Ministry of Popular Power for the Environment and Water

MINPAL Ministry of Popular Power for Food MPPS Ministry of Popular Power for Health

MEUCT Ministry of Popular Power for Science, Technology and Innovation

MIC Ministry of Popular Power for Industry and Trade

MTE Mid-Term Evaluation

NBF National Biosafety Framework
NCA National Competent Authority
NEA National Executing Agency
NPC National Project Coordinator
PSC Project Steering Committee
R+D Research and Development

TE Terminal Evaluation

UNEP United Nations Environment Programme

UCV Central University of Venezuela

USB Simon Bolivar University

Appendix 1: Supervision plan

Separate document

Appendix 2: Procurement plan

UNEP/GEF Project Procurement Plan

Project title: Implementation of the National Biosafety Framework in Venezuela in accordance to the Cartagena Protocol on Biosafety

ADDIS Number: 01068

UNI	EP Budget Line	List of Goods and Services required	Budget (US\$)	Year	Brief description of anticipated procurement process
1101	Project Manager	Administrative responsibilities	12,750	1 to 4	Administrative coordinator to be hired through TDRs publication and review of the CV of proposals by EA.
1200	Consultants	See annex E of the CEO ER for full list of consultants	235,000	1 to 4	TDRs publication and Review CV of proposals.
4101	Office supplies and consumables	Various items for admin operation of the project.	4,186	1 to 4	Selection of goods providers by marker rates of the equipment and request of purchase order to the administrator.
4102	Laboratory supplies and consumables	-General RT-PCR kit. FastStart DNA. Capacity for 96 reactionsDNA Extraction kit for plant samplesTaq DNA Polymerase 10X Buffer B and 25 mM MgCl2 solution 500uD1 LE Agarose EEO GQT. 100g 152 Conda -Acrylamide, 99% Pure, Dangerous (UN2074). 100gAmmonium Persulfate 25g, Dangerous (UN1444)Bisacrylamide 25gTAE, 10X 1,000mlTBE, 10X 1,000 mlTEA. 1X Buffer. 500mlEthidium bromide -SYBR GreenMolecular Grade 100ml FormamideGlycine, Molecular Grade 1kgSodium chloride 1kgSodium lauryl sarcosinate (Sarcozil)Tris Base 500gTris-HCl, Molecular Biology Grade.	50,850		Selection of goods providers by marker rates of the equipment and request of purchase order to the administrator.

		T =			T
		-Triton X-100 100 mL.			
		-Tween 20 100ml.			
		-Urea, 99% Pure 1kg.			
		-Liters of acetic acid.			
		-Silver nitrate. 100 g.			
		-CTAB			
		-Ethanol 99%			
		-Glacial acetic acid			
		-Potassium acetate for molecular			
		biology			
		-Hydrochloric acid (HCL)			
		isoamyl alcohol			
		-Phenol			
		-Chloroform			
		-Tris (hydroxymethyl) - aminomethane			
		-Disodium EDTA (NA2-EDTA)			
		-Potassium hydroxide (KOH)			
		-Potassium Chloride (KCL)			
		-Sodium dodecyl sulfate (SDS)			
		-protein K			
		-RNase, DNase free			
		-isopropanol			
		-Sodium hydroxide (NaOH)			
		-Alfha- amylase			
		-Boric acid P.M: 61.84			
		-EDTA free acid P.M: 292.2			
		-Glycerol			
		-Bromophenol Blue			
		-Kit lateral flow strips, protein			
		detection RUR (CP4 EPSPS) level			
		leaves and seeds			
		-Kit lateral flow strips, Cry3Bb protein			
		detection (Bt-Cry3Bb) level leaves and			
		seeds			
		-Kit lateral flow strips, protein			
		detection Cry1Bb (Bt-Cry1Bb) level			
		leaves and seeds			
		-Kit lateral flow strips, triple protein			
		detection level stored grains			
		_			
4201	Favinment for	Buffer to load gels, Blue / Orange.	11 000	1	Coloation of and de
4201	Equipment for	Purchase one Xerox machine,	11,000	1	Selection of goods
	project office	computers, printers, projector a for			providers by marker
		use of all components			rates of the equipment
					and request of purchase
					order to the
					administrator.
4202	Lab equipment	-Termociclador In real time.	528,724	1	Selection of goods
		-Termociclador Final time.			providers by marker
		-Double boiler for temperatures of 5 $^{\circ}$			rates of the equipment
		C-200 ° C			and request of purchase
		-Water filter			order to the
		-system Water purification.			administrator.
		-iron Heating and agitation ceramic			
		stop.			
		Ultra Low Temperature -Freezer.			
		-Refrigerator With sliding doors.			
		-Analytical balance			
		-Precision scale.			
		-Punzón For sampling and			
1		-1 unzon roi samping and			I

