



GEF-6 REQUEST FOR ONE-STEP MEDIUM-SIZED PROJECT APPROVAL

TYPE OF TRUST FUND: GEF Trust Fund

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PART I: PROJECT IDENTIFICATION

Project Title:	Institutional Capacity to Enhance Biosafety Practices in Malaysia		
Country(ies):	Malaysia	GEF Project ID: ¹	5804
GEF Agency(ies):	UNEP (select) (select)	GEF Agency Project ID:	01003
Other Executing Partner(s):	MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT	Submission Date:	April 01, 2015
GEF Focal Area(s):	Biodiversity	Project Duration (Months)	48 Months
Integrated Approach Pilot	IAP-Cities <input type="checkbox"/> IAP-Commodities <input type="checkbox"/> IAP-Food Security <input type="checkbox"/>		
Name of Parent Program:	Biosafety Program	Agency Fee (\$)	94,525

A. FOCAL AREA STRATEGY FRAMEWORK AND PROGRAM²:

Focal Area Objectives/programs	Focal Area Outcomes	Trust Fund	(in \$)	
			GEF Project Financing	Co-financing
BD-2 Program 5 (select) (select)	Outcome 5.1	GEFTF	995,000	2,986,500
(select) (select) (select)		(select)		
Total project costs			995,000	2,986,500

B. PROJECT FRAMEWORK

Project Objective: To strengthen the biosafety management system in Malaysia with special emphasis on thematic interventions to facilitate handling and decision making on LMOs.

Project Components/ Programs	Financing Type ³	Project Outcomes	Project Outputs	Trust Fund	(in \$)	
					GEF Project Financing	Confirmed Co-financing
1) Needs Assessment	TA	A consolidated action plan developed to guide the design of project.	<ul style="list-style-type: none"> Stocktaking report capturing the current status of biosafety issues, identified gaps, planned training interventions and long term funding plans. National Consultative meeting reports (with a stakeholder participation plan). 	GEFTF	25,000	75,000
2) Risk	TA	A technical and	• Updated RA	GEFTF	150,000	450,000

¹ Project ID number will be assigned by GEFSEC and to be entered by Agency in subsequent document submissions.

² When completing Table A, refer to the excerpts on [GEF 6 Results Frameworks for GETF, LDCF and SCCF](#).

³ Financing type can be either investment or technical assistance.

and socio economic assessment with related management framework		<p>regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMO(s) risk.</p> <p>Socio-economic assessment framework established.</p>	<p>and RM procedures and guidelines in line with recent developments under CPB.</p> <ul style="list-style-type: none"> • Monitoring Guidelines developed for regulators and applicants. • Survey reports on socio-economic issues in relation to LMOs and socio-economic guidelines and methodologies are developed for assessment of LMOs. • Cost benefit analysis guidelines developed for socio-economic assessors. 			
3) Framework for handling LMOs	TA	<p>A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB.</p> <p>Administrative and legal framework for the implementation of</p>	<ul style="list-style-type: none"> • National codes of best practices and procedural guidelines for handling, transport, packaging and identification of LMOs developed. • Strategic guidance document on sampling, thresholds and inventory of LMOs from selected countries prepared. • Policy or action plan on low level presence is formulated. • A plan to implement the Nagoya – Kuala Lumpur 	GEFTF	140,000	450,000

		the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety established..	Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety developed. • Amended laws or Regulations on Liability and Redress gazetted.			
4) Institutional Capacity Building	TA	Institutional capacity on biosafety especially in the areas of risk evaluation and enforcement measures at the ports of entry is enhanced.	<ul style="list-style-type: none"> • A feasibility study is carried out on public-private partnership for LMOs detection. • Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMOs in agriculture. • Current methodology and procedures are reviewed and upgraded for LMOs detection. • Institutionals capacity on liability and redress are developed. • Biology documents are developed on fields identified by technical committee. • Training modules/manuals are prepared for conducting/ evaluating risk assessment and management, monitoring field trials of LMOs and compliance evaluation and training of quarantine and inspection 	GEFTF	250,000	750,000

			officials for enhanced enforcement at the ports of entry.			
5) Biosafety Communication Framework	TA	Public awareness on biosafety issues (including liability and redress) enhanced.	<ul style="list-style-type: none"> • Innovative outreach programs are developed on risk communication for both through print and electronic/social media. • Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies. • Primers/ brochures/ booklets /FAQs/biosafety newsletters and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc. • A mechanism is established to communicate regulatory decisions on LMOs to the public. • Biosafety topic including BCH is incorporated in school and university curricula. 	GEFTF	300,000	900,000
6) Project Monitoring and Evaluation	TA	Effective project implementation	Project Monitoring and Evaluation Reports at Mid-term and Terminal	GEFTF	40,000	90000

			Evaluation.			
	(select)			(select)		
	(select)			(select)		
Subtotal					905,000	2,715,000
Project Management Cost (PMC) ⁴				(select)	90,000	271,500
Total GEF Project Financing					995,000	2,986,500

For multi-trust fund projects, provide the total amount of PMC in Table B, and indicate the split of PMC among the different trust funds here: ()

C. SOURCES OF CO-FINANCING FOR THE PROJECT BY NAME AND BY TYPE

Please include confirmed co-financing letters for the project with this form.

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Amount (\$)
Recipient Government	Ministry of Natural Resources and Environment	In-kind	2,586,500
Recipient Government	Ministry of Natural Resources and Environment	Grants	400,000
(select)		(select)	
(select)		(select)	
Total Co-financing			2,986,500

D. GEF/LDCF/SCCF RESOURCES REQUESTED BY AGENCY(IES), TRUST FUND, COUNTRY(IES), FOCAL AREA AND PROGRAMMING OF FUNDS

GEF Agency	Trust Fund	Country/ Regional/Global	Focal Area	Programming of Funds	(in \$)		
					GEF Project Financing (a)	Agency Fee ^{a)} (b)	Total (c)=a+b
UNEP	GEF TF	Malaysia	Biodiversity	(select as applicable)	995,000	94,525	1,089,525
(select)	(select)		(select)	(select as applicable)			0
Total Grant Resources					995,000	94,525	1,089,525

a) Refer to the [Fee Policy for GEF Partner Agencies](#).

E. PROJECT'S TARGET CONTRIBUTIONS TO GLOBAL ENVIRONMENTAL BENEFITS⁵

Provide the expected project targets as appropriate.

Corporate Results	Replenishment Targets	Project Targets
1. Maintain globally significant biodiversity and the ecosystem goods and services that it provides to society	Improved management of landscapes and seascapes covering 300 million hectares	hectares
2. Sustainable land management in production systems (agriculture, rangelands, and forest landscapes)	120 million hectares under sustainable land management	hectares

⁴ For GEF Project Financing up to \$2 million, PMC could be up to 10% of the subtotal; above \$2 million, PMC could be up to 5% of the subtotal. PMC should be charged proportionately to focal areas based on focal area project financing amount in Table D below.

⁵ Provide those indicator values in this table to the extent applicable to your proposed project. Progress in programming against these targets for the projects per the *Corporate Results Framework* in the [GEF-6 Programming Directions](#), will be aggregated and reported during mid-term and at the conclusion of the replenishment period. There is no need to complete this table for climate adaptation projects financed solely through LDCF and/or SCCF.

3. Promotion of collective management of transboundary water systems and implementation of the full range of policy, legal, and institutional reforms and investments contributing to sustainable use and maintenance of ecosystem services	Water-food-ecosystems security and conjunctive management of surface and groundwater in at least 10 freshwater basins;	<i>Number of freshwater basins</i>
	20% of globally over-exploited fisheries (by volume) moved to more sustainable levels	<i>Percent of fisheries, by volume</i>
4. Support to transformational shifts towards a low-emission and resilient development path	750 million tons of CO _{2e} mitigated (include both direct and indirect)	<i>metric tons</i>
5. Increase in phase-out, disposal and reduction of releases of POPs, ODS, mercury and other chemicals of global concern	Disposal of 80,000 tons of POPs (PCB, obsolete pesticides)	<i>metric tons</i>
	Reduction of 1000 tons of Mercury	<i>metric tons</i>
	Phase-out of 303.44 tons of ODP (HCFC)	<i>ODP tons</i>
6. Enhance capacity of countries to implement MEAs (multilateral environmental agreements) and mainstream into national and sub-national policy, planning financial and legal frameworks	Development and sectoral planning frameworks integrate measurable targets drawn from the MEAs in at least 10 countries	<i>Number of Countries:</i>
	Functional environmental information systems are established to support decision-making in at least 10 countries	<i>Number of Countries: 60+</i>

F. DOES THE PROJECT INCLUDE A “NON-GRANT” INSTRUMENT? No

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

G. PROJECT PREPARATION GRANT (PPG)⁶

Is Project Preparation Grant requested? Yes ☐ No **X** If no, skip item G.

PPG AMOUNT REQUESTED BY AGENCY(IES), TRUST FUND, COUNTRY(IES) AND THE PROGRAMMING OF FUNDS*

GEF Agency	Trust Fund	Country/ Regional/Global	Focal Area	Programming of Funds	(in \$)		
					PPG (a)	Agency Fee ⁷ (b)	Total c = a + b
(select)	(select)		(select)	(select as applicable)			0
(select)	(select)		(select)	(select as applicable)			0
Total PPG Amount					0	0	0

PART II: PROJECT JUSTIFICATION

1. *Project Description.* Briefly describe: a) the global environmental and/or adaptation problems, root causes and barriers that need to be addressed; b) the baseline scenario or any associated baseline projects, c) the proposed alternative scenario, with a brief description of expected outcomes and components of the project, d) [incremental/ additional cost reasoning](#) and expected contributions from the baseline, the GEFTF, LDCF/SCCF and [co-financing](#); e) [global environmental benefits](#) (GEFTF), and [adaptation benefits](#) (LDCF/SCCF); and 6) innovation, sustainability and potential for scaling up.

Malaysia was one of the 12 GEF-funded demonstration projects on biosafety. Unlike the 8 UNEP-implemented demonstration projects, Malaysia did not participate in the pilot phase project on the development of regulatory framework prior to the demonstration project. Although the Malaysian

⁶ PPG of up to \$50,000 is reimbursable to the country upon approval of the MSP.

⁷ PPG fee percentage follows the percentage of the Agency fee over the GEF Project Financing amount requested.

Project on “Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety” demonstration project was approved in 2002, this UNDP- implemented project only started in mid-2007. The delay was partly because Government approval of the Biosafety Bill took much longer than anticipated, and partly, because the National Execution Agency (NEA), which was the then Ministry of Science, Technology and Environment (MOSTE), was reorganised into two new ministries - Ministry of Natural Resources and Environment and Ministry of Science, Technology and Innovation. The project was completed in June 2012. The main outcome of the project was the implementation of the national biosafety framework in the country. Malaysia has developed a transparent biosafety process with the capacity to receive, review and publish decisions on applications for activities with LMOs. Other successes include the wide diversity of biosafety stakeholders that participated in the implementation process and a significant level of capacity building in the major aspects of biosafety regulation. During the final year of the project, one of the targets was to come out with a report on the perception of the public on modern biotechnology and biosafety as there were no baseline documents on this matter published by agencies promoting modern biotechnology and also it was felt that such a report was essential to plan the way forward. Furthermore, it was important to know whether the public was aware of the Malaysian Biosafety Act 2007 (Act 678), the existence of biosafety regulatory bodies in this country as well as gauge on the public awareness and understanding of biosafety issues. The biosafety regulatory framework developed and the related legislations and uploaded on the Central Portal of the BCH at <http://bch.cbd.int/database/results?searchid=603872> and also the Malaysian Biosafety Clearing House <http://www.biosafety.nre.gov.my/default.shtml>.

The following regulatory instruments were developed as part of the demonstration project

- i. Biosafety Act 2007 (Act 678)
- ii. Biosafety (Approval and Notification) Regulations 2010
- iii. Institutional Biosafety Committee (IBC) Guidelines
- iv. Guidelines for Contained Use Activity of Living Modified Organisms
- v. The Simplified Procedure - Exemption under S68 of Biosafety Act
- vi. User's Guide to the Malaysian Biosafety Act and Regulations
- vii. Biosafety Guidelines: Confined Field Trial of Living Modified Plants in Malaysia
- viii. Biosafety Guidelines: Environmental Risk Assessment of Genetically Modified Plants in Malaysia
- ix. Biosafety Guidelines: Risk Assessment of Genetically Modified Microorganisms

The following existing legislations were amended to take care of LMO based Pharmaceuticals and vaccines:

Control of Drugs and Cosmetics Regulations 1984 (Amendment 2009) and the Animals Act 1953.

As indicated, the project conducted a survey to study the stakeholders’ perception on biotechnology and biosafety. This study was mainly aimed at collecting information to establish baseline data on stakeholder awareness and perception towards modern biotechnology (LMOs), biosafety and the regulatory body. Results from the study showed that stakeholders’ awareness towards biosafety legislations in this country is still very low. Except for those from research institutions and universities and regulatory bodies/enforcement bodies/policy makers, not many respondents were aware of the Biosafety Regulatory framework in Malaysia. On the government’s capability of handling LMOs matters, most stakeholders were generally positive except members from NGOs, religious bodies and organic shops and industry players. In general, all stakeholder groups felt that the public awareness activities on LMOs conducted by the government were insufficient. In fact, most of the feedback received from the respondents was on the lack of information about biosafety, low exposure to the subject matter to the general public and the need to conduct more awareness activities and

stakeholder consultations. The results obtained through this survey provided key inputs as an initial baseline data to guide the development of a more effective roadmap or Biosafety Communication strategy to raise awareness about biosafety to various stakeholders. The terminal evaluation for the UNDP GEF Biosafety project was undertaken in May 2012. It served to promote accountability for the resources used and to document and provide feedback on the lessons learned. In the evaluation report, it was recommended that Malaysia applies for additional GEF funding to address those aspects of the national biosafety process that still need capacity building for implementation. It provided a basis for the Government of Malaysia to apply for another GEF funding to address those areas of biosafety that need capacity building including measures on liability and redress, socioeconomic considerations and awareness programmes on biosafety to facilitate public participation. In addition, the government was encouraged to continuously review and formulate strategies to sustain the development of biosafety capacity in the country as biosafety and related modern biotechnology developments are dynamic and needs continuous strategic focus. In addition, with Malaysia's role as a potential key player both in the import and export of LMOs, it is imperative that Malaysia develops additional capacity in the deliberate release and handling of LMOs also strengthen the designated regulatory institutions. The interventions could include i) coordination of inspection and compliance regulatory functions with relevant agencies; ii) provision of sustainable capacity building measures/tools on risk assessment, risk management and risk communication as new LMOs are developed and the technology evolves; iii) integration of socio-economic impact issues and analytical frameworks into decision making on applications for release of LMOs; iv) development of a sustainable way to utilize its existing detection services and capacity for risk management and pre- and post- approval monitoring, such as using this service only for products with identified high risks and also sharing this installed capacity with other parties in the region through the existing institutionalized training; v) development of streamlined procedures for the existing officers to cope efficiently as applications increase.

