



PROJECT IDENTIFICATION FORM (PIF)

PROJECT TYPE:

TYPE OF TRUST FUND:

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PART I: PROJECT IDENTIFICATION

Project Title:	Implementation of the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety (CPB)		
Country(ies):	Sri Lanka	GEF Project ID:¹	
GEF Agency(ies):	FAO	GEF Agency Project ID:	628897
Other Executing Partner(s):	Ministry of Environment and Renewable Energy	Submission Date:	March 21, 2014
GEF Focal Area (s):	Biodiversity	Project Duration (months):	48 months
Name of parent program (if applicable):		Agency Fee (\$):	224,767
<ul style="list-style-type: none"> For SFM/REDD+ <input type="checkbox"/> For SGP <input type="checkbox"/> For PPP <input type="checkbox"/> 			

A. FOCAL AREA STRATEGY FRAMEWORK²:

Focal Area Objectives	Trust Fund	Indicative Grant Amount (\$)	Indicative Co-Financing (\$)
BD-3: Build Capacity for the Implementation of the Cartagena Protocol on Biosafety	GEFTF	2,365,964	2,366,000
Total project costs		2,365,964	2,366,000

B. PROJECT FRAMEWORK

Project Objective: To strengthen institutional, regulatory and technical capacities for the effective implementation of the National Biosafety Framework in conformity with the Cartagena Protocol on Biosafety (CPB)

Project Component	Grant Type ³	Expected Outcomes	Expected Outputs	Trust Fund	Indicative Grant Amount (\$)	Indicative Co-financing (\$)
1. Strengthening policy, institutional and regulatory frameworks for biosafety	TA	1.1 Enhanced capacity to develop, implement and coordinate biosafety legislations and regulations 1.2 Administrative systems for biosafety fully functional	1.1.1 National Biosafety Act enacted 1.1.2 National Biosafety Master Plan (Strategy & Action Plan) elaborated and endorsed 1.1.3. Relevant regulations reviewed, drafted and endorsed 1.2.1 Administrative and operational procedures for biosafety reviewed and updated 1.2.2 Guidelines developed to support the tasks of National Competent Authority (NCA) and Sectoral Competent Authorities	GEFTF	382,000	462,000

¹ Project ID number will be assigned by GEFSEC.

² Refer to the reference attached on the Focal Area Results Framework and LDCF/SCCF Framework when completing table A.

³ TA includes capacity building and research and development.

		1.3 National Biosafety Clearing House (BCH) operational	<p>(SCAs)</p> <p>1.2.3 Staff of NCA, SCAs and related organizations trained</p> <p>1.3.1 An enhanced website established</p> <p>1.3.2 The BCH focal point trained to collect and manage information</p> <p>1.3.3 Stakeholders trained to access and share information through BCH</p>			
2. Enhancing system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC)	TA	2.1 National institutions strengthened for RA, RM and RC including monitoring and enforcement	<p>2.1.1 Methodologies for RA, RM and RC reviewed, refined and updated</p> <p>2.1.2 Technical guidelines and manuals on RA and RM developed</p> <p>2.1.3 Decision making tools prepared for RA, RM and RC</p> <p>2.1.4 Training strategy for RA, RM and RC developed</p> <p>2.1.5 Staff of relevant institutions trained on RA, RM and RC</p> <p>2.1.6 National and regional institutional networks strengthened to implement National Biosafety System</p>	GEFTF	673,299	670,000
3. Developing technical capacity for detection and identification of living modified organisms (LMOs) and strengthening biosafety-related infrastructure	TA	<p>3.1 Improved capacity for detection and identification of LMOs</p> <p>3.2 Laboratories fully operational with the necessary infrastructures to carry out risk assessment, and detection of LMOs, which allow Sri Lanka to meet its obligations under the CPB</p>	<p>3.1.1 Testing needs and capacities for LMO detection assessed and key public laboratories identified for upgrading and accreditation</p> <p>3.1.2 Inspection plan prepared and inspectors trained</p> <p>3.1.3 Personnel trained on LMO detection and identification</p> <p>3.2.1 Key government laboratories identified, established, strengthened and appropriately equipped for risk management and detection of LMOs</p> <p>3.2.2 Laboratories accredited by SLAB for risk assessment, LMO detection and identification based on ISO and ISTA standards</p>	GEFTF	990,000	775,000

4. Knowledge development, public awareness, education and participation	TA	4.1 Enhanced awareness, education and public participation in decision-making on biosafety	4.1.1 Public awareness and participation strategy developed 4.1.2 Targeted awareness-raising activities implemented 4.1.3 Curriculum, syllabus and course materials prepared for post-graduate course for biosafety, and the gaps in primary (Ordinary Level), secondary and university level education for biosafety filled through improvement of curricula. 4.1.4 Information materials developed and disseminated through various media 4.1.5 Monitoring & Evaluation system established to measure project progress and impact 4.1.6 Mid-term and final evaluations carried out	GEFTF	208,000	288,000
Sub-Total					2,253,299	2,195,000
Project management Cost (PMC) ⁴					112,665	171,000
Total project costs ⁴					2,365,964	2,366,000

C. INDICATIVE CO-FINANCING FOR THE PROJECT BY SOURCE AND BY NAME IF AVAILABLE, (\$)

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Amount (\$)
National Government	The Government of Sri Lanka	In-kind	1,866,000
National Government	Universities and Research Institutes	In-kind	100,000
GEF Agency	FAO	In-kind	400,000
Total Co-financing			2,366,000

D. INDICATIVE TRUST FUND RESOURCES REQUESTED BY AGENCY, FOCAL AREA(S) AND COUNTRY¹

GEF Agency	Type of Trust Funds	Focal Area	Country Name/ Global	Grant Amount (\$ (a)	Agency Fee (\$ (b) ²	Total (\$) c=a+b
FAO	GEFTF	BD-3	Sri Lanka	2,365,964	224,767	2,590,731
Total Grant Resources						2,590,731

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.