measurement in stored grain moisture		
in sacks or bales, 10 "length		
-Mixer Vortex.		
-Sterilizer. Internal water pump.		
UV -Transluminador.		
-Transluminador White light.		
-Pump Vacuum / pressure.		
UV / VIS Spectrophotometer compact		
for application in molecular biology.		
-system Gel documentation.		
-Camera Horizontal electrophoresis		
-Camera Vertical electrophoresis.		
-Stove For drying seeds		
-Power Power to electrophoresis		
chamber		
Analytical -Mill for grinding grain,		
A11, IKA * Works		
-PC notebook (laptop) Core2Duo /		
2GB / 320GB / DVD-RW / 14 "		
Voltage-regulators.		
-Team ultrasonic washing materials		
-Regulador Computer UPS for 115V		
60 Hz Mod. 1062F		
-Cabin For PCR with UV light		
Materials:		
-IENCEWARE Spatula, stainless steel,		
teflon coated tips, length 8 1/4 "with a		
spearhead.		
-CIENCEWARE Spatula, stainless		
steel, teflon coated tips, length 7 1/4		
"with a spearhead.		
-CIENCEWARE Spatula, stainless		
steel, I with a tip bucket capacity area		
1 "1 / 2 and the other flat tip.		
-CIENCEWARE Spatula, stainless		
steel, teflon coated, length 7 1/4 "with		
a square toe and the other rounded.		
-Porcelain mortar with pestle 65 mL		
capacity.		
-Porcelain mortar with pestle 275 mL		
capacity.		
-magnetic bars kit with ring, Cole-		
Parmer, 2 bars 1/2 x 5/16 ", 2 5/8 x		
5/16 bars", 2 bars 1 x 3/8 ", 2 bars 1-1 /		
2 x 3/8 "x 2 3/8 bars 2", 2 bars 2-1 / 2		
x 3/8 "		
-Graduated bottle for storage, capacity		
50 mL, screw top in clear glass wide		
mouth.		
-Graduated bottle for storage, capacity		
100 mL, screw top in clear glass wide		
mouth.		
-Graduated bottle for storage, capacity		
250 mL, screw top in clear glass wide		
mouth.		
-Graduated bottle for storage, capacity		
500 mL, screw top in clear glass wide		
1 , 1	 	

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1.5 -Porta PCR tubes 0.2 ml -Tube support system of laboratory wall rack for drying glassware -Polycarbonate Enclosures with lid w /				
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-Tube support system of laboratory wall rack for drying glassware -Polycarbonate Enclosures with lid w /		-Porta PCR tubes 0.2 ml		
wall rack for drying glassware -Polycarbonate Enclosures with lid w /	1			
-Polycarbonate Enclosures with lid w /				
-Polycarbonate Enclosures with lid w /		wall rack for drying glassware		
1 temp resistant tube 1. 135 °C at 21 °				
		1 emp resistant tube 1. 135 ° C at 21 °		