The table below presents a summary of planned activities and the achieved outputs under the earlier GEF Biosafety Demonstration Project on **“Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety in Malaysia”**

Component 1: Establish legal and regulatory framework that permits effective evaluation	
Planned	Outputs
Series of workshops on drafting regulations and guidelines	Biosafety Regulations developed and implemented
Consultation on regulations and guidelines	Guidelines provided for : IBCs; Contained use; Applicants
Training for IBCs	Notification and Approval process established
<i>Biosafety review of GM Research</i>	Exemption list and exemption process established
Training for 50 enforcement officers	Printed: Biosafety Act and Protocol in 2 languages; Poster on processing.
Training for biosafety Regulators	Administrative Standard Operating Procedures (SOPs) developed for:
Study tours for GMAC	Handling documents, notifications & approvals; Public announcements; Procedures for National Biosafety Board (NBB) and

Members	Genetic Modification Advisory Committee (GMAC) meetings
Attendance at international biosafety meetings	Capacity building provided for: 130 Institutional Biosafety Committee (IBC) officers; 125 enforcement officers 96 biosafety regulators
	Completed study tours for 6 regulators (Australia; India)
	8 members of Department of Biosafety attended international biosafety meetings.

Component 2: Enhanced scientific, socio-economic and institutional capacities for risk Assessment

Planned	Outputs
Series of workshops on: detection (60-80 scientists),	Functional GM testing laboratory at Department of Chemistry Malaysia
environmental impact assessment (60 delegates),	Risk assessment capacity available
food safety assessment (60 delegates),	160 Applicants trained to complete dossiers
monitoring, and preparation of dossiers, (60 delegates)	Mobile lab at ports for primary screening
	Curriculum implemented for postsecondary biosafety training
	The NBB, GMAC and IBCs are functioning

Component 3: Increased capacity for developing and implementing a risk management Programme

Planned	Outputs
Series of workshops on risk management of LM plants for 80 to 100 regulators and applicants	6 workshops for 344 delegates
Series of workshops on risk management of microbes, aquatic species and animals for 80 to 120 delegates.	Risk management capacity available
Series of workshops on risk management of tree species for 60 to 80 delegates.	Established a procedure for applying risk management conditions to LMOs in containment

Series of workshops on risk management of biopharming organisms for 60 to 80 delegates.

Component 4: Develop capacity for long-term operation and maintenance

Planned

Train 50 to 60 technical staff in molecular biology & sample handling and recording

Strengthen Dept. of Chemistry (DOC) laboratory

Establish detection laboratories in two more states

Training for 50 delegates on IPR, international obligations, legal issues related to biosafety

Achieved

SOPs developed for handling and testing of samples for LM content

NBB and GMAC biosafety bodies formed and functional

Strengthened LM detection laboratory at DOC

DOC staff members were trained in sample handling and record keeping.

Capacity building in detection provided for 125 enforcement officers

Administrative SOPS for Department of Biosafety

Training on handling of Confidential Business Information (CBI)

Component 5: Develop institutional coordination and sharing of information

Planned

Training for 60 to 80 government staff and some private and NGO delegates on implementation of the Biosafety Act

Establishment of a regulatory database that links to the BCH

Training of 30 to 50 IT officers in other ministries to establish biosafety databases and link these to the national database

Achieved

Several Presentations on the role of biosafety and the Biosafety Act to stakeholders, other professional & civic groups

Networking between government ministries

Clarity on inter-ministerial responsibilities with respect to the Act

National database that links to the BCH

Development of a website that meets Government of Malaysia and BCH requirements

4 BCH workshops that trained 78 officers

Component 6: Raise public awareness and promote stakeholder participation

Planned

Appoint communications

Achieved

Website running on the BCH format

Officer

Establish interactive
biosafety website for DOB

Training workshop on risk
communication (120 to 150
staff and stakeholders)

Conduct consumer education
and public awareness
programmes (CEPA)

Biosafety into secondary and
tertiary school curricula

Public awareness
consultations

Conduct a survey of public
awareness of biosafety

Increased awareness of biosafety among stakeholders

Partnership with NGO to implement public awareness
programmes

Public awareness materials:
Myths;
Q+A;
3 x newsletter issues
DVD on biosafety

3 Road shows held to interact with public &
stakeholders on biosafety

Public survey completed

Invited presentations given at international biosafety
workshops and meetings

The design and elaboration of the proposed project is guided by the capacity building needs and priorities as highlighted in the BCH (<http://bch.cbd.int/database/record.shtml?documentid=101816>). The proposed new project is very timely as it will help Malaysia to focus on the gaps and weaknesses already identified in the earlier project and as recommended by the terminal evaluation. The project has 6 components. It will begin with a need assessment (**Component 1**), where updated information will be consolidated to refine the project design and to assist in priority setting of project activities to ensure that all project outcomes are achieved. **Component 2** aims to strengthen the Regulatory and technical frameworks, whilst **Component 3** will develop an enhanced framework for handling LMOs. **Component 4** is designed to enhance institutional capabilities whilst raising public awareness will be undertaken under **Component 5**. Project monitoring and evaluation forms **Component 6**. As the project is built on the foundations of the previous project, the 8 outcomes of the project are expected to contribute to the project objective of enhancing the biosafety management capacity of Malaysia, which will in turn, contribute to the overarching goal of GEF to support Parties in the implementation of the Cartagena Protocol on Biosafety. Since Malaysia has invested huge resources into biotechnology, it has several LMO products which are in the pipeline to advance from the laboratory to field testing and possible deliberate releases into the environment. Expertise and experience are lacking in regulatory compliance for application to undertake field testing, monitoring for environmental impact of LMOs released in field tests among the regulatory and scientific communities. Capacity building in regulatory compliance, confined field tests and monitoring for environmental impact, to confirm risk management measures established, as well as risk communication to the beneficiaries, policy makers and the public will form the critical components of this project and also provide capacity for deliberate release to the environment.

According to the 2001 Global Diversity Outlook, Malaysia is one of 12 megabiodiverse countries of the world (see <http://www.cbd.int/countries/?country=my>). Although Malaysia has only 0.2% of the

world's land mass, the diversity of its flora and fauna makes it one of the richest countries in the world in terms of biodiversity per unit area, as measured by the World Development Indicators. Notwithstanding that there is no definite data on the exact number of species in Malaysia, especially for small organisms such as insects and worms, a conservative estimate is that Malaysia has at least 170,000 species. With such rich biodiversity housed in diverse habitats such as seas, rivers, swamps, mountains and forests, it is imperative that modern biotechnology products advance safely from the laboratory to field and are released to the environment without adverse impact on its biodiversity and the environment. This stepwise safe application will prevent unintended adverse effect of the environmental release of LMOs, whilst at the same time, allow the country to benefit from adoption of new technologies such as modern biotechnology through increasing crop yields for food security, food and pharmaceuticals for human consumption, wealth creation and improved livelihoods, with concomitant reduction of agro-chemical usage and leaving a smaller carbon footprint. The project will also assist in the conservation and sustainable use of the vast biodiversity (150,000 species of invertebrates, 15,000 species of flowering plants, 4,000 species of marine fishes, 1159 species of ferns and fern allies) of Malaysia, and at the same time, minimize the potential risk to wild and cultivated agricultural biodiversity, especially rice in the country.

Incremental cost reasoning and expected contributions from the baseline, the GEFTF, LDCE/SCCF and co-financing;

This project will build upon the foundations laid by earlier project GEF ID 1399 - *“Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety”*. Because this was an initial initiative on biosafety, it was limited to sensitization of various stakeholders on biosafety regulation and understanding the requirement for capacity building to meet the objective under CPB. The project is already completed. Cognizant of the wide range of biosafety issues that needs to be addressed, capacity building through national resources alone would be inadequate to implement an effective system that could keep pace with the rapid national and international development in modern biotechnology. Therefore, this project will assist Malaysia, as Party to CPB, to meet its obligations by building on and strengthening existing national capacity to fulfill commitments under CPB especially in critical areas such as risk assessment and management, handling, transport, packaging and identification of LMOs and socio economic consideration in decision making. This will ensure that every request for intentional movement of LMOs across national borders as well as for all use will be administered and assessed by an administrative and regulatory system, that are consistent with the CPB.

The Incremental cost reasoning is further presented below to showing the reasoning and the expected contributions from the baseline

1. Incremental cost analysis of this project is based on the GEF Operational Guidelines for the Application of Incremental Cost Principle¹ which were developed from the 1996 GEF policy paper on incremental cost².
2. Incremental cost is estimated as the difference in scenarios between the “baseline” or “what would happen without GEF intervention” (where national activities are already being carried out to achieve the present project objectives for domestic benefit), and an “alternative” (where a series of additional activities will be carried out to contribute to global environmental benefit

(GEB)). The activities to be carried out by this project proposal will result in that “alternative” scenario, the cost of which will be borne by GEF.

3. Recently, the term “baseline” is replaced by “business-as-usual”¹. The baseline values described below were determined at the end of the earlier GEF4 biosafety capacity building project. However, cognizant that baseline is dynamic and evolves with time; these will be re-evaluated after the stock taking analysis, as a mandatory first component of this project.

Project Component	Baseline or “Business as usual”	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
I) Needs Assessment	5,000	25,000	20,000	<p>Comprehensive data on National capacity in biotech and biosafety are compiled and updated</p> <p>National RA procedures and documentation requirements for LMOs are reviewed for compliance to CPB</p> <p>Existing facilities are reviewed for strengthening in LMO detection</p>	<p>Updated comprehensive baseline information consolidated and validated.</p> <p>Strategic entry points for GEF intervention are identified</p> <p>GEF interventions are more cost effective.</p>
II) Risk Assessment and Socio-economic Assessment with Related Management Framework					
2A) Risk Assessment and Management	15,000	75,000	60,000	<p>A risk assessment system was already in place in Malaysia prior to being a Party to CPB.</p> <p>RA and RM</p>	<p>Risk assessment (RA) and risk management (RM) system is improved through the strengthening of national legal instruments and institutional arrangements/capacity.</p> <p>RA will be science-based</p>

Project Component	Baseline or "Business as usual"	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
				procedures will be streamlined and updated for emerging technologies and products	<p>according to agreed international principles and methods.</p> <p>RM and emergency response plans are in place to minimise damage to the environment and biodiversity.</p> <p>All decisions are made within CPB timelines</p>
2B) Socio Economic (SE) Assessment	10,000	75,000	65,000	Parameters and methodologies for SE assessment are in place to facilitate informed decision making to minimise any possible negative impact on farming communities	Minimising possible negative effects on farming community, will contribute to national and global food security and improved livelihood.
III) Framework for Handling LMOs					
3A) Handling, transport, packaging and identification of LMOs	10,000	65,000	55,000	<p>Streamline export/import procedures for LMOs</p> <p>Safe handling and transfer of LMOs within the country</p>	Facilitate international trade in line with CPB.
3B) Liability and Redress	5,000	75,000	70,000	Mechanism is in place to address issues of liability	Clear procedures in the field of liability and redress for damage

Project Component	Baseline or "Business as usual"	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
				and redress. Increased capacity on handling liability and redress issues.	resulting from transboundary movements of LMOs.
IV) Institutional Capacity Building	20,000	250,000	230,000	<p>Institutional capacity for LMO detection will be strengthened for better enforcement and compliance.</p> <p>Trained manpower will result in an effective and efficient biosafety management system.</p>	<p>Facilitate compliance to CPB during transboundary movement of LMOs.</p> <p>Strengthened institution can serve as centre of excellence for the region.</p> <p>Enhanced national capacity will expedite compliance with CPB</p> <p>The products of training can be utilised in other similar projects to achieve global benefits</p> <p>The outcome of the project will cut across institutional and sectoral barriers to build not only on national but also regional capacity in key areas such as RA, RM etc</p>
V) Biosafety Communication Framework	20,000	300,000	280,000	<p>Outreach material will be translated into various languages for wider dissemination of</p>	<p>Innovative training tools and outreach materials can be utilized or replicated in other similar projects in the region</p>

Project Component	Baseline or "Business as usual"	Alternative/ With GEF	Increment	Domestic Benefits	Global Benefits
				<p>information on biotechnology and biosafety information</p> <p>Upgraded national biosafety websites will be more user friendly</p> <p>Innovative training tools will be developed for continuous training beyond the project cycle</p>	<p>Timely updating of BCH and biosafety websites is an effective mechanism to share information with the international community</p> <p>The training in project management can be replicated in other similar projects to achieve global benefits</p>
VI) Project Monitoring and Evaluation	5,000	40,000	35,000	Enhanced national capacity in biosafety project implementation	Experience gained by project monitoring and evaluation can be replicated in other similar projects to achieve global benefits
VII) Project Management	15,000	90,000	75,000	Enhanced national capacity in biosafety project implementation	The training in project management can be replicated in other similar projects to achieve global benefits
Total	105,000	995,000	890,000		

¹Available from <http://thegef.org/council/C.31/12>.

²Available from <http://thegef.org/council/C.7/Inf.5>.