⁴ To be calculated as percent of subtotal

E. PROJECT PREPARATION GRANT (PPG)⁵

Please check on the appropriate box for PPG as needed for the project according to the GEF Project Grant:

- | | <u>Amount
Requested (\$)</u> | <u>Agency Fee
for PPG (\$)⁶</u> |
|--|----------------------------------|--|
| • No PPG required | | |
| • (Upto) \$50k for projects up to & including \$ 1 million | | |
| • (Upto) \$100k for projects up to & including \$ 3 million | USD 100,000 | USD 9,500 |
| • (Upto) \$150k for projects up to & including \$ 6 million | | |
| • (Upto) \$200k for projects up to & including \$ 10 million | | |
| • (Upto) \$300k for projects above \$ 10 million | | |

PPG AMOUNT REQUESTED BY AGENCY (IES), FOCAL AREA(S) AND COUNTRY(IES) FOR MFA AND/OR MTF PROJECT ONLY

Type of Trust Funds	GEF Agency	Focal Area	Country Name/ Global	PPG (\$) (a)	Agency Fee (\$) (b)	Total (\$) c=a+b
GEFTF	FAO	BD	Sri Lanka	100,000	9,500	109,500
Total Grant Resources						

⁵ On exceptional basis, PPG amount may differ upon detailed discussion and justification with the GEFSEC.

⁶ PPG fee percentage follows the percentage of the GEF Project Grant amount requested.

PART II: PROJECT JUSTIFICATION⁷

A. PROJECT OVERVIEW

A.1. Project description. Briefly describe the project, including: 1) the global environmental problems, root causes and barriers that need to be addressed; 2) baseline scenario and any associated baseline projects; 3) the proposed alternative scenario, with a brief description of expected outcomes and components and the project; 4) incremental cost reasoning and expected contributions from the baseline, the GEFTF, LDCF/SCCF and co-financing; 5) global benefits (GEFTF, NPTF) and adaptation benefits (LDCF/SCCF); 6) innovativeness, sustainability and potential for scaling up.

Background:

1. Sri Lanka possesses a very rich wealth of biological diversity, reportedly the richest per unit area of land in the Asian region. Sri Lanka's unique biodiversity has a very high global significance. It has been classified by Conservation International (CI) as one of the "biodiversity hot spots" together with the Western Ghats in India based on the number of endemic plants and vertebrates. Sri Lanka has several distinct climatic zones, each with their characteristic forests. They include rainforests, montane cloud forests, dry zone monsoon forests and arid thorn scrub forests. Sri Lanka's wetlands are also diverse, comprising 103 major rivers with their associated marshes and about 12,000 irrigation tanks that harbour wetland species. Being an island, the country has a rich marine and coastal biodiversity along its 1,620 km coastline including coral reefs, mangroves, sea grass beds, salt marsh vegetation, sand dunes and beaches. The conservation and sustainable use of biological diversity is of special significance to Sri Lanka because of its predominantly agriculture based economy and the high dependence on agricultural biodiversity including many plant species for food, medicines and domestic products.

Threats:

2. Sri Lanka has identified the promotion of biotechnology as one of its national priorities in agriculture and formulated National Biotechnology Policy (NBP) in 2009 to harness the potential of biotechnology for economic development and for the improvement of quality of life of people. The NBP highlights the need for promotion of biotechnology and supports R&D in various government institutions to develop biotech products to enhance food production, to increase opportunities for local industries and to use biodiversity in a sustainable manner.

3. Production and global trade of living modified organisms (LMOs) are also rapidly increasing. Sri Lanka's food security and local industry needs require importing some of these LMOs for direct consumption and for propagation under local condition.

4. It is recognized, however, that modern biotechnology, in particular genetic engineering, should be developed and used with adequate safety measures for the protection of environment, biodiversity and human health since much is still unknown about how LMOs may behave and evolve, and how they may interact with other species and impact on biodiversity. For example, an ability of LMOs to tolerate herbicides may transfer to related wild species. Plants that have been genetically-modified to repel pests also might harm beneficial insects. The increased competitiveness of LMOs may cause damage to biologically-rich ecosystems.

5. It is therefore imperative for Sri Lanka to develop and implement an effective national biosafety system by establishing practical rules and procedures for risk analysis, safe transfer, handling and use of LMOs, with a specific focus on ensuring the safe movements of LMOs across borders.