		C (caja10 pcs)		
		-Pipettes dispensing capacity of 1 ml		
		dispensing pipettes 3 ml capacity		
		dispensing water bottles 250 ml.		
		-High resolution Thermometer		
		-Kit glass thermometers		
		-Laboratory filter paper 18.5 cm in		
		diameter system vacuum filtration		
		nitro cellulose filters, capacity of 1000		
		ml.		
		-Check valve of 1 1/2 ° with filter for		
		passage of water into the laboratory		
		facility		
4302	Research	-Supply and installation of mesons	200,240	Selection of goods
	facilities	with marble top or COLORBAK, with		providers by marker
		40 linear meters covered in 9		rates of the equipment
		workrooms		and request of purchase
		-Supply and installation of 2 display		order to the
		cases floor with the following		administrator.
		dimensions 120 X 40 X180 cm, with		
		two hinged doors of glass and metal		
		frame with four panels		
		-ATM -type chairs with adjustable		
		height		
		-Supply and installation of an		
		integrated emergency system,		
		consisting of shower and eyewash		
		ceiling		
		cennig		
		Services:		
		-Supply and installation of electric		
		plant with a capacity of 100 KVA,		
		with storage tank Disel approximately		
		500 L		
		-Window type air conditioner, 220 W.		
		12000 BTU		
		-Construction of infrastructure for		
		electric plant dispocision taking into		
		account the safety PROVISIONS ON		
		this type of equipment		
		-Supply and installation of electrical		
		connection inside the halls of the		
		laboratory where currently some		
		power failures occur.		
		-Supply and installation of grounding		
		system around the laboratory facilities		
		in order to provide safety standards for		
1		good functioning of electrical		
		equipment		
		-Maintenance and replacement of parts		
		comprising the hydraulic system of the		
		laboratory: the activity includes the		
1		cleaning of storage tank, check valves		
1		change in poor condition, instalci filter		
1		carbon-clay to reduce the hardness of		
1		the water entering the laboratory.		
		-Project Implementation:		
		Electrification of medium voltage		
		Biological Station Rancho Grande		
<u> </u>	<u> </u>	Diological Station Kancilo Grande		<u> </u>

	Museum and Reference Laboratory for the Detection of Genetically Modified Organisms. -Supply, transportation and placement of lattice panoramic System -Supply, transportation and placement of anti-insect mesh -Supply, transportation and placement of decorative shutters. Silver Colour -Supply, transportation and placement antipanico aluminum doors for laboratories -Supply, transportation and placement Aluminium doors for bathrooms -Supply, transportation and placement Guarda clothes (locker)Supply, transportation and placement of toilet paper (A / I) -Supply stainless steel bins -Supply, transportation and installation of bathroom accessories for draping (60cm long) stainless steel screws to fixSupply, transportation and placement of decorative mirrors. Length: 1.30m, height: 1.00m, to fix with screws.			
5100	Total Equipment			
5375	MOU with a Third Party for the management of GEF funds of the project. Third party will issue contracts, advertise vacancies, process payments and contribute with the generation of expenditure repots and audits.	137,250	1 to 4	Review, approval and sign of the MOU by the two parties involved in it
GRAND TOTAL		1,180,000		

Appendix 3: TORs for key personnel

NPC TOR

This is a full time position. The NPC will be based at MINEA offices, under the supervision of the director of the biological diversity unit, and will work closely with the fund management agency to ensure proper project execution and reporting.

Profile:

Person should have a degree in areas such as: agronomy, biology, biotechnology, forestry, or related areas; with advance knowledge of biosafety related matters and the Cartagena Protocol in Biosafety. At least 4 years technical experience in biosafety and 4 years experience in project management.

The responsibilities of the NPC will be of technical and administrative nature. The following table describes the main duties and the outputs expected.

Main Duty	Output	Timing
Administrative duties (15 % of the time)		
Prepare a specific work plan and time table that includes the methodology to achieve the expected results (outcomes) and products (outputs) of the current Project, and discuss it with the EA. This work plan must be based on the project work plan and time table and will be revised annually. This work plan will indicate technical aspects to consider when undertaking the activities, selecting candidates for positions, amongst others.	Detailed work plan and time table	Activities will be realized during the 4 years of project management and in accordance with the provisions of the project work plan.
Maintain close communication and coordination directly with the executing agency, fund manager, project staff as well as all subcontracted consultants. Provide technical advice and supervision to consultants and project's activities.	Work plan executed according to timeframes and requested details	Idem
Establish, coordinate and maintain effective communication with different sectors, stakeholders and National Competent authorities (Governmental entities, nongovernmental entities, academic sectors, private sector, and civil society) to facilitate the achievement of project objectives and outcomes and create synergy among sectors.	Work plan executed according to timeframes and requested details	Idem
Exploring and promoting synergies with other relevant existing biosafety initiatives	MoU's, Letters of Intend, Strategic Alliances/partnerships.	Idem
Review TOR's and participate in interviewing consultants according to the project procurement plan and requirements, in coordination with the funds management agency	Consultancy contracts, services and acquisitions.	Idem
Coordination for the execution of all work plan activities to ensure timely and smart implementation of the project components according to the project M&E.	Activities efficiently executed according to the project M&E plan	Idem
To coordinate and lead high level meetings with politicians and decision-makers to seek their support to the project and to promote project outputs.	Meetings held and minutes developed.	idem
Organizing Steering Committee (SC) meetings and acting as SC's secretary	SC's meetings, aide-mémoire.	Idem