Innovativeness, sustainability and potential for scaling up;

The proposed project focuses on an issues based approach as a sequential step to address issues raised in the terminal evaluation, national operational practice in implementing the Malaysian Biosafety and the government's strategic focus in handling modern biotechnology in a scientifically safe manner. The key innovative approach is the planned tailor specific and not generic approach in developing tools and measures to strengthen the capacity of the Department of Biosafety and the designated competent institutions in the

handling of LMOs. It also focuses on developing policy and strategic response and experience on new and emerging trends including handling of Low Level Presence of Living Modified Materials in shipments. Lessons learnt and experience in this approach will be useful to countries in the region as they build up their national biosafety systems. The Government of Malaysia has designated and resourced a full Department of Biosafety under the Ministry of Natural Resources and Environment to lead the Biosafety Regulatory process in partnership with other competent authorities. With the legal backing and institutional approach, the project and the expected deliverables will be effectively sustained and mainstreamed into the national regulatory processes and related environmental protection and sustainable utilization goals. This approach supported by the expected deliverables gives a good template for scale up and replication in the region and beyond. In addition, the Department of Biosafety in partnership with the Department of Chemistry established a LMO Testing Service both as analytical and training service with a biannual training program. The project will be further strengthened and supported in the current project. The DOC activities has gradually become a sub-regional supportive service which is already been utilised by other Parties to support their training needs on LMO Testing.

2. *Child Project?* If this is a child project under a program, describe how the components contribute to the overall program impact.

N/A

3 *Stakeholders.* Will project design include the participation of relevant stakeholders from [civil society](#) and [indigenous people](#)? (yes **X** /no ☐) If yes, identify key stakeholders and briefly describe how they will be engaged in project design/preparation:

The stakeholder involvement element is embedded in the description of several activities within this project which will be consultative and participatory in nature. A full stakeholder involvement plan will be developed as part of the project inception workshop. Measures will be put in place to allow dynamic update and inclusion of more stakeholders throughout the execution period and even beyond as a best practice in evolving and strengthening the national biosafety system. This plan will depart from the following indicative and non-exhaustive list.

Stakeholder(s)	Roles and responsibilities	Potential stake/involvement in the project
Ministry of Natural Resources and Environment (NRE)	Formulation, coordination and implementation of policies related to natural resources and the environment.	Being the focal point for CBD and CPB. The Ministry will lead in the facilitation and coordination of project implementation amongst various agencies.
Department of Biosafety	Formulation, coordination and implementation of policies related to biosafety.	National focal point for this GEF project. It will be directly responsible for project formulation and implementation.
Forest Research Institute of Malaysia	Coordination and implementation of policies related to biodiversity.	Project implementing partner. It will be directly responsible for project agreement execution and finance related responsibilities.
Ministry of Science, Technology and Innovation –	Policy formulation and regulation related to biotechnology.	Potential consultation partner in establishing/reviewing policy relating to modern biotechnology/biosafety

Stakeholder(s)	Roles and responsibilities	Potential stake/involvement in the project
Biotechnology Division & Department of Chemistry		and collaboration partner for LMO detection.
Ministry of Agriculture and Agro-Based Industry – Department of Agriculture & Malaysian Quarantine and Inspection Services	Formulation, coordination and implementation of policies related to agriculture.	Potential collaboration partner in developing programme of work for enforcement and monitoring activities.
Attorney General Chambers	Formulation of legislations related to Biosafety.	Potential consultation partner in developing new laws or reviewing current laws/regulations relating to Biosafety.
Economic Planning Unit	Development of strategies and policies in determining financial allocations for the various sectors of the national economy.	Key policy inputs on the performance-based system for allocation of Federal development funds.
State Economic Planning Units (including Sabah and Sarawak)	Cross-sectoral coordination and development planning and implementation.	Coordination of agencies related to project implementation at State level. Integration of Federal policies into State planning.
Malaysian Biotechnology Corporation	Coordination and implementation of specific components of the Project	Coordination of activities related to project implementation at the industries level.
Public/private universities and research institutions	Coordination and implementation of specific components of the Project	To provide support in coordinating and implementing capacity building and awareness activities at universities, public/private institutions and community level. And to provide experts for institutional capacity building and training activities
Malaysian environmental NGOs	Advocacy for better project management and to provide support in project implementation.	To provide technical inputs to the project and help to carry out awareness activities (e.g. Malaysian Nature Society and Malaysian Biotechnology Information Centre) at community level. Complementary interventions at national level (e.g. Third World Network)

4. *Gender Consideration.* Are [gender considerations](#) taken into account? (yes **X** /no ☐). If yes, briefly describe how gender considerations will be mainstreamed into project preparation and implementation, taken into account the differences, needs, roles and priorities of men and women.

In line with the planned communication strategy, education and public awareness programmes will be developed to encourage local authorities to reach out to major groups such as children and youth, women, local parliamentarians/assemblymen and/or legislators, NGOs and businesses, to raise awareness about the importance of biodiversity and promote partnerships on local action for biodiversity conservation and sustainable utilization

5. *Benefits.* Describe the socioeconomic benefits to be delivered by the project at the national and local levels. Do any of these benefits support the achievement of global environment benefits (GEF Trust Fund) and/or adaptation to climate change?

The biosafety regulatory body in Malaysia i.e. Department of Biosafety under the Ministry of Natural Resources and Environment needs to ensure that biotechnology R&D is guided by a process of prudent decision making that safeguards biodiversity and human, animal and plant health. Since Malaysia has embarked in R&D activities involving LMOs, Malaysia will soon be both an exporter and an importer of LMOs. This new role will require Malaysia to comply with the transboundary requirements of LMOs under the CPB. Furthermore, since modern biotechnology is developing rapidly, there is a need for continuous sharing of best practices in biosafety regulation to ensure effective implementation of the CPB. In line with CBD guidance (see <http://www.cbd.int/doc/publications/cbd-ts-49-en.pdf>), and as part of the policy formulation process, public participation and training, Malaysia will access different biosafety needs, knowledge, perceptions and vulnerabilities. Data on potential and actual LMOs users and risk perception, levels of knowledge and access to information will be disaggregated by sex.

In addition, special measures will be put in place to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities on biodiversity conservation, the national biosafety processes and sustainable utilization of biodiversity guided by the broad national protection goals. In the preparation of biosafety tools and instruments, social and environmental safeguard measures which are a key anchor of the Cartagena Protocol on Biosafety will be mainstreamed throughout the development and related training processes.

6. *Risks.* Indicate risks, including climate change, potential social and environmental future risks that might prevent the project objectives from being achieved, and if possible, propose measures that address these risks:

While all possible efforts will be done to ensure the successful implementation of the proposed project, there are certain risks that are anticipated, which the project will also endeavor to mitigate. The following table summarizes the potential risks that might prevent the project objective from being achieved, the level of risk and the proposed mitigating actions for each risk is outlined in the table below:

No.	Risk	Priority	Risk Mitigation Strategy
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1.	Inability to sustain the capacity building programs upon completion of the project.	Medium	Measures to overcome the identified risk would include preparation of training modules and documents as an integral part of institutional and human resource capacity building activities through the inclusion and mainstreaming follow up training programs in the budgeted activities of the Department of Biosafety.
2.	Inadequate participation of the targeted stakeholders (especially at the state level) in the capacity building program.	Medium	To overcome this constraint, extensive efforts would be made to: - involve high level functionaries in this capacity building initiative. - stimulate interest from stakeholders to leverage support for the program.
3.	Overall change in government direction.	Low	Change in government overall direction e.g. national policy on biotechnology, may require reprioritization of some of the activities. This can be identified during annual/mid-term project reviews and where applicable appropriate risk mitigation measures shall be developed to manage the identified risks.
4.	Lack of commitment and low participation from the private sector and other stakeholders.	Low	The private sector just like other key identified stakeholders has been involved right from the project design phase and will be continually engaged as required by the biosafety regulatory process. In addition, new information shall be disseminated through the appropriate channels and efforts will be made to identify needs and demands through continuous dialogue as a responsive mechanism.
5.	Proposed improvements to the institutional and regulatory framework are delayed by private/public institutions	Low	Measures will be put in place to ensure close cooperation of the project partners at the Project Steering Committee level. In addition, cooperative measures will be evolved to provide detail guidance on roles and responsibilities of each project partner through TORs and MoUs where applicable and also through the coordination mechanisms at the project inception phase and at various stages of project execution.
6.	Various other risks that may arise from climate change, social and environmental factors.	Low	The project will not be much affected by climate change risks as it is not a physical infrastructure development project. To mitigate other potential risks, contingency action plans will be developed for every

			component. The action plan will be regularly monitored and be adapted to current situation.
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7. *Cost Effectiveness.* Explain how [cost-effectiveness](#) is reflected in the project design:

This project will be cost effective because:

- The project has been designed so as to ensure that all activities and components are not duplicative and directed to addressing gaps identified previously.
- The project will build upon the foundations laid by previous project and related national biosafety initiatives.
- The multi-agency Project Steering Committee (PSC) of this project will further ensure that all activities will be coordinated, reducing transaction costs.
- As part of the stocktaking assessment and project management, efforts would be made to leverage participation from existing resources and institutional infrastructure to ensure wider outreach in various programmes.
- The project design provides for regional and sub-regional approaches and also places emphasis on training of trainers which can be replicated throughout the country and the region.

The project has adopted an issue-based or thematic approach as per the guidance from the Terminal Evaluation of the previous biosafety project and national operational and capacity building interventions; focusing on Risk Assessment and Risk Management, Handling, Transport, Packaging and Identification of LMOs, Socio-economic Considerations, Liability and Redress and Public Awareness. This approach will cut across institutional and sectoral barriers to build national capacity in these critical areas. This approach will also foster pooling of resources, promote international coordination and be cost effective.

8. *Coordination.* Outline the coordination with other relevant GEF-financed projects and other initiatives [not mentioned in 1]:

The project is well coordinated with issued based interventions in other ongoing GEF Biosafety Implementation Projects in the region. In addition, planned interventions under component 5 will strengthen the existing national activities under the Malaysian Biosafety Clearing House (<http://www.biosafety.nre.gov.my/>) and will also provide hands on experience through Malaysia's participation in the recently approved UNEP-GEF BCH Project (BCH III – GEF ID – 5688).

The project is in line with a number of ongoing capacity building initiatives under the aegis of various stakeholder Ministries/Agencies which include; Ministry of Natural Resources and Environment (NRE), Department of Biosafety, Ministry of Agriculture and Agro-Based Industry (MOA), Ministry of Science, Technology and Innovation (MOSTI), Ministry of Health (MOH), Ministry of International Trade and Industry (MITI), Ministry of Plantation Industry and Commodities and Ministry of Domestic Trade, Co-Operatives and Consumerism. The

Government of Malaysia intends to leverage GEF resources to complement their ongoing activities and facilitate effective implementation of the CPB. All efforts will be made to ensure synergy between the ongoing programs, avoid overlaps and optimize the available resources. Effective project oversight will be ensured through establishment of a Project Steering Committee (PSC), chaired by the Secretary General of NRE, with members from relevant agencies. The PSC will review the project activities at least once a year, and will work closely with various ongoing initiatives carried out by other Ministries and stakeholders. Project management and coordination among different agencies will be carried out by the Project Management Unit (PMU) led by the National Project Director (NPD). Refer to Annex H for the project organizational structure.

Malaysia through the Department of Biosafety of the Ministry of Natural Resources and Environment has a full-fledged national program of work on biosafety supported by the Government of Malaysia. The Government through the Department has an annual operational budget to cover biosafety activities including the work of the National Biosafety Board in reviewing and providing guidance on biosafety applications and related biosafety activities. As part of the Government's ongoing support, the Department of Biosafety is executing the following activities:

- 1) Annual seminars for Institutional Biosafety Committees (IBCs) - These 2 day seminars are open to all institutions involved in LMO R&D related activities that have established their IBCs with the objectives to build their capacity and responsibilities. It also provides a platform to all participants to raise any biosafety related issues for discussion;
- 2) Periodic Biosafety Training Workshops – These 2 day workshops are specifically designed to suit the need of institutions in building their knowledge and capacity on the national biosafety system and also new and emerging trends in biosafety and regulatory issues;
- 3) Publication of Biosafety Newsletter - The newsletter is published on yearly basis to cover all programs and publications made within 1 year period;
- 4) Regular updating of BCH Central Portal and Malaysia BCH (<http://www.biosafety.nre.gov.my/default.shtml>);
- 5) Periodic BCH training for relevant stakeholders including lecturers, students, technology developers and potential applicants;
- 6.) In addition the Department of Biosafety is using social media tools including its Facebook page (<https://www.facebook.com/pages/Department-of-Biosafety-Malaysia/241181925916017>), youtube (<http://www.youtube.com/user/nreportal2011#p/a/u/2/Ny71zUEJw5w>) and its capacity building page on the Malaysian BCH to reach out to the public as an ongoing activity (http://www.biosafety.nre.gov.my/capacity_building/activities.shtml)

Several publications have been developed and these are continually updated as an ongoing process (http://www.biosafety.nre.gov.my/capacity_building/publication.shtml)

The project will contribute and provide inputs into the regional initiative on Environment and Health. The forum is to effectively deal with the environmental health problems within countries and among themselves by increasing the capacity of Southeast and East Asian countries on environmental health management. It aims to strengthen the cooperation of the ministries

responsible for environment and health within the countries and across the region by providing a mechanism for sharing knowledge and experiences, improving policy and regulatory frameworks at the national and regional levels, and promoting the implementation of integrated environmental health strategies and regulations. UNEP and WHO jointly provide the secretariat for this initiative and the last ministerial meeting of the forum was held in Malaysia in September 2013. <http://www.environment-health.asia/>

9. *Institutional Arrangement.* Describe the institutional arrangement for project implementation:

The institutional arrangements for project supervision at the national level will be carried out as indicated in the Organizational Chart (Annex H) as follows:

- i. **National Executing Agency (NEA):** The Ministry of Natural Resources and Environment (NRE), the national competent authority for CPB will be the National Executing Agency (NEA) for this project. The Ministry will execute the project through its Department of Biosafety and Forest Research Institute of Malaysia and will work on behalf of Government of Malaysia to manage the project and will take overall responsibilities for the implementation and execution of the project and achievements of its objectives. NEA will also provide the necessary scientific, technical, financial and administrative support to the project, working in close cooperation with relevant government agencies, the scientific community and other stakeholders.
- ii. **Project Steering Committee (PSC):** A Project Steering Committee (PSC) will be constituted by the NRE to advise and guide the implementation of the project. The committee will be chaired by Secretary General of NRE and the members will include senior representatives from concerned ministries/agencies with mandates relevant to the CPB, scientific experts, NGOs and a UNEP representative. It would meet at least once a year. Individual experts may be invited to provide inputs as appropriate to specific meetings. The PSC will oversee the project progress through receipt of half-yearly progress reports and make recommendations to UNEP on the need to revise any aspects of the Results Framework or the M&E plan. The PSC will participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan.
- iii. **National Project Director (NPD):** The Director General of Department of Biosafety under the NRE will be appointed as NPD of the project and would be responsible for managing the overall project, ensuring that all outcomes are achieved in a timely and cost-effective manner, in accordance to GEF and UNEP procedures. The NPD will oversee the NPC in the preparation of the annual Project Implementation Report (PIR); the GEF Tracking Tool and participate in the mid-term review and terminal evaluation. At the conclusion of the project, he/she will be responsible for the completion of the project closure procedures including timely submission of all technical, financial and audit reports to UNEP.
- iv. **National Project Coordinator (NPC):** A National Project Coordinator (NPC) will be appointed for day to day coordination of project activities. The NPC will ensure implementation of the project activities as set out in the project document. He/She would assist the NPD in discharging its functions as guided by PSC. The NPC will work with UNEP in the preparation of the annual Project Implementation Report (PIR), the mid-term and terminal evaluations, and the GEF Tracking Tool (Annex J) and is responsible for preparation of project management and expenditure reports and project terminal

reports, at the completion of the project. The NPC will also work in close collaboration with the Project Management Unit (PCU) as well as manage all other consultants and contractors appointed for the execution of the project. The TOR for the NPC team is in Annex O.