Baseline:

6. The proposed project will build on ongoing initiatives by the Government of Sri Lanka to establish and implement effective national biosafety system. The baseline scenario provides a solid basis for the envisioned activities of this GEF project. However, limitations in institutional and technical capacity as well as knowledge and awareness about biosafety will significantly impede the success of the baseline activities without GEF's incremental investment. The proposed project will target these barriers and catalyze the achievement of Global Environmental Benefits building on the baseline situation.

Policy and legal framework:

⁷ Part II should not be longer than 5 pages

7. The Government of Sri Lanka signed and ratified the Cartagena Protocol on Biosafety in 2000 and in 2004 respectively. Recognizing the importance of establishing credible and effective safeguards for LMOs to maximize the benefits of modern biotechnology while minimizing its potential risks, Sri Lanka committed itself to develop and implement national biosafety framework based on sound science and precautionary principle.

8. Under UNEP/GEF funded “National Biosafety Framework Development Project” (2003 - 2005), Sri Lanka developed its National Biosafety Framework, comprising five sections, namely; government policy on biosafety, regulatory regime, system to handle notifications or requests for authorizations, mechanisms for public awareness, education and participation, and system of monitoring and enforcement. National Biosafety Policy was prepared in 2005 in order to set the overall framework under which Sri Lanka can identify and manage potential risks of LMOs to environment and human health while maximizing benefit from modern biotechnology.

9. The country has also recently drafted a Biosafety Act, which is being reviewed at Legal Draftsman’s Department at present. The draft Act stipulates that release of LMOs or GMOs should be undertaken in a manner that prevents or reduces risks to biological diversity and human health. It requires any exporter to notify the National Competent Authority in writing prior to the transboundary movement of LMOs/GMOs. It is a legal requirement to provide complete and accurate information of all required particulars in the application. The National Competent Authority, if it is deemed necessary, requires Sectoral Competent Authorities to carry out risk assessment on a case by case basis.

10. At the moment, until the Biosafety Act is enacted, some provisions in existing laws are used to control the introduction of GMOs. Food Act 2006, for example, regulates GM food items and includes provisions concerning import, labelling and sale of GM food. According to the act, no person shall import, store, transport, distribute, sell or offer for sale, any GMO as food for human consumption, any food containing of GMOs or any food produced from ingredients produced from GMOs without approval of Chief Food Authority. In addition, Plant Protection Act (No 35 of 1999) aims to make provisions to prevent the introduction and spread of any organism harmful or injurious to plants or destructive to plants found in Sri Lanka. These provisions can be used to prevent the import of any genetically-modified plasmids that could be potentially harmful to plants.

Institutional setup and implementation mechanisms:

11. National Biosafety Framework (2005) proposes that Sri Lanka’s national biosafety system be implemented through a range of government institutions. The Ministry of Environment and Renewable Energy (MoERE), which is the National Focal Point for the Convention on Biological Diversity and for Cartagena Protocol on Biosafety, functions as National Competent Authority for biosafety. MOERE also serves as National Focal Point for the Biosafety Clearing-House (BCH) to liaise with the Secretariat regarding the development and implementation of the BCH. National BCH of the country was established with the support of UNEP-GEF project on “Building capacity for effective participation in the Biosafety Clearing House (BCH-I, 2006-2009)” in order to fully participate and benefit from the international BCH and to comply with its obligations under the Protocol.

12. National Coordinating Committee on Biosafety (NCCBS), comprising relevant ministries as well as representative from NGO, oversees and coordinates all matters related to biosafety including risk assessment. Six government organizations were proposed to serve as Sectoral Competent Authorities (SCAs), namely; Department of Agriculture, Department of Animal Production and Health, Department of Health, Department of Fisheries and Aquatic Resources, Department of Wildlife Conservation, and Ministry of Industry. Qualified personnel from those departments are requested to conduct risk analysis when application of importation of LMOs is submitted. The Ministry of Health, in particular, is mandated to enforce regulations related GM food under Food Act and it also conducts inspection of GMOs for human consumption through random sampling by inspectors. The Customs Department and National Plant Quarantine Service also plays a significant role in controlling and monitoring import of LMOs/GMOs to the country.

13. The Sri Lanka Accreditation Board for Conformity Assessment (SLAB) is the National Accreditation Authority for Sri Lanka established under the Act No. 32 of 2005. The main objectives of SLAB are to strengthen the Quality Infrastructure and conformity assessment procedures in Sri Lanka, and enhance the recognition and acceptance of products and services in international and domestic markets. Accreditation is an endorsement of an organization’s competence, credibility, impartiality and integrity in carrying out its

conformity assessment activities. SLAB is a full member and signatory to the Mutual Recognition Arrangement (MRA) of the Asia Pacific Laboratory Accreditation Corporation (APLAC), International Laboratory Accreditation Cooperation (ILAC) and Pacific Accreditation Council (PAC). MRA means that an accreditation obtained in one country will be recognized in other member countries. SLAB is also in the process of seeking membership of the International Accreditation Forum (IAF) and has established a technical cooperation program with Swedish Board of Accreditation and Conformity Assessment (SWEDAC). These international accreditation bodies have established ISO standards for GMO detection in addition to ISO 17025.

14. The Department of Agriculture- Sri Lanka Central Seed Testing Laboratory is a member of the International Seed Testing Association (ISTA). ISTA has established an ISTA Rules Chapter for the detection, identification and quantification of GMO in conventional seeds, organizes proficiency tests on GMO testing, promotes exchange of information between laboratories through workshops and offers training programmes.