Main Duty	Output	Timing	
Present technical and financial progress reports at different stages of the Project (according to UNEP and GEF formats), based on the products specified and on the expected dates. All reports are subject to revision and are not considered final until any comments and observations are incorporated and reports approved by the EA and IA. Reports include, but are not limited to these outputs. NCP will be responsible for the coordination of all financial and administrative processes, plans and reports, in coordination with the EA,the fund management agency, in line with the Project document and the respective agreements signed with UNEP	Procurement plan; Inception Workshop Report; Quarterly expenditure report accompanied by explanatory notes (Fund management agency generates first draft and NCP should revise adapt if needed and input co-finance data and obtain signature for the report); Quarterly cash advance request and details of anticipated disbursements ; Half yearly progress report; Yearly audited report for expenditures; Yearly inventory of non- expendable equipment; Yearly co-financing report; Yearly project implementation review (PIR) report; Quarterly minutes of steering committee meetings; Final report; Final inventory of non- expendable equipment; Equipment transfer letters; Final expenditure statement; Mid-term review or Mid-term evaluation; Final audited report for expenditures of project; Independent terminal evaluation.	Idem	
Technical tasks (85 % of the time)			
Provide technical advice and supervision to consultants and project's activities. The NPC will revise all technical products produced by consultants to ensure alignment with project objectives and quality standards.	Finalized and approved technical products	Idem	
The NPC will be key as a technical facilitator of the process and to promote the acceptance of project technical outputs by NCAs and other partners.	Finalized and approved technical products		
Technical expertise of the NPC will be mandatory to promote synergies of this project with other initiatives as well as to successfully identify key information or materials that have been generated by other initiatives and that could be beneficial for this project.	MoU's , Letters of Intent, Strategic Alliances/partnerships	Idem	
Technical leader facilitator of the project components. He/she will also be in charge of producing and delivering specific technical products based in his/her professional experience. 1) finalized and approved technical products (1.1.1a, 1.1.5 a, 2.1.1a 3.1.1a, 3.1.2a, 3.1.2b, 3.3.1a) as indicated in the project's work		Idem	

Appendix 4: Summary of reporting requirements and responsibilities

Reporting requirements	Due date	Format appended to legal instrument as	Responsibility of
Procurement plan (goods and services)	2 weeks before project inception meeting	N/A	Project Manager
Inception Report	1 month after project inception meeting	N/A	Project Manager
Expenditure report accompanied by explanatory notes	Half-yearly on or before 31 July and 31 January	Annex 11	Project Manager
Cash Advance request and details of anticipated disbursements	Hal-yearly or when required	Annex 7B	Project Manager
Progress report	Half-yearly on or before 31 July and 31 January	Annex 8	Project Manager
Audited report for expenditures for year ending 31 December	Yearly on or before 30 June	N/A	Executing Agency to contract firm
Inventory of non-expendable equipment	Yearly on or before 31 January	Annex 6A	Project Manager
Co-financing report	Yearly on or before 31 July	Annex 12	Project Manager
Project implementation review (PIR) report	Yearly on or before 31 July	Annex 9	Project Manager, UNEP Task Manager and FMO
Minutes of steering committee meetings	Yearly (or as relevant)	N/A	Project Manager
Mission reports and "aide memoire" for executing agency	Within 2 weeks of return	N/A	UNEP Task Manager and FMO
Final report	2 months of project completion	Annex 10	Project Manager
Final inventory of non-expendable equipment	date	Annex 6A	Project Manager
Equipment transfer letter		Annex 6B	Project Manager
Final expenditure statement	3 months of project completion date	Annex 11	Project Manager
Mid-term review or Mid-term evaluation	Midway through project	N/A	Task Manager or UNEP-EOU (as relevant)
Final audited report for expenditures of project	Within 6 months of project completion date	N/A	Executing partner to contract firm
Independent terminal evaluation report	Within 6 months of project completion date	Appendix 9 to this Project Document	UNEP-EOU