- v. **Project Management Unit (PMU):** A Project Management Unit (PMU) will be established to provide accountability and in the execution of the project. The PMU will be chaired by NPD and will be located at the Department of Biosafety.

The Terms of Reference for the designated institutions are captured as Annex O

10. Knowledge Management. Outline the knowledge management approach for the project, including, if any, plans for the project to learn from other relevant projects and initiatives, to assess and document in a user-friendly form, and share these experiences and expertise with relevant stakeholders.

UNEP has an existing platform through the library of its project management database ANUBIS (A New UNEP Biosafety Information System) for the Biosafety projects and related initiatives to learn from each other, share experience and expertise and also tools and methodologies to support Biosafety Decision making. ANUBIS also allows the projects to assess project outputs and reports in a user-friendly form. In addition, UNEP has created an annual forum for the projects to physically meet at regional/subregional level to learn and share experiences on project management including best practices and challenges, in addition to training on emerging issues in Biosafety. The project will also have access to UNEP Biosafety's YouTube channel to access medial files and also share materials for the benefit of the projects in the portfolio. Existing mechanisms and training will be offered for the project to assess and share information on the Biosafety Clearing House in line with obligations of Article 20 of the Cartagena Protocol on Biosafety.

11. Consistency with National Priorities. Is the project consistent with the National strategies and plans or reports and assessments under relevant conventions? (yes ☒ /no ☐). If yes, which ones and how: NAPAs, NAPs, NBSAPs, ASGM NAPs, MIAs, NCs, TNAs, NCSA, NIPs, PRSPs, NPFE, BURs, etc.

This project is consistent with the national priorities as identified under the National Policy on Biological Diversity, the National Biotechnology Policy, the National Agricultural Policy and the National Biosafety Framework. The project is designed to provide interventions to address key issues highlighted under response numbers 147 and 150 of the Second National Biosafety Report of Malaysia (see <http://bch.cbd.int/database/record.shtml?documentid=102392>).

The National Biotechnology Policy emphasized the importance of agricultural biotechnology to the national development agenda. This policy should be implemented without compromising the sustainable use of natural resources; it should safeguard the environment, and meet safety and the high quality standards of agricultural products. The National Agricultural Policy also underscores the importance of adopting new technologies, including modern biotechnology to meet national agricultural targets like increasing productivity and competitiveness, strengthen linkages with other sectors, venture into new frontiers and at the same time, conserve and utilize natural resources in a sustainable manner. Therefore, the creation of a workable biosafety framework to regulate and address the national concerns mentioned above is of paramount importance. This project will enhance Malaysia's capacity to bring LMO products safely to the

field and the market with due consideration to the conservation of the environment and its vast genetic resources.

12. M & E Plan. Describe the budgeted monitoring and evaluation plan.

UNEP will be responsible for managing the mid-term review/evaluation and the terminal evaluation (see Annex G). The Project Manager and partners will participate actively in the process.

The project will be reviewed or evaluated at mid-term (tentatively in August 2016 as indicated in the project milestones). 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. In addition, it will verify information gathered through the GEF tracking tools. [Note: For a short duration project, PIR will serve as the project MTR.

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.

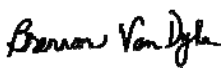
The TE report will be sent to project stakeholders for comments. Formal comments on the report will be shared by the EO in an open and transparent manner. The project performance will be assessed against standard evaluation criteria using a six point rating scheme. The final determination of project ratings will be made by the EO when the report is finalised. 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.

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

- A. Record of Endorsement⁸ of GEF Operational Focal Point (S) on Behalf of the Government(S):** (Please attach the [Operational Focal Point endorsement letter\(s\)](#) with this template. For SGP, use this [SGP OFP endorsement letter](#)).

NAME	POSITION	MINISTRY	DATE (MM/dd/yyyy)
Dr. Gary William Theseira	Deputy Undersecretary, Climate Change and Environmental Management Division	MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT (NRE)	

B. GEF Agency(ies) Certification

This request has been prepared in accordance with GEF policies ⁹ and procedures and meets the GEF criteria for a medium-sized project approval under GEF-6.					
Agency Coordinator, Agency name	Signature	DATE (MM/dd/yyyy)	Project Contact Person	Telephone	Email Address
Brennan Van Dyke Director, GEF Coordination Office, UNEP		April 01, 2015	Alex Owusu- Biney Task Manager	+254 20 7624066	Alex.Owusu- Biney@unep.org

C. ADDITIONAL GEF PROJECT AGENCY CERTIFICATION (*Applicable only to newly accredited GEF Project Agencies*)

For newly accredited GEF Project Agencies, please download and fill up the required [GEF Project Agency Certification of Ceiling Information Template](#) to be attached as an annex to this project template.

⁸ For regional and/or global projects in which participating countries are identified, OFP endorsement letters from these countries are required even though there may not be a STAR allocation associated with the project.

⁹ GEF policies encompass all managed trust funds, namely: GEFTF, LDCF, and SCCF

ANNEXES

Annex A: Project Logical Framework

Annex E: Consultants to be hired

Annex F-1: Detailed GEF Budget

Annex F-2: Detailed Co-finance Budget

Annex G: M&E Budget Workplan

Annex H: Project Implementation Arrangements

Annex I: Detailed Project Workplan Showing Deliverables and Benchmarks

Annex J: Focal Area Tracking Tools

Annex K: OFP Endorsement Letter

Annex L: Co-finance Commitment Letter

Annex M: Environmental and Social Safeguards

Annex N: Abbreviations

Annex O: Terms of Reference

Annex P: Draft Procurement Plan

ANNEX A: PROJECT RESULTS FRAMEWORK (either copy and paste here the framework from the Agency document, or provide reference to the page in the project document where the framework could be found).

Goal			
The Project is designed to respond to the GEF Strategic Objective BD-SO3, which is <i>To Build Capacity for the Implementation of the Cartagena Protocol on Biosafety</i> . The proposed project also responds to the commitment under Article 22 of the Cartagena Protocol on Biosafety (CPB) to provide support for capacity building for the effective implementation of the CPB and the new Biosafety Strategy 2011- 2020 (BS V/16). The project activities confirm with the COP guidance to the GEF with respect to biosafety, in particular the key elements in the 'Updated Action Plan for Building Capacities for the Effective Implementation of the CPB (COP-MOP-3) which identifies institutional capacity building, human resource development and training, risk assessment and management, public awareness and education, identification of LMOs including detection, implementation of documentation requirements under Article 18 (2) and socio economic consideration as the key elements requiring concrete action for effective implementation of the Protocol and as per guidance from COP-MOP5 BS-V para 4f & g.			
Project Objective			
To strengthen the biosafety management system in Malaysia with special emphasis on thematic interventions to facilitate handling and decision making on LMO.			
Objectives	Objectively Verifiable Indicators	Means of Verification	Risk and Assumptions
Component I Needs Assessment			
Outcome:			
1.1 A consolidated action plan is developed to guide the design of the project.	<ul style="list-style-type: none"> Within the first six months of project commencement, the project design will be fine-tuned based on the updated information and needs assessment by the Project Team under the supervision of the National Execution Agency (NEA). 	<ul style="list-style-type: none"> A needs assessment report 	Risk <ul style="list-style-type: none"> Delays in receiving the feedback from respondents Slow response from line departments Assumption <ul style="list-style-type: none"> Response from all concerned line departments Key respondents provide inputs
Outputs:			
1.1.1 Stocktaking report capturing the current status of biosafety issues, identified gaps, planned	<ul style="list-style-type: none"> Draft document prepared and presented for validation through consultations with stakeholders within six months of project 	<ul style="list-style-type: none"> Validated base paper 	Risk <ul style="list-style-type: none"> Difficulties in validation Assumption <ul style="list-style-type: none"> Availability of required information

training interventions and long term funding plans.	commencement.		
1.1.2 National Consultative meeting reports (with a stakeholder participation plan).	<ul style="list-style-type: none"> Final report on the draft outputs submitted by NPC. 	<ul style="list-style-type: none"> Proceedings of national consultations Revised project designs 	<p>Risk</p> <ul style="list-style-type: none"> Lack of consensus <p>Assumption</p> <ul style="list-style-type: none"> Clear recommendations will be obtained
Component II Risk and socio economic assessment with related management framework			
A. Risk Assessment and Management			
Outcome:			
2A.1 A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMOs risk.	<ul style="list-style-type: none"> Within 48 months, technical and regulatory frameworks for risk assessment and risk management adopted by the designated competent authorities. 	<ul style="list-style-type: none"> Notification/Announcement 	<p>Assumption</p> <ul style="list-style-type: none"> Strong government commitment
Output:			
2A.1.1 Updated RA and RM procedures and guidelines in line with recent developments under CPB	<ul style="list-style-type: none"> Within 12 months, RA and RM procedures and guidelines are updated and used. 	<ul style="list-style-type: none"> Report to National Project Steering Committee Report to Genetic Modification Advisory Committee (GMAC) 	<p>Risk</p> <ul style="list-style-type: none"> Overlapping mandates among key agencies <p>Assumption</p> <ul style="list-style-type: none"> To build on ongoing initiatives
2A.1.2 LMOs are monitored by regulatory agencies after	<ul style="list-style-type: none"> Within 24 months, effective post release mechanism in place for monitoring of compliance 	<ul style="list-style-type: none"> Monitoring reports submitted to the GMAC sub-committee on compliance. 	<p>Risk</p> <ul style="list-style-type: none"> Unclear parameters to be monitored Lack of consensus on parameters to

environmental release			be monitored and frequency of monitoring
			Assumption
			<ul style="list-style-type: none"> Resources will be available for monitoring
B. Socio-economic (SE) assessment			
Outcome:			
2B.1 Socio-economic assessment is considered.	<ul style="list-style-type: none"> Within 30 months, parameters and methodologies for socio economic assessments in place to guide assessors. 	<ul style="list-style-type: none"> Decision documents for the National Biosafety Board. 	<p>Risk</p> <ul style="list-style-type: none"> Conflicts with other international obligations e.g. WTO Lack of consensus on methodologies Low priority accorded to SE considerations in decision making <p>Assumptions</p> <ul style="list-style-type: none"> Expertise available in carrying out SE assessments.
Outputs:			
2B.1.1 Survey reports on socio-economic issues in relation to LMOs and socio-economic guidelines and methodologies are developed for assessment of LMOs	<ul style="list-style-type: none"> Within 30 months, model questionnaires are available and survey is conducted. Special emphasis on targeting women throughout the consultation process and gender segregated data will be captured as part of the surveys. 	<ul style="list-style-type: none"> Report of socio economic survey 	<p>Risk</p> <ul style="list-style-type: none"> Effectiveness of survey reduced by lack of proper infrastructure and communication tools. <p>Assumption.</p> <ul style="list-style-type: none"> To build on the experience of GM mosquito.

