



UNITED NATIONS DEVELOPMENT PROGRAMME

**Terminal Evaluation Report: Support to Capacity Building  
Activities on Implementing the Cartagena Protocol on Biosafety  
in Malaysia.**

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## **Acronyms and Terms**

BCH – Biosafety Clearing House

CBI – Confidential business information

CPB – Cartagena Protocol on Biosafety

DOB – Department of Biosafety, NRE

DOC – Department of Chemistry Malaysia, Ministry of Science, Technology and Innovation

GEF – Global Environment Facility

GMAC – Genetic Modification Advisory Committee

GOM – Government of Malaysia

IBC – Institutional Biosafety Committee

LMO – Living modified organism. A subset of genetically modified organisms (GMOs) and used synonymously with the latter in this report.

NBB – National Biosafety Board, decision making body under the Biosafety Act

NRE – Ministry of Natural Resources and Environment

PIR – Project Implementation Report

PMU – Project Management Unit

PSC – Project Steering Committee

UNDP – United Nations Development Programme

UNEP – United Nations Environmental Programme

USD – United States dollar

## 1. Executive Summary

This project was approved by UNDP-GEF in 2006 with the objective of helping to consolidate Malaysia's national capacity for the implementation of the Cartagena Protocol on Biosafety and the National Biosafety Act of 2007. The project was implemented in 2007 by Department of Biosafety in the Ministry of Natural Resource and Environment (NRE). UNDP-GEF allocated a total of USD 911, 380 for three years and a no-cost extension was approved for an additional two years. The project was initiated in March 2007 and completed in June 2012. The DOB is in the process of applying for the next GEF funded capacity building project for national biosafety.

In accordance with UNDP policy a terminal review was arranged to review the project and report on its outcomes, management and impact. This review serves to promote accountability for the resources use and to document and provide feedback on the lessons learned. The terminal review was undertaken in Malaysia in May 2012 and included a review of documentation, discussions with the implementing agency and interviews with key stakeholders in the project's implementation.

It is clear to the evaluator that the project has met its immediate objective, which was to implement a workable national biosafety regulatory process that meets the country's obligations as a Party to the CPB. The project documents record that the Biosafety Act (2007) was implemented with the passing of operational regulations that were drafted as a part of this program. The Department of Biosafety, the National Biosafety Board, the Genetic Modification Advisory Committee and a number of Institutional Biosafety Committees have been formed in accordance with the Act. These bodies comprise the national biosafety framework and are all functioning to provide assessments and decisions on both notifications and approvals with respect to activities with living modified organisms. The project has focused its efforts on establishing these bodies and equipping them with the skills needed to carry out their biosafety functions with efficiency and confidence.

The DOB and the evaluator identified and discussed challenges and lessons learned during the implementation of the project. The application of adaptive management was evident in overcoming the challenges, and the lessons learned will be carried forward to future capacity building projects. Based on the functioning of the DOB, the involvement of the relevant ministries, the judicious use of funding, the Government of Malaysia's strong co-funding of the activities, and the positive feedback from stakeholders, this project implementation was evaluated as **HIGHLY SATISFACTORY**.

It is recommended that Malaysia applies for additional GEF funding to address those aspects of the national biosafety process that still need capacity building for implementation.

## 2. Introduction

This terminal evaluation was initiated by the UNDP to review the outcomes, management and impact of the Government of Malaysia-UNDP/GEF funded project: **Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety in Malaysia**. The terminal evaluation is used to evaluate the results and impact of the project, taking into account adjustments that were required during the implementation phase; to promote accountability for the resources used; and to provide feedback on the project, including lessons learned in its implementation.

The terminal evaluation was carried out by an international consultant, Mrs. Muffy Koch, from Global Biosafety in Canada. The consultant was selected from respondents to a call for proposals to undertake this study. The terms of reference for the review (Annex 1) were devised by the UNDP and guided the terminal evaluation.

### 2.1. Methodology

The review process undertook the following steps:

- Review of the project documentation
- Review of the proposed objectives and achievements
- Consultation with key role players
- Consultation with key stakeholders
- Review of the financial records
- Drafting of the report
- Presentation of the preliminary report to key stakeholders
- Completion of the report

The documents reviewed were:

- Project Document;
- Project Inception Report;
- Project implementation final report
- Quarterly progress reports;
- Terminal report;
- Audit report - 2008;
- M & E reports prepared by the project;
- Financial and Administration guidelines; and
- Minutes of the Project Steering Committee and Project Management Unit meetings.

The review of project management and implementation arrangements included a review of:

- Processes and administration
- Project oversight and active engagement by UNDP and project steering committee;
- Project execution by the Ministry of Natural Resources and Environment , and
- Project implementation by the Department of Biosafety.

Interviews with stakeholders included:

- UNDP staff member who had project responsibilities;
- Executing and Implementing agency (Department of Biosafety)
- Project Steering Committee members
- The Genetic Modification Advisory Committee (GMAC) members
- National Biosafety Board members;
- Project stakeholders, including private sector and NGOs.

Input from stakeholders was crosschecked with other interviews and with the project documentation.

The financial review focused on three priority areas:

- Budget procedures
- Project disbursements
- Coordination mechanisms

The consultant's itinerary and the list of interviewed stakeholders are provided in Annex 2.

A consultation meeting was held with stakeholders at the end of the terminal evaluation mission. At this meeting, organised by the NRE, the interim final evaluation findings were presented by the international consultant and input was received from stakeholders and the DOB. This input was incorporated into the draft final review report.

Specific aspects of the project were assessed using the following six point scale:

**Highly Satisfactory (HS):** The project had no shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Satisfactory (S):** The project had minor shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Moderately Satisfactory (MS):** The project had moderate shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Moderately Unsatisfactory (MU):** The project had significant shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Unsatisfactory (U)** The project had major shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

**Highly Unsatisfactory (HU):** The project had severe shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

### **3. The Project and its Development Context**

As one of the world's 17 mega-diverse countries, the Government of Malaysia has identified biotechnology as a new income source for the nation and is committed to the safe and responsible use of this technology. Malaysia ratified the Cartagena Protocol on Biosafety (CPB) in September 2003. The National Biotechnology Policy was launched in April 2005 and the Biosafety Bill was approved by the Malaysian Cabinet in December 2005. The Act was passed in 2007 and enforced in December 2009 during the course of this project.

This enabling activity began in 2007 as the Biosafety Bill was being enacted. It aimed to help build Malaysia's national capacity for implementing the Biosafety Act (2007), which included the provisions needed to implement national obligations as a party to the CPB. The Ministry of Natural Resources and Environment (NRE), GMAC, and other government agencies were already functioning, but were ill equipped to successfully implement the Act as there was insufficient capacity in the fields of risk assessment, risk management, risk communication and administrative and regulatory implementation. In addition, there was insufficient capacity among customs officials to deal with trans-boundary movement of living modified organisms (LMOs) into and out of Malaysia. The project was conceived to support Malaysia in building capacity to undertake the biosafety tasks required by the Biosafety Act and to initiate mechanisms for information dissemination and public participation.

The three-year project was approved in May 2006 and implemented in March 2007. The delayed implementation was a result of the parliamentary process related to the passing of the National Biosafety Act (2007). Following a request for an extension, the project ended in June 2012.

The objective of the project, as described in the Project Inception Report, was to help consolidate Malaysia's national capacity for the implementation of the Cartagena Protocol on Biosafety as well as the National Biosafety Act of 2007. The development objective was to build national biosafety capacity in a way that would have lasting and sustainable impact on Malaysia's ability to utilize biotechnology for development and economic growth. In particular, the mega-diverse nature of the country's natural heritage makes it important to ensure that LMOs are used carefully with full consideration of their impact on the local environment.

The main stakeholders identified for this project were the national regulatory agencies and policy organs of the GOM; the public and private sector biotechnology community; scientists involved in risk assessment and risk management; advocacy groups; and the interested public.

The project inception report identified six intended outputs and eight expected outcomes from the project, which are detailed and reviewed in Section 4.3. Planned activities were divided between the six components of the project and these are evaluated in Section 4. Establishment of the biosafety regulatory framework, delivery of training workshops, drafting of the regulations and guidance documents and delivery of awareness materials were all designed to help build the biosafety capacity of the country so that a workable biosafety framework could be implemented that meets Malaysia's obligations as a party to the CPB.

The increased biosafety capacity in Malaysia has been noted by other countries that are in the process of developing national biosafety frameworks. Staff members from the DOB have been invited to share the Malaysian biosafety experience at international meetings, and biosafety delegations from two countries, Bhutan and Qatar, have expressed interest in visiting Malaysia to learn from the local biosafety experience.

## 4. Findings

### 4.1. Project Formulation

The project was set up through discussions with the Ministry of Science, Technology and Innovation. Prior to the project's implementation this Ministry divided into two and the project became the responsibility of the new Ministry of Natural Resources and Environment. At this time the Biosafety Bill was completing its final stages in parliament and the project start was delayed until the Biosafety Act was passed in 2007. The Act was promulgated to meet the obligations of the CPB to which Malaysia is a Party. As such, the timing was right to initiate the project which was designed to help implement the Act and the national biosafety framework it legislated.