15. The National Council for Biotechnology was set up in August 2013 by a Coordinating Secretariat for Science and Technology Innovation (COSTI), which was established by the Cabinet of Ministers, in order to promote the conservation and use of biological diversity using modern biotechnology, bearing in mind safety aspects at all times. GM research is being carried out in the universities of Colombo, Peradeniya and University of Ruhuna at laboratory level. The Agricultural Biotechnology Centre at the University of Peradeniya (AgBC) carries out regular workshops on Biosafety, mainly on risk assessment and management and in GM testing procedures. The Board of Study in Agricultural Biology of the Postgraduate Institute of Agriculture (PGIA), University of Peradeniya, conducts the postgraduate course on Biosafety and it intends to propose a postgraduate Diploma course on Biosafety in the future. In addition, experts from the universities and other institutes such as Tea Research Institute, Rubber Research Institute, Coconut Research Institute and Rice Research and Development Institute contribute, as resource persons, to regular workshops on risk assessment and management which are supported by the Ministry of Environment and National Science Foundation.

16. The National Science Foundation (NSF) is a state funded institution under the Ministry of Technology and Research which is mandated to strengthen the Science and Technology sectors in Sri Lanka. It aims to facilitate research, development and innovation in all fields of science & technology including modern biotechnology. NSF has formulated guidelines for the safe use of Recombinant DNA technology under contained use conditions. It has also been contributing to establishing a conducive biosafety regulatory framework that takes into account balance of benefits and risks of genetic engineering technology through provision of scientific and technical inputs to the process of formulation of biosafety regulatory frameworks.

17. The Government of Sri Lanka's annual budget for operations related to establishment and implementation of biosafety system, carried out by various ministries and institutions, is approximately USD 500,000, amounting to USD 2 million over the project life. Main activities include: a) review and formulation of policies, legislations and regulations related to biosafety and biodiversity; b) coordination and implementation of activities in relation to biosafety, food safety, plant protection, and animal and human health, including risk assessment of LMOs; c) provide education and training, support research by universities and public research intuitions and create awareness on biosafety.

FAO's capacity development initiative on biosafety:

18. Another important initiative serving as a baseline activity for the proposed GEF project is the FAO's capacity development support for biosafety "Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia (2013)" and its follow up activities including the operationalization of "Asian BioNet" network. FAO has been assisting member countries, including Sri Lanka, since 1999 to support their efforts to put in place national biosafety regulatory frameworks that would facilitate rapid adoption of modern biotech products for agricultural development. Substantial support has been provided through projects such as "Capacity Development in Biosafety of LMO crops in Asia (GCP/RAS/185/JPN: 2002-2005)" and "Regional Biosafety Workshop (2009)". FAO's technical support on biosafety, with annual investment of around USD 100,000, is continuing through establishment and operationalization of "Asian Bio-Net" that aims to enhance regional cooperation for human and institutional capacity building.

Barriers to be addressed by the GEF project:

19. Despite above mentioned baseline activities in support of developing and implementing biosafety policies and regulations, Sri Lanka's biosafety systems will not be fully functional due to persistence of existing barriers, namely the weak institutional, technical and human resource capacities for implementing NBF. The proposed GEF intervention is designed to address these barriers.

20. **Barrier 1: Inadequate legal and regulatory frameworks:** Although National Biosafety Policy was formulated, there is no legal backing for the implementation of the policy because Biosafety Act is still in a draft stage. Under existing laws, regulations needed to fully operationalize risk analysis system have not yet been prepared for many of the sectoral competent authorities. The lack of effective legal and regulatory frameworks and guidelines to conduct risk assessment and management of LMOs constitute major barriers to the implementation of NBF.

21. **Barrier 2: Limited institutional, technical and human resource capacities:** Staff capacity of government agencies, including sectoral competent authorities and customs, and other relevant public and private research institutions remains insufficient to conduct risk analysis and detection of LMOs. Minimum experience of risk assessment, lack of clear administrative procedure as well as technical guidelines and manuals on Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC) represents a major impediment to the implementation of NBF. Weak inter-Institutional coordination also makes it difficult to implement effective biosafety system. Inadequate infrastructure and lack of accredited public laboratories for risk assessment, LMO detection and monitoring is another critical barrier. Capacity is also lacking to collect, process and manage the information required to effectively run the national BCH. Awareness about biosafety is still low among stakeholders, including in general public, increasing the risk of unauthorized and unintended release of LMOs in the environment.

22. The proposed project, therefore, seeks to address the above barriers by structuring itself around four main components: (1) Strengthening of policy, institutional and regulatory frameworks for biosafety; (2) Enhancing system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC); (3) Development of technical capacity for biosafety-related activities, and strengthening of biosafety related infrastructure, including required risk assessment studies, detection and identification of LMOs, and post-release monitoring; and (4) Knowledge development, public awareness, education and participation.

The proposed alternative scenario and incremental cost reasoning

23. The objective of the project is to strengthen Sri Lanka's regulatory, institutional and technical capacities for the effective implementation of the National Biosafety Framework (NBF). The proposed project will build on baseline activities to establish and implement national biosafety system.