2B.1.2 Cost benefit analysis guidelines developed for socio-economic assessors.	<ul style="list-style-type: none"> • Within 30 months, cost benefit analysis guidelines are available. 	<ul style="list-style-type: none"> • Before the event studies 	<p>Risk</p> <ul style="list-style-type: none"> • Lack of adequate expertise in cost benefit analysis for transgenics. <p>Assumption</p> <ul style="list-style-type: none"> • To build on the experience of GM mosquito
Component III Framework for handling LMOs			
A. Handling, transport , packaging and identification of LMOs			
Outcome:			
3A.1 A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB.	<ul style="list-style-type: none"> ▪ Within 30 months, an operational administrative system for handling, transport, packaging and identification of LMOs is in place 	<ul style="list-style-type: none"> ▪ Establishment of an administrative system for handling, transport, packaging and identification of LMOs is in place ▪ Notification/Announcement 	<p>Risk</p> <ul style="list-style-type: none"> • Lack of consensus on institutional arrangement • Poor inter-departmental coordination <p>Assumption</p> <ul style="list-style-type: none"> • Need has been recognized.
Outputs:			
3A.1.1 National codes of best practices and procedural guidelines for handling, transport, packaging and identification of LMOs.	<ul style="list-style-type: none"> ▪ Within 36 months, national procedures for handling, transport, packaging and identification of LMOs is established. 	<ul style="list-style-type: none"> ▪ Procedural document ▪ Notification 	<p>Risk</p> <ul style="list-style-type: none"> ▪ Lack of experience and national expertise. <p>Assumption</p> <ul style="list-style-type: none"> ▪ International guidelines and expertise available
3A.1.2 Strategic guidance document on sampling, thresholds	<ul style="list-style-type: none"> ▪ Within 24 months, guidance document for sampling, thresholds and inventory of 	<ul style="list-style-type: none"> ▪ Guidance document 	<p>Risk</p> <ul style="list-style-type: none"> ▪ Lack of experience and national expertise. <p>Assumption</p>

and inventory of LMOs from selected countries.	LMOs is in place.		<ul style="list-style-type: none"> International guidelines and expertise available.
3A.1.3 Policy or action plan on low level presence is formulated.	<ul style="list-style-type: none"> Within 24 months, action plan on low level presence in place. 	<ul style="list-style-type: none"> Low level presence action plan document 	<p>Risk</p> <ul style="list-style-type: none"> Lack of experience and national expertise on low level presence issue. <p>Assumption</p> <ul style="list-style-type: none"> International expertise available.
B. Liability and Redress			
Outcome:			
3B.1 Administrative and legal for the implementation of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety established.	<ul style="list-style-type: none"> Within 48 months, having in place national administrative and legal frameworks incorporating rules and procedures on liability and redress for damage caused by LMOs. 	<ul style="list-style-type: none"> Establishment of a national liability and redress regulatory framework Notification 	<p>Risk</p> <ul style="list-style-type: none"> Lack of consensus on institutional arrangement Poor inter-departmental coordination. <p>Assumption</p> <ul style="list-style-type: none"> Need has been recognized.
Outputs:			
3B.1.1 A plan to implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena	<ul style="list-style-type: none"> Within 18 months, implementation plan for the supplementary protocol is in place. 	<ul style="list-style-type: none"> Implementation plan document 	<p>Risk</p> <ul style="list-style-type: none"> Lack of experience and national expertise. <p>Assumption</p> <ul style="list-style-type: none"> Local and international expertise available.

Protocol on Biosafety developed.			
3B.1.2 Amended laws or Regulations on Liability and Redress gazetted.	<ul style="list-style-type: none"> Within 48 months, national laws related to liability and redress in place. 	<ul style="list-style-type: none"> Legal instruments amended or newly enacted 	<p>Risk</p> <ul style="list-style-type: none"> Lack of experience and national expertise. <p>Assumption</p> <ul style="list-style-type: none"> Local and international expertise available
Component IV Institutional Capacity Building			
Outcome:			
4.1 Institutional capacity on biosafety especially in the areas of risk evaluation, detection and enforcement measures at the ports of entry is enhanced	Within 48 months, an institution with a network of 2-3 laboratories is strengthened for LMO detection	An efficient LMO detection institutional network is established	<p>Risk</p> <ul style="list-style-type: none"> Lack of recognition of strengthened institution due to legal and policy changes Staff attrition <p>Assumption</p> <ul style="list-style-type: none"> Training of trainers will mitigate above risks.
Outputs:			
4.1.1 A feasibility study is carried out on public partnership for LMO detection.	<ul style="list-style-type: none"> Within 24 months, of the project inception potential partnerships are identified. 	<ul style="list-style-type: none"> MOUs/letters of intent between potential project partners 	<p>Risk</p> <ul style="list-style-type: none"> Bureaucratic procedures to formalise MoUs <p>Assumption</p> <ul style="list-style-type: none"> Objective is in line with existing Government policies Several funding options are available for sustainability partnership model
4.1.2 Institutions are strengthened	<ul style="list-style-type: none"> Within 30 months, improved infrastructure plans 	<ul style="list-style-type: none"> Key instruments are in place 	<p>Risk</p> <ul style="list-style-type: none"> Delay in procurement of

with improved infrastructure and equipment for detection and verification of LMOs.	and equipment are available.		key instruments
			Assumptions <ul style="list-style-type: none"> ▪ Alternative procurement options could be explored ▪ Build on experience gained in biosafety GEF4 project.
4.1.3 Current methodology and procedures are reviewed and upgraded for LMO detection.	<ul style="list-style-type: none"> • Within 30 months, 20 technicians are trained in LMO detection and operational maintenance of equipment 	<ul style="list-style-type: none"> • Certification training 	of Risk <ul style="list-style-type: none"> ▪ Staff attrition Assumption <ul style="list-style-type: none"> • Training of trainers • Timely recruitment to fill vacancies • Proper working documents are available
4.1.4 Institutional capacity on liability and redress are developed.	<ul style="list-style-type: none"> • Within 48 months, an institutional mechanism established to facilitate the implementation of the procedures on liability and redress at the national level. 	<ul style="list-style-type: none"> • Procedures liability redress 	on and Risk <ul style="list-style-type: none"> • Lack of consensus on institutional arrangement • Poor inter-departmental coordination Assumption <ul style="list-style-type: none"> • Need has been recognized
4.1.5 Biology documents are developed on fields crops/traits identified by technical committee.	<ul style="list-style-type: none"> • Within 48 months, conducted biosafety studies on certain issues/areas following decision on a particular LMO. 	<ul style="list-style-type: none"> • Biology documents 	Risk <ul style="list-style-type: none"> • Availability of required information Assumption <ul style="list-style-type: none"> • Dedicated institutions expected to have the information
4.1.6 Training modules/manuals are	<ul style="list-style-type: none"> • Within 42 months, training manuals and a working 	<ul style="list-style-type: none"> • Training manual and working knowledge 	Risk <ul style="list-style-type: none"> • Enforcement only at points of entry

prepared for conducting/evaluating risk assessment and management, monitoring field trials of LMOs and compliance evaluation and training of quarantine and inspection officials for enhanced enforcement at the ports of entry.	knowledge document for customs and plant quarantine officials for enforcement are in use.	document available.	are	may be inadequate due to porous border Assumption <ul style="list-style-type: none"> Building on existing enforcement mechanisms e.g. quarantine and customs.
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Component V: Biosafety Communication Framework

Outcome:

5.1 Public awareness on biosafety issues (including liability and redress) increased.	<ul style="list-style-type: none"> Within 48 months, extent of feedback from target groups on biosafety issues, regulations and procedures is increased up to 50%. 	<ul style="list-style-type: none"> Participants list in various awareness programmes. Outreach products used as reference material. 	<p>Risk</p> <ul style="list-style-type: none"> Population that can be reached is limited due to the size of the country, time and funds constraints. Strong anti-biotech NGOs <p>Assumptions</p> <ul style="list-style-type: none"> Strong government and private sector support for increasing public awareness.
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Outputs:

5.1.1 Innovative outreach programs are developed for risk communication both	<ul style="list-style-type: none"> Within 18 months, outreach materials for print and electronic media are available for risk communication in Malay and English languages. 	<ul style="list-style-type: none"> Outreach material for risk communication in Malay and English is available. 	<p>Risk</p> <ul style="list-style-type: none"> Population that can be reached is limited due to the geographical of the country, time and funds constraints
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	through print and electronic/social media.			<ul style="list-style-type: none"> Quality of outreach material and timeliness of delivery <p>Assumptions</p> <ul style="list-style-type: none"> Strong government and private sector support for increasing public awareness Increasing public awareness will be part of a future long term communication strategy.
5.1.2	Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies.	<ul style="list-style-type: none"> Within 36 months, at least 3 audio visual educational programmes on biosafety are available for students. 	<ul style="list-style-type: none"> Audio visual educational programme for students is available. 	<p>Risk/Assumptions</p> <p><i>Same as above</i></p>
5.1.3	Primers/brochures/booklets/FAQs/biosafety newsletters and Glossary of terms in different local languages are widely distributed to policy makers,	<ul style="list-style-type: none"> Within 24 months, tailor made primers/brochures/booklets/FAQs are available in different languages. 	<ul style="list-style-type: none"> Country-wide circulation of awareness raising materials for various targeted audience. 	<p>Risk/Assumptions</p> <p><i>Same as above</i></p>

researchers,
students,
farmers,
civil society
etc.

5.1.4 A mechanism is established to communicate regulatory decisions on LMOs to the public.	<ul style="list-style-type: none"> Regulatory decisions are deposited in national biosafety websites including national BCH within 14 days of decision making. 	<ul style="list-style-type: none"> Records in national biosafety website and BCH 	<p>Risk/Assumptions</p> <p><i>Same as above</i></p>
5.1.5 Biosafety topic including BCH is incorporated in school and university curricula.	<ul style="list-style-type: none"> Within 48 months, biosafety is integrated into the curricula and educational programmes for different levels of formal education. 	<ul style="list-style-type: none"> Academic programmes/courses including biosafety issues 	<p>Risk/Assumptions</p> <p><i>Same as above</i></p>

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

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

NA

ANNEX E: Consultants to be hired

<i>Position Titles</i>	<i>\$/pers on week*</i>	<i>Estimated person weeks*</i>	<i>Total</i>	<i>Tasks to be performed</i>
For Project Management				
Local				
International – None				
Justification for Travel, if any N/A				
For Project Management				
Local				
Project Manager and activity coordinator	400	180	72,000	<p>To undertake the general administrative responsibilities of the project, including those related to project management tasks are:</p> <p>Ensure that project Objective, Outcomes, Components and Activities are executed in a timely and appropriate manner.</p> <p>Develop annual work plans and budgets, and submit them to the Steering Committee for approval.</p> <p>Develop TORs for Consultants for technical assistance, consultants, experts, and specifications of materials and equipment by the project, in consultation with the Project Committee.</p> <p>Facilitate, guide and monitor the work of consultants and experts, approve their deliverables in association with the Project Committee.</p> <p>Organize and assist in project related activities and meetings. These may include planning for meetings, workshops, consultations, trips, and other project related activities.</p> <p>Establish and maintain linkages with national and local organizations and persons which/who can help achieve the objectives of the Project.</p> <p>Provide timely reporting of project status as requested by the Project Committee and the UNEP.</p> <p>Maintain records of Project Committee meetings, decisions, actions etc.</p> <p>Coordinate with other initiatives and programs to ensure that outputs are relevant to this project's objectives.</p> <p>Any other duties assigned by the Project Committee and of direct relevance to the project.</p>
Total LOCAL		180	72,000	
For Technical Assistance				
Local				

Senior Consultant/Scientist (Risk Assessment and Risk Management)	1000	10	10,000	To provide technical support and inputs for outcome for Component II: Preparation of guidelines for specific types with specific LMOs. Assessment of roles and responsibilities of post release monitoring and development of for post release monitoring.
Senior Consultant/Scientist (LMO Detection)	1000	10	10,000	To provide technical support and inputs for for sampling, detection, quantification and and identification of institutions to be responsible and testing of LMOs.
Socio-economics specialist	1000	10	10,000	To provide technical support and inputs for outcome for Component II: Preparation of questionnaire for conducting survey Preparation of guidelines and methodologies and risk benefit analysis.
Liability & Redress Expert	1000	20	20,000	To provide technical support for reviewing framework and identifying the best approach national law on liability and redress.
Public consultation expert	1000	10	10,000	To provide technical support and inputs pre communication strategy and for implementation awareness strategy, review developed materials inputs for training.
Total LOCAL		60	60,000	
International				
Socio-economics Expert	2000	1	2,000	To peer review socio-economic guidelines
Risk Assessment Expert	2000	2	4,000	To peer review operational guidelines, case materials on Risk Assessment and Risk Management
LMO Detection	2000	2	4000	To peer review operational manuals on LMO sampling, detection and quantification
Total International		5	10,000	

Annex F-1: Detailed GEF Budget

Project No: GFL-2328-2716-[XXXX]								
Project Name: Institutional Capacity to Enhance Biosafety Practices in Malaysia								
Executing Agency: Ministry of Natural Resources and Environment								
UNEP BUDGET LINE/OBJECT OF EXPENDITURE		ACTIVITY (AS PER ANNEX 1B)						
		A	B	C	D	E	F	G
		US\$	US\$	US\$	US\$	US\$	US\$	US\$
10 PROJECT PERSONNEL COMPONENT								
1101	National Project Coordinator	0.00	0.00	0.00	0.00	0.00	0.00	72,000.00
1102	Project Staff	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1120	Administrative Staff	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1201	International Consultants	0.00	4,000.00	4,000.00	2,000.00	0.00	0.00	0.00
1202	National Consultants	10,000.00	20,000.00	20,000.00	0.00	10,000.00	0.00	0.00
1601	Staff Travel & Transport	2,000.00	10,000.00	7,000.00	8,000.00	6,500.00	0.00	3,000.00
1999	Component Total	12,000.00	34,000.00	31,000.00	10,000.00	16,500.00	0.00	75,000.00
20 SUB-CONTRACT COMPONENT								
2201	Sub-contract to GOV (US\$)ernmental	3,000.00	20,000.00	17,500.00	30,000.00	32,000.00	0.00	0.00
2301	Sub-contract to private firms	2,000.00	10,000.00	9,000.00	13,000.00	11,000.00	0.00	0.00
2999	Component Total	5,000.00	30,000.00	26,500.00	43,000.00	43,000.00	0.00	0.00
30 TRAINING COMPONENT								
3201	Training	0.00	10,000.00	7,000.00	100,000.00	6,000.00	0.00	0.00
3301	Meetings	5,000.00	20,000.00	18,000.00	10,000.00	28,500.00	0.00	5,000.00
3999	Component Total	5,000.00	30,000.00	25,000.00	110,000.00	34,500.00	0.00	5,000.00
40 EQUIPMENT & PREMISES COMPONENT								
4101	Office supplies and consummables	0.00	0.00	0.00	4,000.00	8,000.00	0.00	4,000.00
4102	Laboratory supplies and consummables	0.00	0.00	0.00	0.00	0.00	0.00	0.00
4201	Non Laboratory Purchase	0.00	0.00	0.00	5,000.00	5,000.00	0.00	0.00
4202	Laboratory Equipment	0.00	0.00	15,000.00	0.00	0.00	0.00	0.00
4301	Office Premises	0.00	0.00	0.00	0.00	0.00	0.00	0.00
4302	Research Facilities	0.00	0.00	0.00	0.00	0.00	0.00	0.00
4999	Component Total	0.00	0.00	15,000.00	9,000.00	13,000.00	0.00	4,000.00
50 MISCELLANEOUS COMPONENT								
5101	Equipment Maintenance	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5201	Publication, Translation, Dissemination and	2,000.00	40,000.00	36,500.00	70,000.00	175,000.00	0.00	0.00
5202	Audit Reports	0.00	0.00	0.00	0.00	0.00	5,000.00	0.00
5301	Communications (tel, fax, e-mail, etc..)	1,000.00	6,000.00	6,000.00	4,000.00	12,000.00	0.00	2,000.00
5302	Others	0.00	10,000.00	0.00	4,000.00	6,000.00	0.00	4,000.00
5303	Tech.Supp./Evaluation	0.00	0.00	0.00	0.00	0.00	35,000.00	0.00
5375	UN Agencies Support Charge	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5999	Component Total	3,000.00	56,000.00	42,500.00	78,000.00	193,000.00	40,000.00	6,000.00
TOTAL COSTS		25,000.00	150,000.00	140,000.00	250,000.00	300,000.00	40,000.00	90,000.00