The project funded the initiation of the biosafety regulatory bodies necessary for administration (DOB), risk assessment and risk management (GMAC), biosafety decision making (NBB) and compliance (inspectors of line ministries and customs). Capacity building activities for the members of these bodies were divided according to the six components of the project.

The formulation of the project lacked some clarity between the six components. For example:

- The separation of risk assessment and risk management is not practical;
- The consideration of socio-economic issues, which is relevant in decision making prior to a general release, and less so for research and testing phases;
- The absence of a component on building capacity for compliance and inspection;
- The inclusion of biosafety research, which is not a regulatory function, but rather a requirement for developers of LMOs;
- The need to include all aspects of risk communication in the public awareness component.

However, the Project Management Unit (PMU) was able to work through these potential problems in the planning, and implemented activities that were timely and relevant to the operation of the national biosafety framework. Because the Act had been passed before the start of the project, the funding could focus on implementing the structures required by the legislation. In many other countries, much of the biosafety development funding has been channelled in to policy development activities and the consultations required for these.

Evaluation of the project's relevance and timing is **HIGHLY SATISFACTORY**

#### 4.1.1. Stakeholder consultation

The project was initiated with a stakeholder consultation workshop that was used to review the proposed outputs. Feedback from the wide range of stakeholders who attended this workshop was used to revise the project implementation strategy. These changes were made public in a Project Inception Report that recorded the input and how this was used to modify the implementation plan. In this terminal evaluation a number of stakeholders expressed the



importance of this first workshop in providing transparency to the project and local ownership of its proposed objectives.

Although these were not always clear in the documentation, there were a number of linkages of the project with other interventions in the area of biosafety. Some of the activities were co-ordinated together with other projects in the country, at state level and in the region. There were two interactions with the UNEP-GEF Biosafety programme which enabled information and experience sharing between participants in these very similar projects.

Evaluation of stakeholder consultation: **HIGHLY SATISFACTORY**

The use of training programmes for delivery of a wide range of biosafety skills was an important aspect of the replication approach. These workshops were designed specifically to increase the number of trained technical people in the country and they will need to be repeated at regular intervals and in more locations to ensure a steady stream of people with necessary biosafety skills. The workshop curricula and formats are designed for easy replication and ongoing training will ensure that new role players are adequately trained and that young scientists are included in the pool of trained people.

#### **4.1.2. Cost effectiveness**

The project funding was used to plan and run the activities that were necessary to build the capacity needed for implementation of the national biosafety framework. The range of training workshops and stakeholder awareness activities was significant and compared favourably with similar projects carried out under the UNEP-GEF biosafety development projects. (A large number of the biosafety development projects have focused attention on drafting a national biosafety framework without the experience of applications or a good understanding of GMOs. This has led to unworkable frameworks and in some cases expenditure on extensive public awareness in a context without any access to the products being discussed.)

The output of regulations, guidance documents and SOPs was significant and far exceeded the achievements of many other biosafety development projects. This output provided a cost-effective legacy of tools essential to biosafety implementation and is highly commended.

Examples of cost-effective management are provided below:

- While the inception report lists many of the intended activities as ‘a series of workshops’ to build capacity in specific areas of biosafety, the PMU realised that the cost of workshops would not enable repetition and an effort was made to use each workshop for maximum benefit by including all the relevant stakeholders. This provided a cost effective way to maximize the capacity building with fewer workshops. These workshops can be rerun as needed in the future.
- The stakeholders involved in the detection training indicated that the funding enabled international experts to run detection training in Malaysia. This ensured that far more expertise was developed locally, compared to sending one or two local experts to train internationally. In addition, these training courses can now be offered by local experts.

- When the Project Coordinator resigned her position, the Director General of DOB took over this responsibility as a more cost effective and sustainable mechanism for management of the project.
- The DOB learned from experience that it was more cost effective to task one or two experts to draft guidelines and SOPs than to establish committees of experts for these tasks. The draft documents were then circulated widely for input.

One concern is whether the cost effectiveness of GM detection has been fully evaluated. The DOB needs to assess whether the biosafety value of detection results warrants the cost needed to establish and maintain this facility. In particular, the questions to consider are:

- How are the detection results being used?
- Are the costs of detection commensurate with the risk to the environment posed by GM products?
- How are the detection results benefiting the environment and the conservation of biodiversity?
- Do the costs warrant a stand-alone regulatory detection facility, or should this expertise be located in a research facility where it is used on a daily basis for local research and is available for regulatory investigations when needed?
- Can consumer choice be provided by information on GM content that does not require detection?

As this concern relates to the cost effectiveness of future biosafety activities, the evaluation of cost-effectiveness for this project is **HIGHLY SATISFACTORY**.

#### **4.1.3. Project indicators**

Annex 1 of the inception report clearly outlined the intended outputs, the indicative activities and the milestones for each of the six components of the project. However, there were no clear indicators identified against which the impact of these activities could be measured. In the absence of the indicators the review focused on which planned activities were implemented and which milestones were delivered. This provided an adequate measure of project delivery and, together with input from stakeholders, was sufficient to provide an assessment of the impact of the project.

#### **4.2. Project Implementation**

The NRE, nominated the Biosafety Core Team to implement the project. The Biosafety Core Team became the Department of Biosafety (DOB) during the project implementation period. The Department of Biosafety appointed a National Project Coordinator and an Assistant Project Coordinator to implement the activities set out in the project Inception Report. They were guided by a Project Management Unit within the DOB which met every second month to plan and review the activities, the timeline for implementation and the financial expenditure. In addition, the progress was monitored by a Project Steering Committee which met once a year to review completed activities and provide input on future activities.

The UNDP-GEF funding enabled the DOB to fund local, regional and international technical experts to help with local capacity building. As the training progressed the technical expertise in the national biosafety institutions became stronger, enabling these officers to provide some of the expertise at subsequent training workshops. Interviews with stakeholders specifically acknowledged the value of the funding in bringing the top European experts to lead the training in GMO detection. This established a relationship that is ongoing for the detection facility and supplies this national laboratory with the most up-to-date protocols for detection and free participation in the EU verification testing processes.

The Malaysian biosafety bodies (NBB, GMAC, IBCs, Inspectorates) all received training in their responsibilities and were trained in the skills needed to carry out their roles in national biosafety implementation. In addition to managing the capacity building agenda, the outputs from the project have enabled the DOB to receive, administer and provide decisions on food and feed imports and limited releases of GMOs. This has built capacity in the administration of a national biosafety process and built the confidence of these regulators to carry out their functions effectively and on a sound scientific basis.

In reviewing applications the DOB, IBCs, GMAC and the NBB have exercised their training and proved their competence at fulfilling the biosafety responsibilities entrusted to them under the Biosafety Act. All of this training is sustainable, in that the knowledge of these role players is used again and again with each new application and the experience they accumulate will help to make the process more efficient. The members of these committees should be encouraged to pass on their experience to new members in formal training sessions.

The DOB was responsible for the financial management of the project with oversight by the Project Steering Committee. There were no financial figures reported in the Quarterly Reports. Financial figures were provided in the Project Implementation Reports for all years. None of the stakeholders interviewed were aware of any problems with the management of the project funding. Some stated that the DOB had done a good job of managing this project and its finances.

The evaluation identified that the DOB effectively applied adaptive management when this was needed for the implementation of the project. Some examples include;

- the transfer of the project coordination to the DOB Director General when the Project Coordinator left her position;
- the elimination of poorly timed activities and their replacement with more suited training and an expansion of timely capacity building;
- the transfer of guideline drafting responsibly to individuals rather than committees, which proved inefficient; and
- the inclusion of alternate members for committees when this was required for effective meetings and decision making.

The evaluation for project implementation is **HIGHLY SATISFACTORY**.

#### 4.2.1. Implementation of project activities

As the competent authority for the implementation of the Biosafety Act in Malaysia, the DOB was well positioned to coordinate the project. Biosafety is a multisectoral activity with potential impact on the environment, health, agriculture, forestry, fisheries, industry and energy. This requires the involvement of many ministries in developing and implementing biosafety policy.

The capacity building activities of the project were diverse and included:

- the drafting of regulations and guidelines;
- establishment of biosafety administrative processes;
- establishment of the NBB, GMAC, and IBCs
- provision of risk assessment, risk management and risk communication training;
- strengthening of the GM detection laboratory and training in detection processes;
- provision of a mobile detection lab at ports, and
- provision of public awareness materials, workshops and seminars.

The Biosafety Act empowers the DOB to liaise across ministries which facilitated the implementation of this development project. The many ministries with interest in biosafety were represented on the Project Steering Committee. In addition, GMAC has membership of technical experts from several ministries. Through this representation, participation in the training activities was extended to many government departments. Interviews with stakeholders indicated that there was satisfaction that the project was equitably implemented and general appreciation for the inclusive nature of the project implementation.