24. Without GEF's support, the development of biosafety capacities in Sri Lanka will be slow and unable to effectively address the rapid development in modern biotechnology. The development of regulations and necessary administrative systems would occur only at a slow pace, and thus Sri Lanka's NBF will not be fully operational in the foreseeable future. In the absence of GEF support, the government will not be able to meet the challenge to strengthen technical and human resource capacities in biosafety that are necessary to enable the country to benefit from safe and responsible use of modern biotechnology. Without GEF support, Sri Lanka will not be able to safeguard its biodiversity and its vulnerable ecosystems from potential risks of LMOs. This will result in irreversible loss of biodiversity and ecosystems of significant global importance.

25. The GEF funded alternative will address the capacity barriers described above, enabling the implementation of NBF through executing the following four interlinked project components: (1) Strengthening of policy, institutional and regulatory frameworks for biosafety; (2) Enhancing system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC); (3) Development of technical capacity for detection and identification of LMOs; and (4) Knowledge development, public awareness, education and participation. These components are summarized in more detail below and will be elaborated fully under the PPG.

26. **Component 1: Strengthening policy, institutional and regulatory frameworks for biosafety.** Under Component 1, GEF support will help Sri Lanka to fill in the gaps in existing regulatory and institutional frameworks in order to implement the National Biosafety Framework (NBF) and to support establishment of sound decision making processes and law enforcement on biosafety. GEF incremental resources will also enable stakeholders to develop National Biosafety Master Plan which defines the strategies and steps needed to achieve the objectives outlined in the National Biosafety Policy.

27. This work will include the review, update and modification of biosafety related policies and programs, plans and project and the elaboration of regulations and administrative procedures related to risk analysis of LMOs as well as development of national rules and procedures on liability and redress in line with the

Nagoya-Kuala Lumpur Supplementary Protocol on liability and Redress. Inter-ministerial coordination will be strengthened to enable formulation and implementation of integrated and coherent biosafety regulatory mechanisms.

28. Also, under this component information management and sharing system on biosafety will be re-established, and national BCH will be strengthened. This component will help to collect, generate and share up-to-date national biosafety information in a manner that will promote transparency and accountability of decision-making. This strengthened information management system will provide regulatory bodies and stakeholders access to the latest information on biosafety.

29. Component 2: Enhancing system for Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC). Under this component, GEF funds will be used to strengthen the technical capacity of the relevant institutions to conduct Risk Assessment (RA), Risk Management (RM) and Risk Communication (RC). This work will enable Sri Lanka to execute sound, transparent and science-based analysis and decision-making in biosafety in consistent with international state-of-the-art practices and standards. Sufficient scientific and technical capacities will be installed within competent authorities by assisting in preparing technical guidelines and manuals, as well as decision-making tools, for risk analysis. Rules, procedures and protocols for RA, RM and RC will be elaborated through workshops and consultations. Procedure will also be established for identifying experts to conduct the risk assessment. Strategy to sustain biosafety training program during and beyond GEF support will be developed and human resource capacity will be built in its national institutions, including customs and quarantine services, through implementation of training courses and programmes and networking with other biosafety initiatives in the region.

30. Component 3: Developing technical capacity for detection and identification of LMOs and strengthening biosafety related infrastructure. This component aims to strengthen key laboratories for biosafety-related activities that should be fully operational with the necessary infrastructures to carry out required risk assessment studies, identification and detection of LMOs including post-release monitoring which allow Sri Lanka to meet its obligations under the CPB. This component will also help to enhance institutional, technical and human capacities in the areas of monitoring, inspection, detection and identification of LMOs, in particular those unauthorized or unintentionally released into the environment. The proposed project will allow Sri Lanka to put in place and implement an effective and efficient risk assessment, monitoring and enforcement system by assisting in establishing, upgrading and accrediting reference laboratories that could analyze, detect and identify LMOs in the context of national regulatory frameworks. In this component, technical and technological needs for LMO risk assessment, monitoring and detection, as well as capacities for inspection and regulatory enforcement, will be addressed.

31. This work will include an assessment/study of the testing needs and capacities for LMO risk analysis, detection, formulation of accreditation policies, procedures and requirements for biosafety laboratories; and the identification and accreditation of at least three public sector laboratories and three facilities for contained testing (at least BL2 greenhouses and confined field testing sites) to be established or upgraded and equipped with key instruments so that these laboratories have the appropriate competences for LMO analysis and that they can issue official risk assessment and detection reports according to international standards. Main functions of the laboratories and institutions and their needs for infrastructures and equipment, which will be addressed by incremental GEF investment, are as follows: (i) two laboratories to serve as central LMO biosafety research and detection laboratory fully equipped with state-of-the-art LMO detection equipment such as multiplex qualitative or quantitative real-time PCR, ELISA readers, high-throughput DNA-analysis equipment. The purpose of these laboratories can be divided into two: one laboratory to focus on development, adoption and validation of protocols and techniques for DNA detection and monitoring and provide services for DNA detection and monitoring needs of other partner institutions in biosafety implementation. The other laboratory will focus on development and validation of molecular characterization dossier required for risk assessment and to serve as back-up service laboratory for DNA detection and monitoring. Both laboratories will be involved in providing training in biosafety-related activities, DNA detection and monitoring techniques to risk assessors and other concerned agencies and in providing technical resource persons on DNA detection and monitoring for public awareness and outreach activities; (ii) one upgraded analytical laboratory for compositional and nutritional analysis with state-of-the-art analytical services equipment such as HPLC-MS, amino acid analyzer and related-analytical instruments. The purpose of this laboratory is to develop/adopt protocols and techniques and provide services for development of regulatory dossier to comply with food and feed safety assessment required by the country's biosafety regulations. The laboratory will also be involved in training and outreach activities on LMO food and feed safety assessments; (iii) build at least one BL2

greenhouse and one confined field testing facilities in three institutions involved in biosafety-related research and in risk assessment of crops, animals and other organisms of importance for Sri Lanka. These facilities will be used for LMO that are intended for propagation or cultivation