Annex F-2: Detailed Co-finance Budget

Project No: GFL-2328-2716-[XXXX]		Project Management					
Project Name: Institutional Capacity to Enhance Biosafety Practices in Malaysia							
Executing Agency: Ministry of Natural Resources and Environment							
UNEP BUDGET LINE/OBJECT OF EXPENDITURE		ACTIVITY (AS PER ANNEX 1B)					
		A	B	C	D	E	F
		US\$	US\$	US\$	US\$	US\$	US\$
10 PROJECT PERSONNEL COMPONENT							
1101	National Project Coordinator	0.00	0.00	0.00	0.00	0.00	0.00
1102	Project Staff	30,000.00	72,000.00	72,000.00	6,000.00	30,000.00	55,000.00
1120	Administrative Staff	0.00	0.00	0.00	0.00	0.00	0.00
1201	International Consultants	0.00	0.00	0.00	0.00	0.00	0.00
1202	National Consultants	0.00	0.00	0.00	0.00	0.00	0.00
1601	Staff Travel & Transport	6,000.00	30,000.00	21,000.00	24,000.00	19,500.00	0.00
1999	Component Total	36,000.00	102,000.00	93,000.00	30,000.00	49,500.00	55,000.00
20 SUB-CONTRACT COMPONENT							
2201	Sub-contract to GOV (US\$)ernmental	15,000.00	60,000.00	52,500.00	90,000.00	96,000.00	0.00
2301	Sub-contract to private firms	0.00	30,000.00	27,000.00	39,000.00	33,000.00	0.00
2999	Component Total	15,000.00	90,000.00	79,500.00	129,000.00	129,000.00	0.00
30 TRAINING COMPONENT							
3201	Training	0.00	30,000.00	21,000.00	300,000.00	18,000.00	0.00
3301	Meetings	15,000.00	60,000.00	54,000.00	30,000.00	85,500.00	0.00
3999	Component Total	15,000.00	90,000.00	75,000.00	330,000.00	103,500.00	0.00
40 EQUIPMENT & PREMISES COMPONENT							
4101	Office supplies and consumables	0.00	0.00	0.00	12,000.00	24,000.00	0.00
4102	Laboratory supplies and consumables	0.00	0.00	0.00	0.00	0.00	0.00
4201	Non Laboratory Purchase	0.00	0.00	0.00	15,000.00	15,000.00	0.00
4202	Laboratory Equipment	0.00	0.00	45,000.00	0.00	0.00	0.00
4301	Office Premises	0.00	0.00	0.00	0.00	0.00	0.00
4302	Research Facilities	0.00	0.00	0.00	0.00	0.00	0.00
4999	Component Total	0.00	0.00	45,000.00	27,000.00	39,000.00	0.00
50 MISCELLANEOUS COMPONENT							
5101	Equipment Maintenance	0.00	0.00	0.00	0.00	0.00	0.00
5201	Publication, Translation, Dissemination	6,000.00	120,000.00	109,500.00	210,000.00	525,000.00	0.00
5202	Audit Reports	0.00	0.00	3,000.00	0.00	0.00	15,000.00
5301	Communications (tel, fax, e-mail, etc...)	3,000.00	18,000.00	22,500.00	12,000.00	36,000.00	0.00
5302	Others	0.00	30,000.00	22,500.00	12,000.00	18,000.00	0.00
5303	Tech.Supp./Evaluation	0.00	0.00	0.00	0.00	0.00	20,000.00
5375	UN Agencies Support Charge	0.00	0.00	0.00	0.00	0.00	0.00
5999	Component Total	9,000.00	168,000.00	157,500.00	234,000.00	579,000.00	35,000.00
TOTAL COSTS		75,000.00	450,000.00	450,000.00	750,000.00	900,000.00	90,000.00

Annex G: M&E Budget Workplan

1. Monitoring Framework and Budget

Objective / Outcome	Outcome / objective level indicator	Baseline Conditions	Midpoint Target (as relevant)	End of Project Target	Means of Verification	Monitoring / sampling (frequency / size)	Location / Group	Responsible
Component I Needs Assessment								
Outcome 1 A consolidated action plan is developed to guide the design of the project	The project design will be fine- tuned based on the updated information and needs assessment by the Project Team under the supervision of the National Execution	Information available but scattered	Information will be consolidated and used	Needs assessment report would be used for sustainability of activities	A needs assessment report	NA	National Experts	NEA

	Agency (NEA).							
Component II Risk and Socio-economic Assessment with Related Management Framework								
2A. Risk Assessment and Management								
Outcome 2A.1 A legal and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMOs risk	The legal framework consistent with CPB will be in place	Laws , policies and guidelines are in place	Gaps in the regulatory regime and inconsistencies with the CPB will be identified	Strengthened legal regime consistent with CPB	Government notification	NA	Legal, technical experts and biotech product developers	National Executive Agency (NEA), and UN
2B. Socio-economic (SE) assessment								
Outcome 2B.1 Socio-economic assessment is considered	Parameters and methodologies for socio economic assessments are in place	Limited experience with GM mosquito	Model questionnaires on SE will be available	Parameters and methodologies for SE assessment, including guidelines for cost benefit analysis are in place	Decision documents of the National Biosafety Board	NA	Public including consumers	NEA and PMU
Component III Framework for Handling LMOs								
3A. Handling, transport, packaging and identification of LMOs								
Outcome 3A.1 A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB	An operational administrative system for handling, transport, packaging and identification of LMOs is in place	A basic administrative system exists but it is inadequate for handling, transport, packaging and identification of LMOs	National codes of best practices and procedural guidelines for handling, transport, packaging and identification of LMOs	An operational administrative system is in place including a detection mechanism	Establishment of an administrative system for handling, transport, packaging and identification of LMOs is in place Government notification	NA	Importers, exporters and traders	NEA and concerned institutions
3B. Liability and Redress								
Outcome 3B.1 Administrative and legal for the implementation of the Nagoya – Kuala Lumpur Supplementary Protocol on	A plan to implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the	Malaysia has not sign or ratify the Supplementary Protocol	An implementation plan for Nagoya – Kuala Lumpur Supplementary Protocol is	A national law on liability and redress enforced	Government notification	NA	Key stakeholders	NEA

Liability and Redress to the Cartagena Protocol on Biosafety established	Cartagena Protocol on Biosafety developed		available and being used					
Component IV Institutional Capacity Building								
Outcome 4 Institutional capacity on biosafety especially in the areas of risk evaluation, detection and enforcement measures at the ports of entry is enhanced	Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMOs	Laboratories for LMO detection exist however these institutions needs further strengthening in terms of infrastructure and human resources Limited number of experts available More focused training needed	Plans for infrastructure improvement are in place Training manuals for environmental risk evaluation and management in place Training manual and working knowledge document for custom and plant quarantine officials available	Institution with a network of 2-3 laboratories is strengthened with improved infrastructure At least 1 official at every point of entry will be trained in enforcement of trans boundary movement procedure	An efficient LMO detection institutional network is established	2 times during project cycle at mid-term review and end of project	Experts in RA & RM involved in technical and scientific advisory committees and biotech R & D developers Exporters, importers and traders of LMOs	NEA
Component V Biosafety Communication Framework								
Outcome 5 Public awareness on biosafety issues (including liability and redress) increased	Consolidate systems for public education, awareness, participation and access to biosafety information established	Approximately 1,000 participants representing various stakeholder groups were covered under GEF4 biosafety project.	Development of a risk communication strategy for various stakeholders	Outreach material for both in print and electronic form available for use by various stakeholders. About 5,000 stakeholders representing key segments covered.	Participants list in various awareness programmes Outreach products used as reference material	2 times during project cycle at mid-term review and end of project	Key stakeholders	NEA

2. Cost of acquisition of essential baseline data during first year of project
The cost is estimated above to be US\$200,000 inclusive of national consultants, and their travel to collect data. This has component costs.

3. Cost of project inception workshop (please include proposed location, number of participants):
The cost of project inception workshop is estimated to be about US\$15,000 (GEF at US\$5,000 and co-finance at US\$10,000) to be combined with a 2-day national consultation on findings of the stocktaking assessment to be held in Kuala Lumpur for representatives representing all stakeholders and state government agencies. Cost is factored into Component I.

4. Cost of MTR/MTE:

The MTR/MTE is expected to be a desk review carried out by 1-2 reviewers. The cost is estimated to be US\$10,000.

Responsible Party: UNEP Task Manager/UNEP Evaluation Office

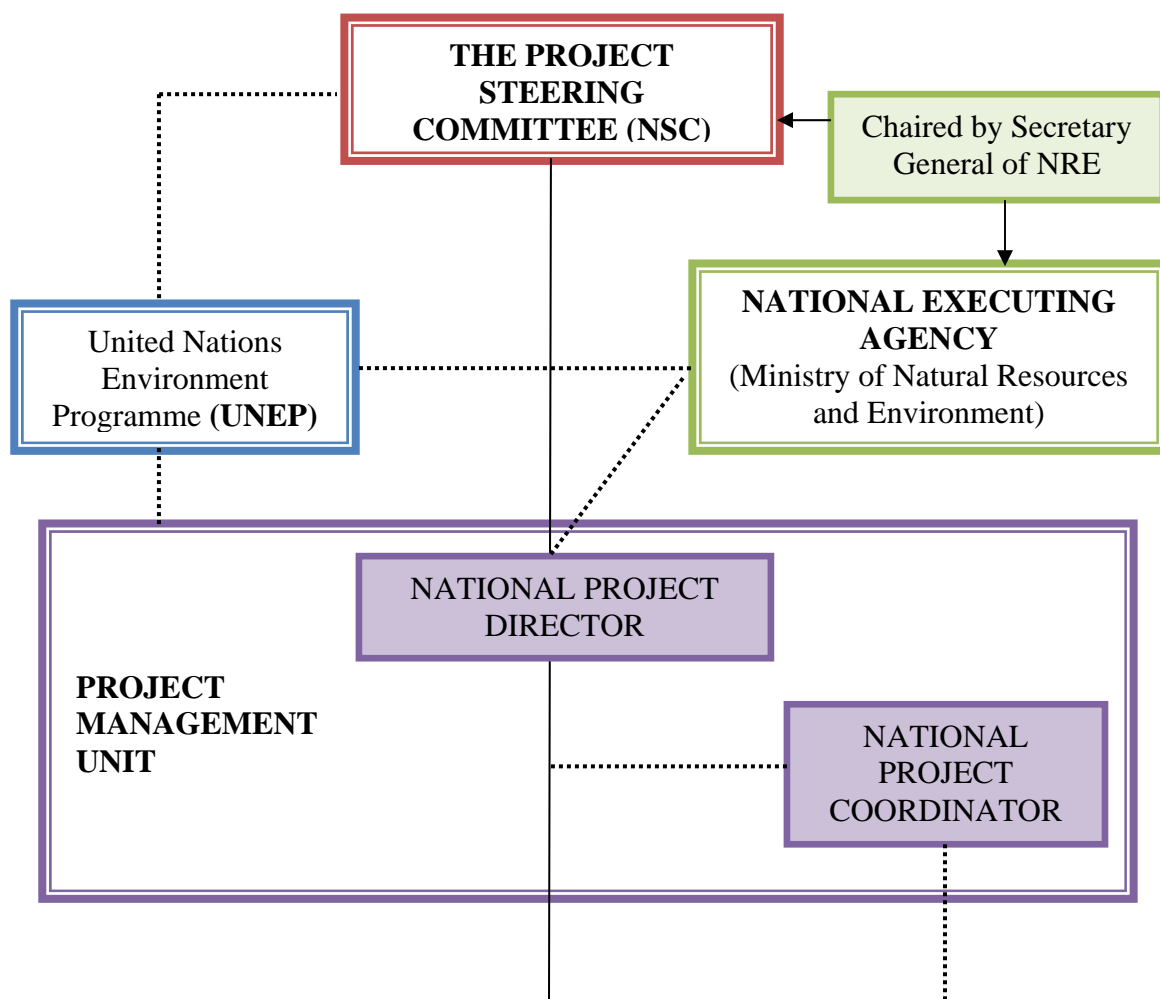
5. Cost of Terminal Evaluation:

The terminal evaluation is expected to be carried by 1-2 independent consultants appointed by the UNEP Evaluation Office. The cost is estimated to be US\$25,000 and will be part of a pool of biosafety projects at the same period of execution to capture lessons learnt and

6. Cost of Annual Audits: US\$5,000

Total costs: **US\$40,000.**

Annex H: Project Implementation Arrangements



Workplan

Component	Year 1				Year 2				Year 3	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Component I: NEEDS ASSESSMENT (GEF 25,000 USD+ Co-Financing 75,000 USD = 100,000 USD)										
Outcome 1.1: A consolidated action plan is developed to guide the design of the project.										
Output 1.1.1: Stocktaking report capturing the current status of biosafety issues, identified gaps, planned training interventions and long term funding plans										
Proposed Activities:										
Review of existing documents and identification of gaps with respect to country obligations under Articles 8, 10 and 18 (2) of CPB.										
Preparation of a base paper on status of facilities, infrastructure, human resource, level of expertise in selected institutions.										
Output 1.1.2: National Consultative meeting reports (with a stakeholder participation plan).										
Proposed Activities:										
National consultation on final project design and project launching workshop.										
Component II: RISK AND SOCIO ECONOMIC ASSESSMENT WITH RELATED MANAGEMENT FRAMEWORK										
2A. Risk Assessment and Management (GEF 75,000 USD + Co-financing 225,000 USD = 300,000 USD)										
Outcome 2A.1: A technical and regulatory framework that is consistent with the CPB, is strengthened to permit effective evaluation, management and monitoring of LMOs risk.										
Output 2A.1.1: Updated RA and RM procedures and guidelines in line with recent developments under CPB.										