The DOB appointed a Project Coordinator and an Assistant Project Coordinator to manage the implementation of the project activities. The Project Coordinator left during the project and the DOB decided not to replace this person, but to coordinate the project from within the department. This was an encouraging move as it is important to provide this experience to DOB staff and to keep these skills within the department at the end of the project. The Assistant Project Coordinator left at the end of the project, essentially taking the three years of skills out of the DOB, where they are most needed.

The evaluation for implementation of the project activities is HIGHLY SATISFACTORY.

#### 4.2.2. Monitoring and evaluation

The inception report established three mechanisms for monitoring and evaluation of the project: the quarterly operational reports; the annual budget reviews; and the final independent evaluation. In addition to these mechanisms:

- the DOB produced a Terminal Project Report;
- the PMU provided review and evaluation of the project progress every two months;
- the PSC functioned to guide the implementation of the project, including monitoring the activities that were carried out and how the funding was used;

- the UNDP liaison played a monitoring role by providing reminders and guidance on which activities were being planned and financial requirements.

In addition to these measures, Project Implementation Reports were compiled annually with assessments of progress towards the development objectives and implementation status of the project. The project progress was rated annually by the project office, UNDP Country Office and the Regional Technical Adviser from the UNDP/GEF section within the Bureau of Development Policy.

Reports were available for the PMU and PSC meetings, as well as quarterly reports for the implementation of the project. Some activity reports were available as attachments to PSC or quarterly reports. These were mostly adequate for the evaluation and indicated that the delivery of the activities was consistent through the duration of the project.

The inclusion of activities such as BCH training in the quarterly reports should have acknowledged the co-funding received from the CBD for this work. In some instances co-funding for activities was noted in PMU meeting minutes. It would have been useful to have a financial update in the quarterly reports that included a cross-check with the planned project budget.

The format of the Terminal Report was bulky with the inclusion of some of activity reports and laboratory procedures. In a sense, the Terminal Report functioned as a final quarterly report with the addition of a summation of activities and deliverable under the six components. The Terminal Report compared the proposed activities to those that were completed. This was a useful tool for evaluating the delivery of the project, but lacked statistics on the number of workshops, delegates, gender balance, etc. It was difficult to get a sense of the delivery timeline when comparing the Inception Report timeline (Annex 2, p.33) to the lists of workshops in the Terminal Project Report (*e.g.*, § 4.5.2. p.201).

The project funding was too small to trigger a mid-term monitoring activity, but two financial audits were requested and these were carried out by the Malaysian Auditor General's office. The audit carried out in 2008 and 2010 was available for the terminal evaluation, and it was noted on both occasion the project was given unqualified audit rating.

The monitoring and evaluation component of the project was evaluated as HIGHLY SATISFACTORY for this level of project funding.

#### **4.2.3. Management by UNDP**

The UNDP liaison for this project played a visible role in the implementation of the project. He was a member of the Project Management Unit and the Project Steering Committee and regularly attended the meetings of both of these management bodies. The minutes of the PSC and the PMU reflect that the UNDP representative was well informed about the project activities and provided useful input and guidance at these meetings. The UNDP Regional Technical Adviser was closely involved in the monitoring and evaluation of the project progress mainly via participation in the annual PIR exercises.

#### **4.2.4. Partnerships**

Biosafety requires strong inter-ministerial partnerships because the regulated articles have applications in many economic sectors. This requirement was met by the inclusions of relevant ministries in the initial stakeholder consultation meeting, as participants at the various project activities, and in the Project Steering Committee. In addition, the national biosafety bodies (NBB, GMAC and inspectorates) have representation from a wide range of ministries. The Ministries that participated in the Project Steering Committee included the following ministries that play a key role in biosafety regulation: Natural Resources and Environment; Health; Science, Technology and Innovation; Agriculture and Agro-based Industry; International Trade and Industry; Domestic Trade and Consumer Affairs; Plantation Industries and Commodities; Higher Education; Education; Information; the Economic Planning Unit in the Prime Minister's Office; Customs Office; and two State government representatives.

The project inception consultation meeting included scientific, technical, regulatory, commercial, academic, and NGO stakeholders. This wide range of stakeholders was reflected in the make up of the Project Steering Committee. This helped to develop the partnerships used for the implementation of the project and served to publicise the project and make transparent the activities that would be funded and the responsibilities of the various biosafety institutions and role players. Interested parties were kept informed of the planned activities of the project and invited to participate when this was relevant.

The evaluation interviews indicated that these partnerships were maintained through the length of the project and were appreciated by the biosafety stakeholders. The DOB will be strengthening these partnerships through coordinated regulation of compliance and inspection responsibilities in the near future.

Evaluation of partnerships established for the project is **HIGHLY SATISFACTORY**

#### **4.2.5. Risks and threats to the project**

The one risk identified for the project was federal interagency coordination, which was identified as Low risk. The project set up a technical working committee at the beginning with members from all of the relevant agencies to reduce this risk. From 2010 onwards, this risk is considered no longer relevant as the interagency coordination for this project was working well. This terminal evaluation concurs that there are no major risks or threats to the project.

### **4.3 Results**

In the absence of clear project indicators, the deliverables from the project were reviewed in the context of what was planned and what was achieved. Changes in the planned outputs were discussed with the DOB and evaluated with respect to the strength of the adaptive management and the value to meeting the immediate capacity building needs to the national biosafety framework.

#### 4.3.1. Intended outputs

The intended outputs of the project were used to formulate the six project components of the capacity building project:

1. Establish legal and regulatory framework that permits effective evaluation
2. Enhance scientific, socio-economic and institutional capacities for risk assessment
3. Increase capacity for developing and implementing a risk management programme
4. Develop capacity for long-term operation and maintenance
5. Develop institutional coordination and sharing of information
6. Raise public awareness of transboundary movement of LMOs and promote stakeholder participation

The evaluation of these components of the Malaysia-UNDP/GEF project are summarised in the Tables 1 to 6 below. *Items in italics were not implemented.* The activities not implemented were either planned too early in the implementation process and these would be logical inclusions for a follow-on programme, or were not viable components of any biosafety regime. The activities that were not implemented were either replaced by new, more urgent, activities, or by expanded participation in other planned activities. This was good adaptive management on behalf of the project management unit.

Importantly, ‘training’ does not imply an endpoint as there is always additional knowledge and experience needed to apply biosafety to new LMOs, applications and release sites.

**Table 1. An assessment of the outputs generated under component 1 of the project.**

<b>Component 1: Establish legal and regulatory framework that permits effective evaluation</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
Series of workshops on drafting regulations and guidelines	Regulations developed and implemented	Industry appreciated the chance to comment on the regulations
Consultation on regulations and guidelines	Guidelines provided for : IBCs; Contained use; Applicants	Longer lead time requested when consultation and comments are required
Training for IBCs	Notification and Approval process established	Provide a structured format for giving comments
<i>Biosafety review of GM research</i>	Exemption list and exemption process established	The guidelines are applauded. They increase transparency and decrease confusion. They are very useful.
Training for 50 enforcement officers	Printed: Biosafety Act (2 lang.); CPB (2 lang.); Process poster.	While seen as strict by investors, the regulations provide clear rules, a transparent process, timelines, and knowledgeable assistance.
Training for biosafety regulators	Admin SOPs developed for: Handling documents, notifications & approvals; Public announcements; Calling NBB & GMAC meetings	IBC has been trained and this benefited the institute when is
Study tours for GMAC members	Capacity building provided for: 130 IBC officers; 125 enforcement officers 96 biosafety regulators	
Attendance at international biosafety meetings		

	Completed study tours for 6 regulators (Australia; India)  8 members of DOB attended international biosafety meetings.	completed an application for approval.
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The DOB exceeded its target for regulatory capacity building and development of policy and administrative tools for implementing an effective biosafety framework (Table 1). The timing for the project was perfect in that it enabled the DOB to develop, consult and implement the biosafety policy and administrative tools required to implement the Biosafety Act.

The evaluation for implementation of component 1 is HIGHLY SATISFACTORY.

**Table 2. An assessment of the outputs generated under component 2 of the project.**

<b>Component 2: Enhanced scientific, socio-economic and institutional capacities for risk assessment</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
Series of workshops on: detection (60-80 scientists), environmental impact assessment (60 delegates), food safety assessment (60 delegates), monitoring, and preparation of dossiers, (60 delegates)	Functional GM testing laboratory  Risk assessment capacity available  160 Applicants trained to complete dossiers  Mobile lab at ports for primary screening  Curriculum implemented for post-secondary biosafety training  The NBB, GMAC and IBCs are functioning	Networking opportunities for regional biosafety were provided.  Industry was pleased to be informed of these activities and to nominate participants.  GMAC review took a long time.  GMAC has strong capacity but is still very cautious.  Decision making is still very cautious.

The DOB achieved its target for capacity building in risk assessment and providing these skills for the regulatory bodies that can undertake biosafety risk assessment reviews (Table 2). This capacity was confirmed by the ability of GMAC and the NBB to review and make decisions on four applications that were received during the project period.