32. The proposed project will also help to establish sampling and analytical methodologies and procedures to identify and quantify LMOs, which will assist in establishing scientific basis for resolving legal disputes on LMO labeling and non-compliance. Manuals, tools and Standard Operation Procedures (SOPs) for different sampling and detection techniques will be developed and made available for laboratories and regulatory authorities. Access to DNA sequence information and reference materials will be improved.

33. Core laboratory staff members will be trained as trainers for LMO analysis and detection as well as for operation and maintenance of detection instruments in order to create a critical mass of scientific and technical personnel who can sustain the national reference laboratories and to implement risk assessment, LMO detection and monitoring systems. Staff of customs and other regulatory authorities will also be trained to understand the accreditation process for risk assessment, LMO detection and the corresponding LMO certificates issued, to test presence of LMOs as well as to seek laboratory confirmation, and a network of control authorities will be established. Exchange of experiences with other countries in the region in the development and use of easy to use, reliable and cost-effective sampling and detection techniques for LMOs will be promoted.

34. **Component 4: Knowledge development, public awareness, education and participation.** The proposed GEF project will support targeted education and outreach campaigns to create awareness of biosafety and to enhance public participation in decision-making. Under this component, enhancement of awareness among policy makers will be pursued to establish political will to incorporate biosafety into national development plans and programmes. A public education and outreach strategy will be designed and implemented to promote awareness and public participation and communication in biosafety issues. Communication materials will be produced, in English and local languages, and made publically available in digital and printed formats. In addition, curriculum, syllabus and course materials for post-graduate course for biosafety will be reviewed and elaborated to train and build sufficient human resources to tackle the challenges of biosafety in the nation. Existing gaps in primary, secondary and university level education for biosafety will also be filled through the improvement of curricula.

35. Information on specific project activities will feed into these campaigns, including information on the benefits of modern biotechnologies and biosafety systems. The knowledge generated through the project will be systematically integrated in all relevant project activities to improve efficiency and sustainability and it will be widely disseminated and made available to stakeholders and public in general through public awareness campaigns, dissemination of guidelines and workshops. These interventions will be filling important knowledge and awareness gaps to support enhancement of public access to information on LMOs. A monitoring system will be put in place to ensure the effectiveness of the project management process and timely implementation of the planned activities, including the mid-term and final evaluations.

Global Environmental Benefits

31. The proposed project will contribute to the conservation and sustainable use of Sri Lanka's biodiversity of global significance through strengthening capacities to manage potential risks arising from transboundary movement of LMOs. Implementing NBF will allow Sri Lanka to ensure that potential risks of LMOs are properly assessed and managed before environmental release, thereby generating significant global environmental benefits.

Innovativeness, sustainability and potential for scaling up

32. The proposed project will help to establish and implement Sri Lanka's biosafety system by addressing the lack of overall capacity to make the National Biosafety Framework operational. The project is innovative in that it deploys an integrated approach for capacity development through the consolidation of institutional arrangement, human resources development and assistance in establishment of necessary infrastructures. The proposed project will also take advantage of regional collaborative initiative on biosafety, "Asian Bio-Net", undertaken by FAO. Good practices and lesson-learned from the project will be disseminated and replicated in the region through this regional network.

33. Sustainability of the proposed project and up-scaling of its impacts are ensured through strengthening of regulatory frameworks and enhancement of institutional and technical capacities of stakeholders including government officials, academics and the public at large. Outreach campaigns to create awareness on the importance of biosafety will ensure continuous knowledge development maximizing the project's long-term impacts in the country.

A.2 Stakeholders. Identify key stakeholders (including civil society organizations, indigenous people, gender groups, and other as relevant) and describe how they will be engaged in project preparation.

34. The key stakeholders in the project include the Biodiversity Secretariat of the Ministry of Environment, Ministries that were proposed to serve as Sectoral Competent Authorities (SCAs) and other concerned government and private institutions as given in the table with the respective roles.