Proposed Activities:
Preparation of a base paper on the status of conformity of existing procedures and guidelines with Article 15, 16 and Annex III of CPB and the new Road Map on RA
Review of International practices in RA and RM through organising an international consultation and/or study tour and preparation of the guidelines.
Output 2A.1.2: LMOs are monitored by regulatory agencies after environmental release.
Proposed Activities:
Identification of roles and responsibilities of various agencies for post release monitoring and development of guidance document for post release monitoring.
2B. Socio-economic (SE) assessment (GEF 75,000 USD + Co-financing 225,000 USD = 300,000 USD)
Outcome 2B.1: Socio-economic assessment is considered
Output 2B.1.1: Survey reports on socio-economic issues in relation to LMOs and socio-economic guidelines and methodologies are developed for assessment of LMOs.
Proposed Activities:
Design model questionnaires for socio economic assessment and their validation of the questionnaire through sample survey.
Output 2B.1.2: Cost benefit analysis guidelines developed for socio-economic assessors.
Proposed Activities:
Drafting guidelines and methodologies for SE assessment and cost benefit analysis through a network of experts from various institutes and consultation with experts and relevant stakeholders for finalising the guidance document.
Component III: FRAMEWORK FOR HANDLING LMOs
3A. Handling, transport, packaging and identification of LMOs (GEF 65,000 USD + Co-financing 225,000 USD = 300,000 USD)
Outcome 3A.1: A national system is established for handling, transport, packaging and identification of LMOs, consistent with the requirements under Article 7 and Article 18 of the CPB.
Output 3A.1.1: National codes of best practices and procedural guidelines for handling, transport, packaging and identification of LMOs.

Output 4.1.6: Training modules/manuals are prepared for conducting/ evaluating risk assessment and management, monitoring field trials of LMOs and compliance evaluation and training of quarantine and inspection officials for enhanced enforcement at the ports of entry.											
Proposed Activities:											
Preparation of training modules for monitoring field trials and compliance evaluation.											
Training of members of monitoring teams responsible for compliance evaluation, technical persons conducting field trials and extension functionaries.											
Preparation of training modules and working knowledge documents for enhanced enforcement at points of entry.											
Training of customs officials on verification of documentation requirements for transboundary movement and use of BCH.											
Training of quarantine officers for on-site verification of LMOs and use of BCH.											
Prepare training modules/manuals for conducting environmental risk assessment and risk management.											
Training of experts in RA & RM involved in technical and scientific advisory committees and biotech R&D developers.											
Training in preparation of guidance documents for dossier development.											
Component V: BIOSAFETY COMMUNICATION FRAMEWORK (GEF 300,000 USD+ Co-Financing 900,000 = 1,200,000 USD)											
Outcome 5.1: Public awareness on biosafety issues (including liability and redress) increased.											
Output 5.1.1: Innovative outreach programs are developed for risk communication both through print and electronic/social media											
Proposed Activities:											
Development of a risk communication strategy for various stakeholders											
Development of a training module and training workshops in risk communication for key policy makers and experts											
Development and dissemination of outreach programmes to implement the risk communication strategy through print and electronic media											
Output 5.1.2: Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level											

agencies											
Proposed Activities:											
Preparation of audio visual educational material on awareness of biotechnology and biosafety issues for teachers and students.											
Organize awareness workshops on biosafety for the media.											
Organization of a quiz programme for school children.											
Output 5.1.3: Primers/ brochures/ booklets /FAQs/biosafety newsletters and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc.											
Proposed Activities:											
Development of primers/brochures/booklets/FAQs, glossary of terms and other outreach material in various languages.											
Output 5.1.4: A mechanism is established to communicate regulatory decisions on LMOs to the public.											
Proposed Activities:											
Upgrading the national biosafety websites.											
Timely deposition of regulatory decisions on LMOs in the BCH.											
Output 5.1.5: Biosafety topic including BCH is incorporated in school and university curricula											
Proposed Activities:											
To conduct awareness programs at schools and universities on biosafety and BCH training modules.											
To incorporate biosafety topic in school and university curricula.											
Component VI: PROJECT MONITORING AND EVALUATION (GEF 30,000 USD+ Co-Financing 90,000 USD = 120,000 USD)											
Proposed Activities:											
Project Monitoring											
Project Evaluation											
Component VII: PROJECT MANAGEMENT (GEF 90,000 USD+ Co-Financing 271,500 USD = 361,500 USD)											
Proposed Activities:											
Establishment of a Project Management Unit											

Key Deliverables and Benchmarks

Deliverables	Benchmarks
COMPONENT I: NEEDS ASSESSMENT	
Objective: To assist Malaysia to update its information on status and capacity for biosafety management, including capacity in RA&RM, documentation and identification for compliance.	<ul style="list-style-type: none"> ▪ A gap analysis of country situation and activities for biosafety management areas. ▪ Status and strategy paper on regulatory framework, documentation and identification.
Outcome 1: A consolidated action plan is developed to guide the design of the project	
Outputs: <ol style="list-style-type: none"> 1. Stocktaking report capturing the current status of biosafety issues, identified gaps, planned training interventions and long term funding plans. 2. National consultative meeting reports (with a stakeholder participation plan). 	<ol style="list-style-type: none"> 1. Draft document prepared and presented for consultations with stakeholders within 3 months of inception. 2. Final report on the draft outputs within 6 months of inception.
COMPONENT II: RISK AND SOCIO ECONOMIC ASSESSMENT WITH RELATED MANAGEMENT	
Objective : To assist Malaysia to strengthen biosafety regulatory framework that is consistent with CPB.	<ul style="list-style-type: none"> ▪ The legal framework consistent with CPB. ▪ Guidelines are available for effective biosafety management. ▪ Parameters and methodologies for risk assessment will be available.
A. Risk Assessment and Management	

Outcome 2A : A technical and regulatory framework that is consistent with the CPB, is strengthened, evaluation, management and monitoring of LMOs risk		
Outputs:		
<ol style="list-style-type: none"> Updated RA and RM procedures and guidelines in line with recent developments under CPB. LMOs are monitored by regulatory agencies after environmental release. 		<ol style="list-style-type: none"> Guidelines for risk assessment types of LMOs e.g. LM trees, L are available. (Year 3) Effective post release mechanism compliance. (Year 2)
B. Socio-economic (SE) Assessment		
Outcome 2B: Socio-economic assessment is considered		
Outputs:		
<ol style="list-style-type: none"> Survey reports on socio-economic issues in relation to LMOs and socio-economic guidelines and methodologies are developed for assessment of LMOs. Cost benefit analysis guidelines developed for socio-economic assessors. 		<ol style="list-style-type: none"> Model questionnaires are been methodologies for socio-economic available. (Year 2) Cost benefit analysis guideline
COMPONENT III: FRAMEWORK FOR HANDLING LMOs		
Objective:		
To assist Malaysia to establish a system for handling, transport, packaging and identification of LMOs and a regulatory framework on liability and redress.		<ul style="list-style-type: none"> An operational administrative and identification of LMOs. Regulatory framework on liability
A. Handling, Transport , Packaging and Identification of LMOs		
Outcome 3A: A national system is established for handling, transport, packaging and identification of requirements under Article 7 and Article 18 of the CPB.		
Outputs:		
<ol style="list-style-type: none"> National codes of best practices and procedural guidelines for handling, transport, packaging and identification of LMOs. Strategic guidance document on sampling, thresholds and inventory of LMOs from selected countries. Policy or action plan on low level presence is formulated. 		<ol style="list-style-type: none"> Guidelines on handling, transport of LMOs are available. (Year 2) Sampling activities are conducted document. (Year 2) A policy on low level presence
B. Liability and Redress		

Outcome 3B: Administrative and legal for the implementation of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety established.	
Outputs: <ol style="list-style-type: none"> 1. A plan to implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety developed. 2. Amended laws or Regulations on Liability and Redress gazetted. 	<ol style="list-style-type: none"> 1. An implementation plan for Nagoya – Kuala Lumpur Supplementary Protocol is available. 2. A national law on liability and redress is enacted.
COMPONENT IV: INSTITUTIONAL CAPACITY BUILDING	
Objective: To assist Malaysia in strengthening institutional capacity in biosafety related matters.	<ul style="list-style-type: none"> ▪ An effective pool of 20 resource persons for assessment and management in line with CPB. 2. Enhanced skills of present experts on compliance with conditions for import and export of LMOs. ▪ Enforcement procedures for transboundary movement of LMOs are strengthened.
Outcome 4: Institutional capacity on biosafety especially in the areas of risk evaluation, detection and control at the ports of entry is enhanced.	
Outputs: <ol style="list-style-type: none"> 1. A feasibility study is carried out on public-private partnership for LMO detection. 2. Institutions are strengthened with improved infrastructure and equipment for detection and verification of LMOs. 3. Current methodology and procedures are reviewed and upgrade for LMO detection. 4. Institutional capacity on liability and redress are developed. 5. Biosafety technical review documents on issues identified by technical committee compiled 6. Training modules/manuals are prepared for conducting/evaluating risk assessment and management, monitoring field trials of LMOs and compliance evaluation and training of quarantine and inspection officials for enhanced enforcement at the ports of entry. 	<ol style="list-style-type: none"> 1. Project inception potential partner identified (within 6 months) 2. More institutions with improved infrastructure and equipment are available. (Year 1) 3. Sampling procedures and methods are reviewed and adopted for compliance. (Year 1) 4. More experts available on liability and redress. (Year 1) 5. Biosafety technical review documents on issues identified by technical committee became source of reference. (Year 1) 6. Training modules for environmental impact assessment and training manuals for customs and plant quarantine enforcement. (Year 1)

COMPONENT V: BIOSAFETY COMMUNICATION FRAMEWORK	
Objective: To assist Malaysia to establish and consolidate systems for public education, awareness, participation and access to biosafety information.	<ul style="list-style-type: none"> ▪ A communication strategy is in ▪ The public have access to biosaf and electronic media. ▪ Awareness raising materials on distributed.
Outcome 5: Public awareness on biosafety issues (including liability and redress) increased.	
Outputs: <ol style="list-style-type: none"> 1. Innovative outreach programs are developed for risk communication both through print and electronic/social media. 2. Educational programs on biosafety issues for TV and radio are developed in collaboration with the local and national level agencies. 3. Primers/ brochures/ booklets /FAQs/biosafety newsletters and Glossary of terms in different local languages are widely distributed to policy makers, researchers, students, farmers, civil society etc. 4. A mechanism is established to communicate regulatory decisions on LMOs to the public. 5. Biosafety topic including BCH is incorporated in school and university curricula. 	<ol style="list-style-type: none"> 1. Outreach materials for print and for risk communication in English (Year 2) 2. Audio visual educational program for students. (Year 3) 3. Tailor made primers/brouchers/ in different languages. (Year 2) 4. Regulatory decisions are deposited on websites including national BCH making. (Throughout the project) 5. Schools and universities that have incorporated in their curricula. (Year 3)

Annex J: Focal Area Tracking Tools



Tracking Tool for Biodiversity Projects in GEF-4 and GEF-5

<p style="text-align: right;">Objective 3:</p> <p style="text-align: center;">Build Capacity for the Implementation of the Cartagena Protocol on Biosafety</p>
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<p>Objective: To measure progress in achieving the impacts and outcomes established at the portfolio level area.</p> <p>Rationale: Project data from the GEF-4 and GEF-5 project cohort will be aggregated for analysis of direction at portfolio-wide level to inform the development of future GEF strategies and to report to GEF Council on portfolio biodiversity focal area.</p> <p>Structure of Tracking Tool: Each tracking tool requests background and coverage information on the project required to track portfolio level indicators in the GEF-5 strategy.</p> <p>Guidance in Applying GEF Tracking Tools: GEF tracking tools are applied three times: at CEO endorsement, project completion.</p> <p>Submission: The finalized tracking tool will be cleared by the GEF Agencies as being correctly completed.</p> <p>NOTE: Please complete sections I, II, III for GEF-4 and sections I and II for GEF-5.</p>
<p>Important: Please read the Guidelines posted on the GEF website before entering your data</p>

I. General Data	Please indicate your answer here	N
Project Title	Institutional Capacity to Enhance Biosafety Practices in Malaysia	
GEF Project ID	5804	
Agency Project ID	01003	
Implementing Agency	UNEP	
Project Type	MSP	FS
Country	Malaysia	
Region	EAP	
Date of submission of the tracking tool	April 2014	M 20
Name of reviewers completing tracking tool and completion date		C
Planned project duration	4	Y
Actual project duration		Y
Lead Project Executing Agency (ies)	MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT	
Date of Council/CEO Approval		M 20
GEF Grant (US\$)	995,000	
Cofinancing expected (US\$)	2,986,500	

II. For each question please identify any intended actions that will improve performance of the biosafety			
Issue	Please select your score from drop down menu	Scoring Criteria	Comment
Biosafety Policy			

1) <i>Has a biosafety policy been developed and is it being fully implemented?</i>	3	<p>0: A stand alone biosafety policy does not exist</p> <p>1: A stand alone biosafety policy has been produced</p> <p>2: A stand alone biosafety policy has been produced and has been formally adopted by the government</p> <p>3: A legally approved biosafety strategy has been incorporated into broader sectoral policies (e.g. agriculture, biotechnology, science and technology, health, etc) and is being enforced</p> <p>4: A biosafety policy is implemented through a multi-year Action Plan that involves more than one sector of Government or society.</p>	<p>Comment: Malaysia Biosafety Act was passed in 2007 and entered into force on 1 December 2009. The Act complements the implementation of the National Policy on Biotechnology (2005) and also the National Policy on Biological Diversity (1992).</p>
Biosafety Regulatory Regime			