A mechanism for integrating socio-economic assessment into decision making will be needed. This capacity building will need to happen in the next phase of implementation, when general release applications are anticipated.

The evaluation for achievement of component 2 is HIGHLY SATISFACTORY.

**Table 3. An assessment of the outputs generated under component 3 of the project.**

<b>Component 3: Increased capacity for developing and implementing a risk management programme</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
Series of workshops on risk	6 workshops for 344	Socio economic issues can be a



<p>management of LM plants for 80 to 100 regulators and applicants</p> <p>Series of workshops on risk management of microbes, aquatic species and animals for 80 to 120 delegates.</p> <p>Series of workshops on risk management of tree species for 60 to 80 delegates.</p> <p><i>Series of workshops on risk management of biopharming organisms for 60 to 80 delegates.</i></p>	<p>delegates</p> <p>Risk management capacity available</p> <p>Established a procedure for applying risk management conditions to LMOs in containment</p>	<p>stumbling block with decision making.</p> <p>Need more capacity in relating risks to risk management strategies.</p> <p>Risk management conditions for importing LM animals were practical and worked well.</p>
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The DOB met its target for capacity building in risk management, focusing these workshops on specific types of organisms (Table 3). The focus on specific types of LMOs was immediately beneficial when the DOB received an application for trial release of LM mosquitoes.

The training for biopharming risk management will be undertaken in the next phase of implementation when applications for biopharming applications are expected. The DOB will integrate risk management with risk assessment in subsequent capacity building activities, as these are linked in regulatory reviews and decision making. Inclusion of training on food and feed safety assessments will be added to a future programme for biosafety capacity building.

The evaluation for implementing component 3 of the project is **HIGHLY SATISFACTORY**.

**Table 4. An assessment of the outputs generated under component 4 of the project.**

<b>Component 4: Develop capacity for long-term operation and maintenance</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
<p>Train 50 to 60 technical staff in molecular biology &amp; sample handling and recording</p> <p>Strengthen Dept. of Chemistry (DOC) laboratory</p> <p><i>Establish detection laboratories in two more states</i></p> <p><i>Training for 50 delegates on IPR, international obligations, legal issues related to biosafety</i></p>	<p>SOP developed for handling and testing of samples for LM content</p> <p>NBB and GMAC biosafety bodies formed and functional</p> <p>Strengthened LM detection laboratory at DOC</p> <p>DOC staff members were trained in sample handling and record keeping.</p> <p>Capacity building in detection provided for 125 enforcement officers</p> <p>Administrative SOPS for DOB institutional memory</p> <p>Training on handling CBI</p>	<p>Equipment and materials were purchased for day-to-day operation and training at the detection facility.</p> <p>UNDP/GEF funding enabled DOC to bring EU experts to Malaysia from the Reference Laboratory in Italy. This allowed many to be trained, gave access to latest protocols, and helped to get accreditation for the laboratory.</p> <p>Are there mechanisms to ensure continuity and institutional memory in the DOB?</p>

The linkage between the establishment of the detection facility and the long term operation and maintenance of the biosafety framework was unclear (Table 4). The DOB will consider including a component on compliance and inspection in a future capacity building programme, which will consider ways to access cost-effective detection services commensurate with levels of risk.

Important achievements for long term operation were the establishment of functional NBB and GMAC committees for decision making and risk assessment / risk management recommendations, respectively. Applying adaptive management for this component enabled the development of administrative SOPs by the DOB. These are a major step forward in ensuring long term operation and stability of the biosafety processes. The SOPs were developed in conjunction with carrying out the daily tasks of the biosafety office and record workable processes that can be used to ensure institutional memory and sustainable implementation of biosafety in the future. The DOB is encouraged to regularly review these SOPs and ensure that they stay current with the experience and practices in the regulatory office.

Applying adaptive management resulted in the IPR training being substituted with training on handling confidential business information (CBI), which was needed for the day-to-day handling of applications in the DOB. Adaptive management also identified that the establishment of detection facilities in two additional states was too early for this phase of development and would be addressed at a later phase of implementation. This funding was allocated for more extensive detection training and the development of a mobile detection facility for use at ports.

The evaluation for implementation of component 4 is HIGHLY SATISFACTORY.

**Table 5. An assessment of the outputs generated under component 5 of the project.**

<b>Component 5: Develop institutional coordination and sharing of information</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
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  <i>Training of 30 to 50 IT officers in other ministries to establish biosafety databases and link these to the national database</i>	Many talks given 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  Developing a website that meets GOM and BCH requirements  4 BCH workshops that trained 78 officers	Project activities provided an opportunity for stakeholders to network and discuss issues.  Project steering committee meetings helped to keep stakeholders up-to-date with what was happening in biosafety.  The level of transparency in the biosafety process is commended.

The DOB successfully developed a national biosafety database that links directly to the Biosafety Clearing House of the CPB (Table 5). Co-funding for this activity came from the BCH project administered by the UNEP-GEF biosafety project. This database provides information about biosafety in Malaysia, including links to legislation and the regulations and guidelines developed by the project. It also provides information on the four decisions taken by the NBB to date, indicating that the biosafety processes are functional and that transparency is a priority for the regulators.

Also under this component, the DOB has been working with other regulatory agencies such as Health, Agriculture and Science and Technology to clarify how overlapping regulatory responsibilities will be coordinated, including monitoring, inspections and compliance. This planning is ongoing and is a priority for efficient biosafety implementation in the future. While the website meets the requirements of the CPB, it needs to be upgraded to meeting the inter-ministry, interactive requirements of the country. This development is underway.

The evaluation for implementation of component 5 is HIGHLY SATISFACTORY.

**Table .6 An assessment of the outputs generated under component 6 of the project.**

<b>Component 6: Raise public awareness and promote stakeholder participation</b>		
<b>Planned</b>	<b>Achieved</b>	<b>Stakeholder comments</b>
Appoint communications 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	Website running on the BCH format 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 Q+A is very popular and a good resource to hand out. Need to avoid biotechnology promotion when communicating on biosafety. Avoid using biotechnology developers as resource people when training in risk communication. Public awareness is still quite low. Can use the new applications and decisions to generate interest. Communication workshop built confidence and ability of DOB staff members.

The DOB used this component to raise stakeholder awareness of the biosafety process in Malaysia (Table 6). This has work effectively with those stakeholders immediately impacted by the new legislation. In addition, the DOB initiated outreach to the interested public and established a partnership with a national NGO (Malaysian Nature Society) to plan and deliver general public awareness. The outreach to stakeholders will continue and the outreach to raise public awareness of biosafety and the Malaysian biosafety framework is expected to increase in the future. The DOB has identified that it will be more cost effective to use existing mechanisms of raising public awareness, such as NGO programmes and outreach

activities already running in related ministries. The DOB has noted that it is important to keep biotechnology and biosafety communication distinct and separate and that the regulatory authority should not be seen to be promoting the technology it regulates.

The evaluation for implementation of component 6 of the project is **HIGHLY SATISFACTORY**.

#### 4.3.2. Timelines

The project funded a significant number of activities aimed at implementing a functional national biosafety framework. The timeline of activities recorded in the Project Terminal Report and in the quarterly reports did not compare actual delivery to planned delivery and so it is difficult to assess how closely the roll out of activities followed the original plan. However, the timeline of project events noted in quarterly reports and in the table below all indicate that there was a steady delivery of capacity building activities and outputs through the duration of the project. The volume of capacity building activities is commendable when compared to other GEF-funded national biosafety projects with this level of funding.

A timeline of capacity building activities that is listed on the Malaysian Biosafety website (<http://www.biosafety.nre.gov.my/activities/>) is provided in Table 7.

**Table 7. Capacity building activities carried out by the DOB from 2009 to June 2012.**

Year	Total	Training	Public awareness
2009	14	8	6
2010	14	11	3
2011	18	9	9
2012 to June	7	6 (4 = BCH funded)	1

From the terminal evaluation interviews, it is clear that the stakeholders were pleased with the outputs from the project, specifically mentioning the capacity building workshops, the guidance materials for accessing the regulatory process and the public awareness materials. The stakeholders provided constructive feedback on the performance of the DOB and this information is provided in Annex 3. These comments indicate that the DOB is seen to have delivered the project effectively and its performance is widely complimented.

#### 4.3.3. Expected outcomes

The intended outcomes of the project were assessed to determine the level of delivery and the effectiveness of the capacity building interventions. These expected outcomes were evaluated as part of the project's final evaluation.

**Enhanced management capacity at national level.** During the course of the GOM-UNDP-GEF project the DOB significantly enhanced its capacity to manage the regulation of biosafety in Malaysia. The implementing regulations were developed, as were guidelines for stakeholders that explain how to access the regulatory system and what requirements must be met. The DOB developed SOPs for all the administrative functions associated with biosafety

regulation, which provides the necessary standardisation and institutional memory for sustainable implementation of the regulatory services offered by the DOB.