Stakeholders	Respective roles
Ministry of Environment and Renewable Energy	The project will be executed through the Biodiversity Secretariat of the MoE, which will play the coordinating role, in close coordination with other line ministries. The MoE will be the key actor in enabling stakeholders to implement the National Biosafety Framework. The MoE will chair the Project Steering Committee, which will include line ministries as well as representatives of civil society.
Department of Agriculture, Department of Animal Production and Health, Department of Health, Department of Fisheries and Aquatic Resources, Department of Wildlife Conservation and Ministry of Industry.	As Sectoral Competent Authorities (SCAs), involved as partners in implementing the project.
Ministry of Technology, Research and Atomic Energy, Plant Genetic Resources Centre, Rice Research and Development Institute, Sri Lanka Customs, National Plant Quarantine Service, Central Environmental Authority, National Science Foundation, Sri Lanka Accreditation Board and Universities, Coordinating Secretariat for Science and Technology Innovation, National Research Council, Ministry of Education, Ministry of Higher Education, University Grants Commission, Council for Agriculture Research Policy, Government Analysts Department	Involved as project partners
Private sector, NGOs, CSOs, Media and local communities and indigenous peoples.	Representatives of private sector, NGOs and local communities will be involved so that their views and perspectives are incorporated into the planning and implementation of the project.

A.3 Risks. Indicate risks, including climate change risks, potential social and environmental risks that might prevent the project objectives from being achieved, and, if possible, propose measures that address these risks to be further developed during the project design (Table format acceptable).

Risk	Rate	Mitigation Strategy
Lack of coordination between Sectoral Competent Authorities to effectively implement the project due to the different level of capacities and commitment.	L	Project partners will fully participate in the project from project design phase in order to establish and operationalize the coordination mechanism and to clarify the roles and responsibilities in project implementation, resulting in their commitment and effective execution of the project.
Low level of awareness on biosafety may make it difficult to gain support, from senior managers and policy makers, for the project at first.	L	Targeted awareness campaigns will be built into the project to secure the commitment of key persons as well to raise public awareness.
The capacity of stakeholders to conduct risk analysis and detection of LMOs is just emerging but not yet enough to fully	L	The project will implement an integrated capacity building program for Sectoral Competent Authorities and organizations that are responsible for LMOs detection by

operationalize the NBF due to minimum experience of risk analysis.		strengthening their institutional and human resource capacities. Training using the actual risk analysis cases will enable technical officers to build their knowledge and skills of risk analysis effectively.
Climate change threatens biodiversity and impacts ecosystem functions of Sri Lanka. Potential harm arising from LMOs may worsen those vulnerabilities.	L	The project, by helping to implement the NBF, will safeguard the resilience of Sri Lanka's ecosystems through protection of its biodiversity from potential risks related to LMOs.

A.4 Coordination. Outline the coordination with other relevant GEF financed and other initiatives.

35. The proposed project will coordinate with a range of ongoing initiatives in Sri Lanka related to conservation of biodiversity. The UNDP/GEF project "Strengthening capacity to control the introduction and spread of alien invasive species in Sri Lanka" (2010-2015) aims to build capacity across sectors to control the introduction and spread of invasive species in Sri Lanka, in order to safeguard globally significant biodiversity. UNEP/GEF project "Mainstreaming agrobiodiversity conservation and use in Sri Lankan agro-ecosystems for livelihoods and adaptation to climate change" (2012-2017) focus on conservation and sustainable use of biodiversity in agricultural production system. UNEP/GEF/FAO project "Mainstreaming biodiversity conservation and sustainable use for improve human nutrition and well being (2012-2016) aims to enhance the well being, livelihoods and food security through the conservation and sustainable use of biodiversity for food and nutrition and the identification of best practices. The proposed FAO/GEF project on "Implementation of the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety (CPB)" will complement and closely coordinate with the UNDP and UNEP projects by sharing the minutes and resolutions of the Project Steering Committees of those projects.

36. The proposed project also provides opportunities for collaboration with another ongoing UNDP/GEF Project "National Biodiversity Planning to Support the Implementation of the CBD 2011-2020 Strategic Plan" that aims to update the National Biodiversity Strategy and Action Plan of Sri Lanka according to the global guidelines of the CBD Strategic Plan 2011-2020. The proposed FAO/GEF project will collaborate with UNDP/GEF project to strengthen effective implementation mechanisms for biodiversity conservation in the country.

B. DESCRIPTION OF THE CONSISTENCY OF THE PROJECT WITH:

B.1 National strategies and plans or reports and assessments under the relevant conventions, if applicable, i.e. NAPAS, NAPs, NBSAPs, national communications, TNAs, NCSAs, NIPs, PRSPs, Biennial Update Reports, etc.

37. Sri Lanka ratified the Convention on Biodiversity in 1994 and since then has been actively pursuing action to implement the provisions of CBD. Sri Lanka also ratified the Cartagena Protocol on Biosafety on 28 April 2004. Biodiversity Conservation Action Plan (BCAP) was developed in 1998, and its Addendum was prepared in 2007 that includes the chapter for Biosafety. The BCAP proposed a course of action to ensure that the development processes do not cause serious or irreversible damage to the indigenous diversity and the country biodiversity is conserved and sustainably used.

38. The proposed project is aligned with "Mahinda Chintana: Vision for the Future", which is the Development Policy Framework of the Government of Sri Lanka for 2010-2016. The policy document states that growth alone does not mean economic prosperity and gives priority for environment and biodiversity conservation.