<p>2) <i>Has a regulatory regime been developed and does it have full legal force?</i></p>	<p>3</p>	<p>0: A regulatory regime has not been developed 1: Interim measures for biosafety decision making, including some modification of existing regulations, have been put in place. 2: A regulatory regime has been developed and adopted but does not yet have full legal force 3: The regulatory regime has full legal force, is operational and linked to the administrative system -i.e. used for decisions 4: The regulatory regime covers all the types of LMOs and transboundary movements referred to in the Cartagena Protocol, including agreements with Non-Parties</p>	<p>Comment: The Biosafety Act 2007 and Biosafety Regulations 2010 form key elements of the biosafety legal framework in Malaysia. Under the Act, National Biosafety Board (NBBS) makes decisions on LMO use and to date, it had made decision on 9 applications for approval for release and notifications on activities contained environment http://www.biosafety.nr.gov.my/</p>
<p>Administrative System</p>			

<p>3) Is an administrative system in place and fully operational?</p>	<p>3</p>	<p>0: Focal Points and National Competent Authorities not appointed nor available via BCH 1: All Focal Points and National Competent Authorities appointed, and roles & responsibilities stated and available on BCH 2: Procedures for handling requests have been designed, legally adopted, and made available to the public. 3: Requests have been received, processed, and decisions communicated to the BCH. Appeal procedures designed and operational. 4: Administrative system fully supported by national budget allocation or alternative (non-donor) system of revenue generation</p>	<p>Comment: To operation the law and to support NBB, a dedicated department named the Department Biosafety was formed May 2010 headed by Director General of Biosafety. The Department also acts as a one stop center for all activities relating biosafety in Malaysia in addition to fulfilling its functions. All information pertaining to biosafety made available in the Malaysia BCH website</p>
<p>Risk Assessment and Decision-making</p>			

4) Are risk assessment procedures employed and contributing to decision-making?	2	<p>0: No risk assessment is applied to LMOs</p> <p>1: Sectoral risk assessment dossiers are required to accompany LMO requests</p> <p>2: Risk assessment/risk management system involves case-by-case analyses by scientific experts that provide recommendations to decision-making bodies. Composition and responsibilities of the decision-making bodies clearly stated and publicized.</p> <p>3: Decisions on LMOs are integrated across sectors (e.g. take into account risks to human health)</p> <p>4: Decision-making system allows for socio-economic considerations and for review of decisions based on new evidence</p>	<p>Comment: The application of risk assessment/risk management procedures under the Genetic Modification Advisory Committee are on a case by case basis.</p>
Follow-up and Monitoring			
5) Does an operational follow-up and monitoring system exist?	2	<p>0: No system for follow-up and monitoring exists</p> <p>1: Institutional and human capacity in place to follow-up and monitor, including Risk Management for field-trials and post-release</p> <p>2: Compliance mechanisms for Risk Management established</p> <p>3: Liability and redress mechanisms in place</p> <p>4: Decisions, risk management plans, and reports on compliance and</p>	<p>Comment: A sub-committee under the Genetic Modification Advisory Committee is established to monitor compliance of trials and conditions imposed</p>

		liability have been posted to the BCH	
Public awareness, education and participation awareness			
6) Is information on LMOs made available to public?	3	<p>0: Little or no official information on LMOs available to the general public</p> <p>1: Information on LMOs generally available in at least one national language</p> <p>2: Information on LMOs generally available in at least one national language and is kept updated</p> <p>3: Information on LMOs is used for awareness-raising campaigns</p> <p>4: Survey results on levels of public awareness available</p>	<p>Comment: Biosafety re publications were used v organizing awareness programs on biosafet</p>

Education			
7) <i>Has coursework and training on biosafety been integrated into higher education?</i>	1	<p>0: No modern biotechnology and biosafety available in the formal (i.e. technical, academic, extramural) education system.</p> <p>1: Basic modern biotechnology and biosafety information included in the curricula at technical and college levels.</p> <p>2: Dedicated short-term courses on biosafety available for government staff at technical schools and higher education institutions.</p> <p>3: National association for biosafety established</p> <p>4: Undergraduate and graduate degree programs offering concentrations and/or degree programs on modern biotechnology, including biosafety</p>	<p>Comment: Modern biotechnology is taught at university and school levels. However, biosafety topics are not covered.</p>
Participation			

8) <i>Has the public been engaged in LMO decision-making?</i>	2	<p>0: Little or no direct involvement of public in LMO decision-making</p> <p>1: Access to information includes other mechanisms in addition to the BCH (i.e. radio and television programs, newspapers columns, blogs, etc.).</p> <p>2: Mechanism for public involvement in LMO decision-making established</p> <p>3: Evidence of level of public involvement in LMO decision-making available via BCH or other means</p> <p>4: Regular open consultation meetings held on biosafety</p>	<p>Comment: The NBB take into account input/ from public when making decision on release of L</p>
	19	TOTAL SCORE	
	32	TOTAL POSSIBLE	

Annex K: OFP Endorsement Letter

See attached

Annex L: Co-finance Commitment Letter

See attached

Annex M: Environmental and Social Safeguards

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

<i>Project Title:</i>	<i>Institutional Capacity to Enhance Biosafety Practices in Malaysia</i>		
<i>GEF project ID and UNEP ID/IMIS Number</i>	<i>ADDIS No: 01003</i>	<i>Version of checklist</i>	<i>MSP Submission</i>
<i>Project status (preparation, implementation, MTE/MTR, TE)</i>	<i>Preparation</i>	<i>Date of this version:</i>	<i>July 2013</i>
<i>Checklist prepared by (Name, Title, and Institution)</i>	<i>Alex Owusu-Biney, Task Manager (Biosafety), UNEP GEF</i>		

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.

	<i>Yes/No/N.A.</i>	<i>Comment/explanation</i>
- Is the project area in or close to -	N/A	
- densely populated area	N/A	
- 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?	N/A	
<i>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.</i>		

Section B: Environmental impacts, i.e.

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.</i>	<i>Comment/explanation</i>
- Are ecosystems related to project fragile or degraded?	N/A	
- Will project cause any loss of precious ecology, ecological, and economic functions due to construction of infrastructure?	N/A	
- 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	
- Will project cause Greenhouse Gas Emissions?	N/A	
- Other environmental issues, e.g. noise and traffic	N/A	
<i>Only if it can be carefully justified that any negative impact from the project can be avoided or mitigated satisfactorily in the long-term, can the project go ahead.</i>		

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.</i>	<i>Comment/explanation</i>
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- Does national regulation in affected country (-ies) require EIA and/or ESIA for this type of activity?	No	
- Is there national capacity to ensure a sound implementation of EIA and/or SIA requirements present in affected country (-ies)?	NA	
- Is the project addressing issues, which are already addressed by other alternative approaches and projects?	No	
- Will the project components generate or contribute to cumulative or long-term environmental or social impacts?	Yes	Improve long term regulation and safe use of GMOs
- Is it possible to isolate the impact from this project to monitor E&S impact?	NA	

Annex N: Acronyms and Abbreviations

GLOSSARY OF TERMS AND ACRONYMS USED

Act	Malaysian Biosafety Act 2007
CBI	Confidential Business Information
DOA	Department of Agriculture
DOC	Department of Chemistry
DOB	Department of Biosafety
GEF	Global Environment Facility
GMAC	Genetic Modification Advisory Committee
Customs	Royal Malaysian Customs Department
FRIM	Forest Research Institute of Malaysia
IBC	Institutional Biosafety Committee
LMO	Living Modified Organism
LLP	Low Level Presence
MAQIS	Malaysian Quarantine and Inspection Services
MOA	Ministry of Agriculture and Agro-Based Industry
MOH	Ministry of Health
MOSTE	Ministry of Science, Technology and Environment

MOSTI	Ministry of Science, Technology and Innovation (prior to 2004, known as MOSTE)
NBB	National Biosafety Board
NEA	National Executing Agency
NGOs	Non-Governmental Organizations
NPC	National Project Coordinator
NPD	National Project Director
NRE	Ministry of Natural Resources and Environment
NSC	National Project Steering Committee
PMU	Project Management Unit
RA	Risk assessment
RM	Risk management
Regulations	Malaysian Biosafety (Approval and Notification) Regulations 2010
SOPs	Standard Operating Procedures
TWN	Third World Network
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

Annex O: Terms of Reference

i) National Executing Agency

The Ministry of Natural Resources and Environment (NRE) will take charge of executing the project, adhering to UNEP rules and procedures for national execution. Its responsibilities include –

- ❖ Managing the resources allocated to the project to achieve the expected results and planning financial disbursements, in accordance with the work plan, and the project document;
- ❖ Maintaining an up-to-date accounting system that contains records and controls to ensure the accuracy and reliability of financial information and reporting; and
- ❖ Recording the receipt and disbursement of UNEP funds and verifying that disbursements do not exceed the available funds or the amount allocated to each approved budgetary category.

ii) Project Steering Committee

The Project Steering Committee (PSC) will monitor the conduct of the project and provide guidance and direction to the project team at the strategic level. PSC's responsibilities include –

- ❖ Reviewing progress of project;
- ❖ Approving major project deliverables;
- ❖ Reviewing issues raised and agreeing to action plans for their resolutions;
- ❖ Monitoring the continued applicability of project benefits; and
- ❖ Approving Change Requests (e.g. scope changes, schedule alterations, personnel).

The Committee will comprise the main stakeholders, including the followings –

- Biodiversity and Forestry Management Division, Ministry of Natural Resources and Environment (NRE);
- National Biosafety Board (NBB) members;
- Genetic Modification Advisory Committee (GMAC) members;
- Economic Planning Unit (EPU);
- Malaysian Quarantine and Inspection Services (MAQIS);
- Department of Agriculture;
- Department of Veterinary Services
- Department of Chemistry;
- Food Safety and Quality Division, Ministry of Health;
- Ministry of Information;
- Royal Malaysian Customs Department;
- Ministry of Higher Education;
- Private corporations (biotechnology companies, plantation companies and other companies dealing or trading in biotechnology products);
- NGOs for biotechnology, environment and consumers; and
- UNEP

iii) National Project Director

The Director General, Department of Biosafety under the NRE will be the National Project Director for this project. This person will be mainly responsible for coordination of project activities among the different partners of the project. These will include various government agencies, NGOs, UNEP and consultants. The responsibilities of the National Project Director include –

- ❖ Leading and managing the National Project Team;
- ❖ Ensuring that all project objectives and outputs are satisfied;
- ❖ Managing the project budget in accordance with GoM/UNEP guidelines;
- ❖ Assisting PSC in the selection of members for the Project Team and consultants;
- ❖ Reviewing annual work plan and budget;
- ❖ Ensuring that all activities are completed according to schedule; and
- ❖ Ensuring that the GEF project document is satisfactorily completed and submitted on time.

iv) National Project Coordinator

- ❖ Act as Executive Secretary to the PMU and the PSC;
- ❖ Prepare an annual work plan on the basis of the project document;
- ❖ Under the direction of NPD and the PSC, and in close consultation with other stakeholders of the project;
- ❖ Coordinate and monitor the implementation of the project as set out in the project document and recommending any such modifications/revisions as may be necessary to the PSC through the NPD;
- ❖ Manage and coordinate with relevant governmental bodies and participating institutions or agencies involved in the project execution;
- ❖ Review consultants' reports (ensuring quality of the reports), project budget revisions and all other administrative arrangements required as per NRE and UNEP;
- ❖ Certify services rendered by contractors and the consultants for purposes of payment, where provided for;
- ❖ Prepare and submit quarterly reports to the PMU on progress and problems faced in the project and any other reports as may be required, through the NPD to the PSC;
- ❖ Preparing project progress and expenditure reports, the annual Project Implementation Review (PIR) and update of the GEF tracking tool at mid-term and end of the project;
- ❖ Chair monthly progress meetings;
- ❖ Implement the project in accordance with the project document milestones; and
- ❖ Undertake any other duties as may be assigned by the NPD and the PSC

v) Project Management Unit

The Project Management Unit will be established to provide accountability and in the execution of the project. The Project Management Unit will be located at the local implementing agency and will comprise –

- a) National Project Director – Chairperson
- b) National Project Coordinator – Secretary
- c) UNEP Representative

d) Consultants when required

The PMU shall –

- ❖ Advise the PSC on all functions of procurement of goods and services;
- ❖ Ensure that all expenditures and financial procedures pertaining to purchases, procurement, award of contracts are on a completion basis and in compliance with GoM/UNEP guidelines;
- ❖ Review annual work plan and budget for timely submission to the PSC;
- ❖ Oversee project activities to ensure that they are consistent with those outlined in the project document;
- ❖ Review progress of work and revise work plan, if necessary;
- ❖ Submit regular progress reports, including any revisions of work plan and budget to PSC and UNEP;
- ❖ Monitor and coordinate all components of the project in accordance with the work plan.

Annex P: Draft Procurement Plan

Project Component	Description	Costs (in USD)	Proposed dates for procurement (as per work plan)
III – Framework for handling LMOs	Laboratory Equipment for LMOs detection and monitoring: - Real-time PCR (additional equipments/accessories) - Laminar flow cabinet - Micro Centrifuge - Gel casting equipment - Electrophoresis apparatus - Hybridization oven - Electrophoresis Power Pack - Camera to record DNA separation - Necessary tools, materials and reagent	35,000 1,000 1,000 500 1,000 500 500 500 5,000	Quarter 1, Year 1 Quarter 1, Year 2 Quarter 1, Year 3 Quarter 1, Year 4
<i>Sub total</i>		<i>45,000</i>	
IV – Institutional Capacity Building	Non laboratory Purchase	15,000	Quarter 2, Year 2 Quarter 2, Year 3
V – Biosafety Communication Framework	Non laboratory Purchase	15,000	Quarter 3, Year 2 Quarter 3, Year 3
<i>Sub total</i>		<i>30,000</i>	
Total		75,000	