**Implementation of the national risk management regime.** The project formed and initiated the regulatory bodies required to establish a workable biosafety process. These include the DOB, NBB, GMAC, IBCs and the DOC detection facility. Follow-on capacity building activities will strengthen biosafety inspection and monitoring. The DOB has notified the BCH of completed risk assessments and decisions that have incorporated risk management terms and conditions. Interviewed stakeholders have indicated that the risk management requirements for specific notifications have been practical and effective.

**Enforcement of laws and regulations under the Biosafety Act.** The focus of this project has been to build capacity to implement the biosafety framework, including the capacity to enforce the requirements of the Act. The DOB has concentrated on providing the institutional capacity to receive, review and make decisions on activities with LMOs. Now that these processes are functional, the DOB has turned its focus to implementing inspection and enforcement under the Act.

**Better coordination between different enforcement agencies.** The DOB has identified the need to coordinate the regulation of LMOs with existing regulatory authorities in sectors that will see applications of biotechnology products. These include agriculture, health, industry, forestry, fisheries, and science and technology. These agencies are represented on the NBB and were part of the Project Steering Committee. They will be engaged in developing a coordinated framework for implementing effective enforcement of the national biosafety laws.

**Better cooperation and partnerships between public and private sectors and civil society.** The Project Steering Committee has included a wide range of interested and affected stakeholders including representatives from relevant government departments, research, academia, industry, and NGOs. In future activities the DOB will partner with other government initiatives to widen its outreach to civil society. This will be increasingly important as applications for LMOs move from research and confined testing to approvals for general use. The DOB has found that publication of notifications has triggered public interest and input. They plan to use this route to keep the interested public informed of the applications and decisions being considered by the regulators and to encourage participation in decision making.

**Increased capacity for focused research in biosafety.** It became clear during the implementation of the project that the role of the regulators is to pose the safety questions that will guide the required biosafety research. The risk assessment and risk management training has helped to build the capacity needed to pose these questions. This was demonstrated in the regulatory decision making on the trial release of genetically modified mosquitoes. The actual biosafety research will be implemented by the developers and may be facilitated by government ministries such as agriculture, fisheries, forestry, health and industry when the biosafety research is needed to obtain clear safety implications for new

products. Risk assessment and risk management capacity will need to expand to deal with new GM products as they are developed, tested and approved for general use.

**Increased capacity in risk assessment for implementation and enforcement of a national risk management programme.** The decisions taken under the Biosafety Act during the implementation of the project indicate that the regulatory bodies have developed the capacity required to ensure the safe and responsible use of LMOs in Malaysia. There is on-going discussion about how to transfer this capacity to a pipeline of trained experts who will be able to advise the regulatory authorities as the number of applications increases and the complexity of the safety issues changes. In addition, the role of other ministries in coordinated enforcement of the biosafety requirements is being discussed.

**Increased awareness and understanding on biosafety issues among government officials and policy makers.** The line ministries directly impacted by the use of LMOs have been participants in this development project to implement the national biosafety framework. Representatives from these ministries have sat on the Project Steering Committee, participated in capacity building activities and helped to guide the implementation of the project. Awareness among these ministry representatives is high and will continue to expand as the role of biosafety becomes central to developments in these sectors.

The evaluation for meeting the intended outcomes of the project is **HIGHLY SATISFACTORY**.

#### **4.3.4. Project impact**

The impact of the project was measurable in terms of the functionality of the biosafety framework in Malaysia. All of the components of this framework benefited from capacity building during the project duration:

- The regulations, guidelines and administrative processes were developed to support the implementation of the Biosafety Act.
- The DOB was established as the primary competent authority for biosafety in Malaysia, tasked with implementing the Biosafety Act. This office developed the regulations and guidelines needed for implementation, consulted routinely with stakeholders and received and processed notification and release applications. It has established an administrative process that is functional and transparent.
- The NBB is the national decision making body on biosafety issues. It was established during the project and, in consultation with DOB, underwent some modifications to improve its functionality. The decisions of NBB are provided within the allocated timeframe and are accessible on the website.
- The GMAC provides the scientific expertise to review the safety of applications for activities with LMOs. GMAC advises the NBB on potential risks and on risk management measures that can be used to implement activities safely. This committee has received considerable risk assessment and risk management training and is

confident in its ability to assess risk. These assessments take time, but the committee has reached safety recommendations on all the applications it has reviewed to date.

- Inspectorates of relevant ministries have received training in biosafety and are working with the DOB to establish compliance and inspection processes prior to approvals for general release of LMOs in Malaysia.
- The website is the primary communication tool for biosafety stakeholders. It is functional and links directly to the BCH, helping to fulfil Malaysia's obligations under the CPB. The website provides access to the policy documents, regulations and guidelines. It also describes the biosafety processes in Malaysia, lists the roles of the various bodies and advertises which applications have been received. The website provides access to public awareness information on biosafety and links to other key biosafety ministries and international sites.
- The DOB has been asked to share the Malaysian biosafety framework with other countries and has presented the national biosafety framework at a number of international meetings. In this way, Malaysia has taken its place in the international biosafety community and as a party to the CPB.
- Biosafety stakeholders in Malaysia have noted that while the policy is strict, the implementation of the regulations is transparent and the guidelines are clear. This means that the regulatory regime is accessible and useable.

Based on the functionality of the Malaysian national biosafety framework and its growing role in international biosafety activities, the impact of this project has been evaluated as **HIGHLY SATISFACTORY**.

#### **4.4. Financial Review**

The UNDP-GEF funding for this project totalled US \$ 911,380. By May 2012 the project had spent US \$ 788,045, leaving US \$ 123,335 that the DOB will be using to settle outstanding payments for biosafety activities conducted up to 30 June 2012.

The Inception Report budget (Table 8) provided clear guidance on how the project funding would be used. For the terminal evaluation there were no available figures in the terminal report or from DOB for the actual expenditure per project component, so it was difficult to assess how closely the original budget was followed.

**Table 8. The planned project budget from the Inception Report.**

Component	GEF	%	US \$		%
			GOM	Total	
1. Legal & regulatory framework	89,375	10	682,890	772,275	14.8
2. Risk assessment	105,505	12	1,423,906	1,529,423	29.3
3. Risk management	208,500	23	1,087,650	1,296,173	24.9
4. Long term regime management	165,700	18	168,000	333,718	6.4
5. Information sharing & coordination	55,600	6	72,000	127,606	2.4
6. Stakeholder awareness & participation	59,700	7	846,729	906,436	17.4
7. Project management	185,368	20	22,000	207,388	4.0
8. Monitoring & evaluation	41,632	5	-	41,637	0.8
<b>TOTAL</b>	<b>911,380</b>	<b>100</b>	<b>4,303,175</b>	<b>5,214,655</b>	<b>100</b>

A summary of the GOM spending is provided in Table 9 and confirms that the government has met and exceeded its financial commitment to this UNDP-GEF biosafety project.

**Table 9. A summary of the Government of Malaysia in-kind contribution to the project and the sources of this funding.**

No.	Sources	RM	USD
1	<i>DOB operating expenditure</i>		
	2008	395,000	
	2009	702,000	
	2010	1,150,000	
	2011	1,468,300	
	to June 2012	846,750	
		<u>4,562,050</u>	<u>1,520,683</u>
2	<i>Costs for GMO Facility</i>		
	JKM	1,514,554	
	UMS (30% of total cost)	10,770,000	
		<u>12,284,554</u>	<u>4,084,851</u>
3	<i>Time contribution</i>		
	NBB meetings	20,000	
	GMAC meetings & visits	66,500	
	Various consultations	25,510	
		<u>112,010</u>	<u>37,337</u>
	<b>Total</b>		<b>5,642,871</b>
	Amount committed at start		4,303,175



The GOM financial commitment to the project (Table 9) does not include the costs covered by other Ministries involved in biosafety implementation (*e.g.*, Health, Agriculture, Science and Technology). It is important to note that the majority of the funding for the implementation of the Biosafety Act and the capacity building activities came from the GOM budgets, including the running budget for the DOB. This bodes well for sustainability of the biosafety framework once international funding is no longer available for biosafety activities.

The costs for setting up and running the detection facility are a major component of the GOM's contribution and the DOB will be investigating mechanisms to fund sustainable access to detection services in the future.

The annual expenditure of the UNDP-GEF funding provided in Table 10 indicates that there was a steady outlay of funding through the duration of the project. This indicates that the capacity building activities were spread out through the project period, as noted in the Table 7 showing the number of activities in the final three years of the project.

**Table 10. Annual expenditure figures for the GOM-UNDP-GEF project (Source: DOB)**

Year	Amount spent (USD)
2007	61,136
2008	107,842
2009	197,994
2010	221,005
2011	177,460
2012	30,827
TOTAL	796,263

The 2008 and 2010 financial audit performed by the Malaysian Auditor General's Office was satisfied that the project finances were being disbursed in accordance with the project proposal and with financial best practices. There were no major budget changes requested during the running of the project, except for the no-cost extension.