39. The government's broad vision for environmental conservation in the development policy framework has been transformed into a detailed action plan called 'National Action Plan for the Haritha Lanka (Green Lanka) Programme' in 2009. It has set 10 missions namely "Clean Air-Everywhere", "Saving the Fauna, Flora and Ecosystems", "Meeting the Challenges of Climate Change", "Wise Use of the Coastal Belt and the Sea Around", "Responsible Use of the Land Resources", "Doing Away with the Dumps", "Water for All and Always", "Green Cities for Health and Prosperity", "Greening the Industries" and "Knowledge for Right Choices". Under the second mission of biodiversity conservation, four strategies relevant to Biosafety have been set out namely "Strengthen policy, legal and institutional framework for biodiversity conservation", "Wise use of genetic resources for agriculture in sustainable manner", "Integrate and promote research and development on bio-diversity conservation in all sectors" and "Integrate agenda on biodiversity into education

and agendas of other related sectors". In order to implement the strategies and actions in the Haritha Lanka programme, the government has established a National Council for Sustainable Development (NCSD) which is chaired by HE the President.

40. The Second Regular National Report on the Implementation of the Cartagena Protocol on Biosafety (2012) provides the list of capacity-building needs, including institutional and human resources capacity, which the proposed project aims to address.

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

41. The proposed project is in consistency with GEF focal area objective BD - 3: Build Capacity for the Implementation of the Cartagena Protocol on Biosafety (CPB). The project contributes to the Outcome 3.1: Potential risks of living modified organisms to biodiversity are identified and evaluated in a scientifically sound and transparent manner. This will be addressed through Components, Outcomes and Outputs designed in the project and will be achieved through building and enhancing individual and institutional capacities in operationalizing the system of risk assessment, risk management, risk communication and monitoring and detection of LMOs.

42. In addition, the proposed project will support the achievement of Aichi Biodiversity Targets by contributing to Target 1 and target 2 under the Strategic Goal A "Address the underlying causes of biodiversity loss by mainstreaming biodiversity across government and society" and Target 13 under the Strategic Goal C "Improve the status of biodiversity by safeguarding ecosystems, species and genetic diversity".

B.3 The GEF Agency's comparative advantage for implementing the project

43. The country of Sri Lanka, which was then known as Ceylon, became a member nation of the Food and Agriculture Organization of the United Nations in 1948 and development support to Ceylon's agriculture and livestock sectors dates back to 1953. Since then, FAO has played an active role through trust fund arrangements and with the Technical Cooperation Programme to address national needs and priorities within the sectors of agriculture, animal husbandry, fisheries and forestry. The government and the people of Sri Lanka have significantly benefited from the technical expertise and support provided by FAO over time.

44. FAO has worked to assist the people of Sri Lanka by supporting the government in policy planning and legislation, while implementing projects and programmes across different sectors. FAO has assisted in the collection, analysis, interpretation and dissemination of information related to food, nutrition, agriculture, forestry and fisheries that has provided farmers, scientists, government planners and the private sector with the information required to make rational decisions on planning, investment, marketing, research and training.

45. Regarding the technical aspects of this project, FAO has been assisting its member countries since 1999 on the issue of biosafety by providing policy advice, technical assistance and capacity building, as well as updating their capacities through provision of better access to science-based information, training, workshops, seminars and by enhancing the laboratory facilities of some countries.

46. Biosafety is an integral component of the FAO Biosecurity Framework, which promotes a strategic and integrated approach, encompassing the policy and regulatory frameworks, for analyzing and managing relevant risks to human, animal and plant life and health and the associated risks to the environment. FAO has taken the lead in expanding the knowledge base in areas such as post-release monitoring, environmental and socio-economic impacts, and consumer issues of modern biotechnology.

47. FAO hosts the Secretariats of the Codex Alimentarius Commission and of the International Plant Protection Convention. These international standard-setting bodies are responsible for the development of globally recognized principles, guidelines and standards for the safety assessment of foods derived from biotechnology and for analyzing the environmental risks of LMOs for quarantine measures.

48. FAO's comparative advantage in implementing the proposed project also lies in its synergy with ongoing regional initiative "Strengthening Regional Cooperation and National Capacity Building on Biosafety in Asia (2013)" which aims to support 15 Asian countries to develop and implement biosafety regulatory frameworks that would facilitate rapid adoption of modern biotech products for agricultural development. The proposed

FAO/GEF project also draws on lessons learned from the completed capacity development projects concerning biosafety technically assisted by FAO: (i) “Regional Biosafety Workshop (2009)” and “Capacity Building in Biosafety of GM Crops (GCP/RAS/185/JPN: 2002-2005)” implemented with funding support from the Government of Japan. Through these projects, FAO has been supporting the establishment and operationalization of a coordinated network “Asian Bio-Net” in participating countries for enhancing collaboration and exchange of information, and FAO continues to support institutional capacity building in member countries for the implementation of science-based and functional biosafety systems.


49. The convergence of its competence in the technical and regulatory aspects of biodiversity, biotechnology and biosafety gives FAO a natural comparative advantage in formulating and implementing the proposed project that takes into account cross-cutting issues and national development goals.

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 Points endorsement letter(s) with this template. For SGP, use this OFP endorsement letter).

NAME	POSITION	MINISTRY	DATE (MM/DD/YYYY)
B.M.U.D. Basnayake	Secretary (National GEF Operational Focal Point)	Ministry of Environment and Renewable Energy	02/20/2014

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 project identification and preparation.					
Agency Coordinator, Agency name	Signature	Date (MM/DD/YYYY)	Project Contact Person	Telephone	Email Address
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