The outputs from the project and the impact on the functionality of the biosafety processes have been significant, especially when the progress made in implementing the national biosafety framework is compared to progress of many other national biosafety development projects funded by GEF. These observations, together with the final expenditure figures indicate careful management and use of the project funding.

The evaluation for the efficiency and effectiveness of the project budget management is **HIGHLY SATISFACTORY**.

## **5. Successes, Lessons Learned and Challenges**

The main success of the project is the implementation of the national biosafety framework in Malaysia. The country has 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.

Lessons learnt during the project included the value of using in-house human resources to manage the implementation so that the expertise remains within the biosafety institutions at the end of the project. The importance of detailed quarterly reports was an important lesson for systematic record keeping and easy evaluation and monitoring of the project. It was noted that quarterly reports on project implementation should contain full reports on the completed activities and the delivery timeline so that the project management team can document the deliverables against the planned outputs. This would facilitate a review of the project and ongoing monitoring for areas where additional effort is needed. In addition, the quarterly reports should have a financial report comparing the actual expenses to those outlined in the project plan.

Challenges for the DOB in implementing the project included the need to balance the demands from stakeholder groups that promoted and those that rejected biotechnology and its application in Malaysia. The DOB has achieved an excellent level of neutrality and credibility in the execution of their biosafety activities and in the distribution of funding from this project. (Feedback on the DOB from the stakeholder interviews is provided in Annex 3.) Challenges for the national biosafety framework in the future will be to:

- coordinate inspection and compliance regulatory functions with relevant line ministries;
- provide sustainable capacity building in risk assessment, risk management and risk communication as new GMOs are developed and the technology evolves;
- integrate socio-economic impact into decision making on general release applications;
- find a sustainable way to use the detection services for risk management, such as using this service only for products with identified high risk;
- find a sustainable way to fund the DOB while there are few applications; and
- develop streamlined procedures for the existing staff to cope efficiently when applications increase to over 100 a year. For example, consider distinguishing between confined releases for experimentation and releases for general use as these have very different risk parameters.

The DOB should make use of its experience in this project and shared it with other countries through south –south cooperation activities.

## **6. Conclusions**

The project aimed to build biosafety capacity that could support and sustain the implementation and running of the national biosafety framework and meet the obligations of Malaysia as a Party to the Cartagena Biosafety Protocol. The project implementation by the Department of Biosafety in the Ministry of Natural Resources and Environment was well managed. There was consultation with stakeholders on the format and content of the project

deliverables and several stakeholders commented that this commitment to consultation is relatively new to government projects and has been appreciated. The DOB worked consistently to maintain a steady timeline for delivery of the planned activities. From the development of the project outline to the delivery of the activities, the DOB has been complemented by the Malaysian stakeholders for their effort at reaching a wide range of stakeholders.

It is clear that the project has met its immediate objective, which was to implement a workable national biosafety regulatory process that meets the country's obligations as a Party to the CPB. The project documents record that the Biosafety Act (2007) was implemented with the passing of operational regulations that were drafted as a part of this program. The Department of Biosafety, the National Biosafety Board, the Genetic Modification Advisory Committee and a number of Institutional Biosafety Committees have been formed in accordance with the Act. These bodies comprise the national biosafety framework and are all functioning to provide assessments and decisions on both notifications and approvals with respect to activities with living modified organisms. The project has focused its efforts on establishing these bodies and equipping them with the skills needed to carry out their biosafety functions with efficiency and confidence. This biosafety capacity building is never completed. There needs to be a steady influx of trained experts to assist in the delivery of efficient and transparent biosafety services.

### **6.1. Indicators**

The project has been assessed for its relevance, effectiveness and efficiency.

The relevance of the project is deemed to be **HIGHLY SATISFACTORY**, because applications for biosafety assessment are routinely received and successfully processed by the national biosafety framework, using the capacity generated by the project activities. This confirms that there is a demand at national level for a functioning biosafety system and the outputs of the project have been successful in making the national biosafety framework workable.

The effectiveness of the project is deemed to be **HIGHLY SATISFACTORY**, because the activities have been effective in preparing the biosafety framework to receive and process applications, including making clear decisions and placing these on the national website for increased transparency and stakeholder awareness. Stakeholders comment that the regulations are strict, but the guidelines provide clear rules, a transparent process, timelines that are met and there is support from knowledgeable regulators.

The efficiency of the project is rated as **HIGHLY SATISFACTORY**, as the implementing agency has delivered most of the planned outputs within a reasonable timeframe and within budget. The outputs that were not delivered were poorly timed for this period of the implementation and were replaced by additional more urgently needed activities or expanded activities that met the immediate needs of biosafety implementation.

The overall rating for the project implementation and the achievement of the project outcomes and objectives is **HIGHLY SATISFACTORY**.

## 7. Recommendations

Malaysia is well positioned to make effective use of additional GEF funding for further implementation of its national biosafety framework. Based on the progress made during this project, the GEF implementation funding could be used to:

- undertake a gaps analysis of existing policy;
- expand existing policy to include new aspects of the CPB;
- streamline processes for applications to the DOB, building on experience and familiarity gained to date;
- strengthen coordinated regulation of compliance and inspections between line ministries; and
- extend biosafety information dissemination to the interested public.

During the terminal evaluation interviews stakeholders identified a number of activities that they would like to see addressed in future biosafety capacity building programmes. These are provided in Annex 4.

From the assessment process the following recommendations emerged that would help to guide the implementation of a follow-on project:

- Manage future capacity building projects within the DOB without the need for additional temporary staff in order to keep the skills in the department.
- Include financial updates in the quarterly reports
- Include activity reports in the quarterly reports for each activity, with input and statistics on delegates, facilitators, gender, partnerships, co-funding, impact, etc.
- Implement short activity assessment forms for delegates to provide feedback on the capacity building activities. Summarise this feedback in activity reports.
- Investigate mechanisms for coordinated regulation of LMOs in Malaysia using the existing regulatory functions of relevant ministries, such as field trial and facility inspection, export and import control; socio-economic impact assessments and food safety assessments.

## Annex 1

**Government of Malaysia - United Nations Development Programme/  
Global Environment Facility Funded Project**

**“Support to Capacity Building Activities on Implementing the Cartagena Protocol on  
Biosafety in Malaysia”**

**TERMS OF REFERENCE for TERMINAL EVALUATION**

**(PIMS 2182) Project ID 00034097**

**Project Title:** Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety in Malaysia

<b>GEF Project ID:</b>	PIMS: 2182
<b>UNDP Project ID:</b>	00034097
<b>Focal Area:</b>	Biodiversity Conservation
<b>GEF Strategic Priority:</b>	SP 6: Building capacity for the implementation of the Cartagena Protocol on Biosafety Protected Areas
<b>GEF Programming Framework:</b>	Enabling Activity
<b>GEF Agency:</b>	UNDP
<b>Country:</b>	Malaysia
<b>Duration:</b>	3 years
<b>Executing Agency:</b>	Ministry of Natural Resources and Environment
<b>Implementing Agencies:</b>	Department of Biosafety
<b>Approval Date:</b>	May 6, 2006
<b>Effective Date:</b>	March 2007
<b>Budget:</b>	USD 911,389

### 1. Introduction

With the recent development of “new” biotechnologies, such as living modified organisms (LMOs), hope was raised that these would contribute greatly to an increase in world agricultural production and thereby help reduce hunger and diseases. However, the emergence of LMOs has also led to concerns

about potential harmful effects on the environment and human health. These concerns were addressed through the Convention on Biological Diversity (CBD), which provided a framework to negotiate the Cartagena Protocol on Biosafety (CPB), which regulates international transfers of LMOs and aims to reduce risks for human health and the environment. The Protocol has only recently come into force and its provisions have not yet been fully implemented. Concern about the safety of new biotechnologies and their products continues and has led to heated debates among many stakeholders.

In November 2001, the GEF Council approved 12 proposals for projects to support countries with the implementation of their national biosafety frameworks (NBFs). Of these, eight (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland, Uganda) were UNEP-executed and -operated as a follow up to the pilot projects. The World Bank and UNDP each executed two projects in countries that had not participated in the pilot but that had some experience with LMOs, namely Malaysia and Mexico (UNDP) and India and Colombia (World Bank). The project period was typically three years, and the GEF allocation to each country ranged between \$500,000 and \$1 million.

The UNEP NBF implementation projects have received more direct assistance (substantive as well as administrative) from the UNEP coordinators than was provided to the NBF development projects. The UNDP and World Bank projects, where operational, have been approached very differently. UNDP limited its role to administrative oversight in the two implementation countries for which it was responsible. By contrast, the World Bank has provided both administrative oversight and technical backstopping, including sending initial and mid-term expert missions to address substantive issues and decisions. UNDP has limited itself to an administrative project oversight role and has drawn on the capacity of the UNEP team for substantive technical backstopping. In the latest GEF Project Cycle (GEF 5), UNDP centrally decided not to develop technical capacity as UNEP, and opted out of the role in the GEF's biosafety program.

## 2. Project Background

The Government of Malaysia (GoM) has identified biotechnology as one of the new income sources of the nation and envisioned it as the engine of growth for knowledge based economy in the country. The National Policy on Biological Diversity (NPBD) which was launched in 1998 calls for the sustainable utilization of biological resources among others through biotechnology. This was further augmented with the establishment of The National Biotechnology Policy in 2005. This Policy provides a guideline for a conducive environment for R&D and industry growth through leveraging on country's existing strength and capabilities. The government's emphasis on the agriculture sector is seen in the Biotechnology Policy where it is placed as the first thrust of the policy.

Furthermore, under the 3rd National Agriculture Policy for 1998-2010 (NAP3), where the main goal is to enhance food security and wealth creation through increased food production, biotechnology was identified as one of the five core technologies to transform the country into a highly industrialized nation by 2020. The attractive biotechnology incentives given to new biotechnology companies are one of the many efforts by the government to encourage biotechnology development in the country.

Malaysia together with Sweden played a key role in the early days (in 1991) of the CBD negotiation to introduce biosafety provisions. In 1997, Malaysia demonstrated its commitment to biosafety and proactively set up the Genetic Modification Advisory Committee (GMAC) to formulate the National Guidelines on the release of genetically modified organism (GMOs) into the environment.

Malaysia signed the CPB in the year 2000. Malaysia ratified the Protocol on the 3rd of September, 2003 and its entry into force was on the 2nd of December, 2003. Malaysia's recently passed Biosafety Act (11th July, 2007) states that before LMOs or its products can be imported, prepared, placed in the market, shall go through GMAC for scientific assessment before its approval by the National Biosafety Board (NBB). These LMOs will have to be exhaustively tested by the developer, independently evaluated for safety by scientists or experts in nutrition, toxicology, allergen city and other aspects of food science before approval can be obtained. It will also have to comply with the Ministry of Health's labeling provision that's being formulated.

Under the Act, the Ministry of Natural Resources and the Environment (NRE) is to establish a National Biosafety Board (NBB) as the national focal point on biosafety to implement and enforce the Biosafety Act. NRE and other government agencies are ill equipped to successfully implement the Biosafety Act as there are insufficient capacities in risk assessment and risk management, administrative and regulatory implementation.

At present, GMAC assists the Ministry of NRE on Biosafety matters. Additionally, little attention seems to have been given to the study of the socio-economic impacts of risks and the potential adverse effects on biotechnology on the environment. This project will help Malaysia build capacity to undertake these tasks as well as to build channels for information dissemination and public participation. For effective implementation of the Biosafety Act, and to fulfill the obligations under the CPB for transboundary movement of LMOs, customs officials must have full knowledge of the LMOs that will be crossing the country's national boundaries. This will again require capacity building in LMO detection among these enforcement officers.

The Project Brief for this *Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety* in Malaysia was approved in 2002 but the preparation and finalization of this Project Document was delayed because the tabling of the Biosafety Bill to the Malaysian Cabinet was delayed as the inter-ministerial consultation on the Bill took more time than expected. The inter-ministerial consultations, an integral component in the process of drafting a piece of legislation on a subject matter which is new and cross-sectoral in nature had to be done effectively with full participation of all relevant ministries. Moreover, in 2004 a cabinet reshuffle saw some delay in finalizing the Project Document as the former Ministry of Science, Technology and the Environment was split into two separate ministries i.e. Ministry of Science, Technology and Innovations and Ministry of Natural Resources and Environment which will be the executing agency of this project.

### 3. Project Goal and Objectives

The overall goal of this project is to assist Malaysia to fully implement the obligations under the Cartagena Protocol related to the transboundary movement of LMOs. This includes the assessment, management and long term monitoring of the risks to the sustainable use of biodiversity and to human health potentially posed by the introduction of LMOs.

The objective of this project is that at the end of the three, there will be sufficient capacity in the country and effective coordination between the responsible agencies to assess and manage risks associated with the transboundary movement of LMOs. This will be achieved through the strengthening of the national biosafety framework with the necessary regulations, enhanced technical capacity and enforcement and monitoring capacities as well as a well managed information and coordination network.

### 4. UNDP-GEF M&E objective and purpose of terminal evaluation

The Monitoring and Evaluation Policy (M&E Policy) at the project level in UNDP/GEF has four objectives to:

- a) Monitor and evaluate results and impacts;
- b) Provide a basis for decision making on necessary amendments and improvements;
- c) Promote accountability for resource use; and
- d) Document, provide feedback on, and disseminate lessons learned.

A mix of tools is used to ensure effective Project Monitoring and Evaluation (M&E). These might be applied continuously throughout the lifetime of the project e.g. periodic monitoring of indicators through the annual Project Implementation Reports (PIR), Project Steering Committee meetings – or as specific and time-bound exercises such as Mid-Term Reviews (MTR), Audit Reports and Final Evaluations (FE).

Monitoring and evaluation in the Global Environment Facility (GEF) projects have the following overarching objectives:

- To promote accountability for the achievement of GEF objectives through the assessment of results, effectiveness, processes, and performance of the partners involved in GEF activities. GEF results are monitored and evaluated for their contribution to global environmental benefits.
- To promote learning, feedback, and knowledge sharing on results and lessons learned among the GEF and its partners, as a basis for decision-making on policies, strategies, program management, and projects, and to improve knowledge and performance.

The purposes of conducting evaluations includes the understanding of why and the extent to which intended and unintended results are achieved, and their impact on stakeholders. Evaluation is an important source of evidence of the achievement of results and institutional performance, and contributes to knowledge and to organizational learning. Evaluation should serve as an agent of change and play a critical role in supporting accountability.

In accordance, all full and medium-size projects supported by GEF are subject to a final evaluation upon completion of implementation. In addition to providing an independent in-depth review of implementation progress, this type of evaluation is responsive to GEF Councils' decisions on transparency and better access to information during implementation and on completion of a project.

Specifically, the Terminal Evaluation (TE) must provide a comprehensive and systematic account of the performance of a completed project by assessing its project design, process of implementation and results vis-à-vis project objectives endorsed by the GEF including the agreed changes in the objectives during project implementation. TEs have four complementary purposes as follows:

- To promote accountability and transparency, and to assess and disclose levels of project accomplishments;
- To synthesize lessons that may help improve the selection, design and implementation of future GEF activities;
- To provide feedback on issues that are recurrent across the portfolio and need attention, and on improvements regarding previously identified issues; and,
- To contribute to the GEF Evaluation Office databases for aggregation, analysis and reporting on effectiveness of GEF operations in achieving global environmental benefits and on quality of monitoring and evaluation across the GEF system.

## 5. Objectives of this Terminal Evaluation

This terminal evaluation (TE) is being carried out to provide a comprehensive and systematic account of the performance of the Support to Capacity Building Activities on Implementing the Cartagena protocol on Biosafety in Malaysia project by assessing its project design, the process of implementation and results and outputs as they relate to project objectives endorsed by the GEF and UNDP. Specifically, the Terminal Evaluation will undertake the following tasks:

- Assess overall performance and review progress towards attaining the project's objectives and results including relevancy, efficiency and effectiveness of the actions taken given the available funding and capacities for implementation;
- Review and evaluate the extent to which the project outputs and outcomes have been achieved and provide rating employing the six-point rating scale (HS to HU );
- Assess the project results and determine the extent to which the project objectives were achieved, or are expected to be achieved, and assess if the project has led to any positive or negative consequences and provide a rating of project objective achievement on the six-point rating scale;
- Assess the extent to which the project impacts have reached or have the potential to reach the intended beneficiaries;
- Critically analyze the implementation arrangements and identify strengths and weaknesses in the project design and implementation and provide a rating of the project implementation, employing the six-point rating scale;

Describe the project's adaptive management strategy – how have project activities changed in response to new conditions and have the changes been appropriate;

- Review the clarity of roles and responsibilities of the various agencies and institutions and the level of coordination between relevant players;
- Assess the level of stakeholder involvement in the project from community to higher Government levels and recommend on whether this involvement has been appropriate to the goals of the project;

Describe and assess efforts of UNDP in support of implementation;

Review donor partnership processes, and the contribution of co-finance;

- Describe key factors that will require attention in order to improve prospects for sustainability of project results achieved; and,
- Identify and document the main successes, challenges and lessons that have emerged.

## 6. Scope of the evaluation

Three main elements to be evaluated are Delivery, Implementation and Finances. Each component will be evaluated using three criteria: effectiveness, efficiency and timeliness

**Project delivery:** The TE will assess to what extent the Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety in Malaysia project has achieved its immediate objectives. It will also identify what outputs, impacts and results have been produced and how they have enabled the project to achieve its objectives. The consultants are required to make assessment of the following issues under each priority area outlined below:

### **Institutional arrangement**

- Preparatory work and implementation strategies
- Consultative processes
- Technical support
- Capacity building initiatives
- Project outputs



- Assumptions and risks
- Project related complementary activities

#### **Outcome, results and impacts**

- Efficiency of all project activities under the six components
- Progress in the achievement of the immediate objectives (include level of indicator achievement when available)

#### **Partnerships**

- Assessment of federal agencies' level involvement and perception
- Assessment of state level involvement
- Involvement of stakeholders like non-governmental organisations, private sectors and universities

#### **Risk management**

- Were problems/constraints, which impacted on successful delivery of the project identified at the project design stage and subsequently as part of adaptive management?
- Were there new threats/risks to project success that emerged during project implementation?
- Were both kinds of risk appropriately dealt with?

#### **Monitoring and Evaluation**

- Assess the extent, appropriateness and effectiveness of adaptive management at all levels of the project implementation
- Has there been a monitoring and evaluation framework for the project and how was this developed?
- Is the reporting framework effective/appropriate?
- Is this framework suitable for replication/continuation for any future project support?

#### **Project Implementation**

- Review the project management and implementation arrangements at all levels, in order to provide an opinion on its efficiency and cost effectiveness. This includes:
  - i. Processes and administration:
    - Project related administration procedures
    - Milestones(Log-frame matrix)
    - Key decisions and outputs,
    - Major project implementation documents prepared with an indication of how the documents and reports have been useful
  - ii. Project oversight and active engagement by UNDP and project steering committee
  - iii. Project execution: Ministry of Natural Resources and Environment
  - iv. Project implementation: Biosafety Department

#### **Project Finances**

How well and cost effectively have financial arrangements of the project worked? This section will focus on the following three priority areas:

1. Project disbursements
  - Provide an overview of actual spending against budget expectations
  - Critically analyse disbursements to determine if funds have been applied effectively and efficiently.
2. Budget procedures

- Did the Project Document/Inception Report provide adequate guidance on how to allocate the budget?
  - Review of audits and any issues raised in audits and subsequent adjustments to accommodate audit recommendations;
  - Review the changes to fund allocations as a result of budget revisions and provide an opinion on the appropriateness and relevancy of such revisions
3. Coordination mechanisms
- Evaluate appropriateness and efficiency of coordinating mechanisms between executing agencies, implementing agencies and UNDP

## 7. Expected output

The TE evaluators will be expected to produce:

**A) An evaluation report**, of approximately 35-40 pages, structured along the outline indicated in Annex 1.

A detailed record of consultations with stakeholders will need to be kept and provided (as part of the information gathered by the evaluators), as an annex to the main report.

If there are any significant discrepancies between the impressions and findings of the evaluation team and stakeholders these should be explained in an Annex attached to the final report.

**B) A Power Point Presentation** (circa 20-25 slides) covering the key points of the TE.

**C) A presentation to the project stakeholders of initial finding at the end of in-country mission**.

A draft of both A) and B) above should be submitted within two weeks of the end of the in-country component of the evaluators' mission, and a final copy within two weeks after receiving written comments on the drafts.

The draft and final versions of the products should be submitted to the Project Management Unit who will be responsible for circulating it to key stakeholders.

## 8. Methodology of evaluation approach

The evaluation will be conducted in a participatory manner through a combination of processes. It is anticipated that the methodology to be used for the TE will include the following:

**A) Review of documentation including but not limited to:-**

- Project Document and Project Inception Report;
- Project implementation reports (APR/PIR's);
- Quarterly progress reports and work plans of the various implementation task teams;
- Audit reports;
- M & E Operational Guidelines, all monitoring reports prepared by the project; and
- Financial and Administration guidelines.
- Minutes of the National Steering Committee and Project Management Unit meetings;

**B) Interviews in the field with stakeholders shall include:**

- UNDP staff who have project responsibilities;
- Executing and Implementing agencies (including MNRE, Economic Planning Unit, Prime Minister Department and Department of Biosafety)
- Project Steering Committee members
- The GMAC committee members
- National Biosafety Board members;

- Project stakeholders, to be determined at the TE inception meeting, including Federal line ministries, State governments, private sector and NGOs.

## 9. Attributes of the evaluation consultants

The TE Team will consist of one International Expert (IE) and one National Expert (NE). The IE will be the Team Leader. The team will be responsible for the delivery, content, technical quality and accuracy of the evaluation, as well as the recommendations.

IE should have the following attributes:

- Min 10 years of experience dealing with Biosafety issues, including capacity building;
- Master's or Phd in the field of biological sciences,
- Project/programme evaluation/assessment, specifically undertaking complex programmatic reviews.

NE should have the following attributes:

- Min 5 years of experience dealing with Biosafety issues, including capacity building;
- Master's or Phd in the field of biological sciences,
- Project/programme evaluation/assessment, specifically undertaking complex programmatic reviews.

The team should ideally also have the following competencies:

Some prior knowledge of the following would be ideal:

- GEF, UNDP and/or other GEF agencies' reporting frameworks;
- GEF principles and expected impacts in terms of global benefits;
- The Cartagena Protocol and CBD

Competency in the following is also required:

- Demonstrated experience in institutional analysis;
- Excellent English writing and communication skills. Demonstrated ability to assess complex situations in order to succinctly and clearly distil critical issues and draw forward looking conclusions;
- Ability to assess complex situations in order to succinctly and clearly distil critical issues and draw forward looking conclusions; and,
- Excellent facilitation skills.

## 10. Implementation Arrangements

The evaluation will be conducted for a period of 20 working days, with in-country mission to be within the period 26 May 2010 to 5<sup>th</sup> June 2012. UNDP Malaysia will recruit the consultants and coordinate the evaluation. The project management unit will be responsible for logistical arrangements in the field (setting up meetings and organizing travel).

The detailed TE methodology and actual evaluation schedule will be agreed as part of the contract finalisation process in May 2012 between UNDP, MNRE and the consultants.

The evaluation will start with an inception meeting with the TE Steering committee and the joint World Bank/ UNDP Mission and a review of the key project documentation including key reports and correspondence. It will include presentations from the various project components, visits to executing and implementing agency offices, interviews with key individuals both within the project, the government, and independent observers of the project and its activities, as well as project personnel.

### **Annex 1. Report Sample Outline**

Terminal Evaluation Report – Sample outline

#### 1. Executive summary

- Brief description of project;
- Context and purpose of the evaluation;
- Main conclusions, recommendations and lessons learned;

## 2. Introduction

- Purpose of the evaluation;
- Key issues addressed;
- Methodology of the evaluation;
- Structure of the evaluation.

## 3. The project(s) and its development context

- Project start and its duration;
- Problems that the project seek to address;
- Immediate and development objectives of the project;
- Main stakeholders;
- Results expected.

## 4. Findings and Conclusions

### 4.1 Project Formulation

- ✓ Implementation
- ✓ Stakeholder participation
- ✓ Replication approach
- ✓ Cost effectiveness
- ✓ Linkage of the project and other interventions within the sector
- ✓ Indicators

### 4.2. Project Implementation

- ✓ Delivery
- ✓ Financial management
- ✓ Monitoring and evaluation
- ✓ Execution and implementation modalities
- ✓ Management by UNDP
- ✓ Coordination and operational issues

### 4.3 Results to date

- ✓ Attainment of Objectives
- ✓ Sustainability
- ✓ Contribution to upgrading skills at National level

## 5.0 Lessons learned

6.0 Conclusions and recommendations, including overall rating of project implementation and the achievement of project outcomes and objective.

## 7.0 Evaluation report Annexes

- Evaluation TORs , Itinerary and list of persons interviewed
- Summary of field visits, including evaluators findings, issues raised and recommendations by different stakeholders
- List of documents reviewed
- Questionnaire used and summary of results if any
- Comments by stakeholders (only in case of discrepancies with evaluation findings and conclusions)

## **Annex 2. Tentative schedule for the evaluation**

TBC

## **Annex 3: Explanation on Terminology provided in the GEF Guidelines to Terminal Evaluations**

**Implementation Approach** includes an analysis of the project's logical framework, adaptation to changing conditions (adaptive management), partnerships in implementation arrangements, changes in project design, and overall project management.

Some elements of an effective implementation approach may include:

- The logical framework used during implementation as a management and M&E tool
- Effective partnerships arrangements established for implementation of the project with relevant stakeholders involved in the country/region
- Lessons from other relevant projects (e.g., same focal area) incorporated into project implementation
- Feedback from M&E activities used for adaptive management.

**Country Ownership/Driveness** is the relevance of the project to national development and environmental agendas, recipient country commitment, and regional and international agreements where applicable. Project Concept has its origin within the national sectoral and development plans

Some elements of effective country ownership/driveness may include:

- Project Concept has its origin within the national sectoral and development plans
- Outcomes (or potential outcomes) from the project have been incorporated into the national sectoral and development plans
- Relevant country representatives (e.g., governmental official, civil society, etc.) are actively involved in project identification, planning and/or implementation
- The recipient government has maintained financial commitment to the project
- The government has approved policies and/or modified regulatory frameworks in line with the project's objectives

For projects whose main focus and actors are in the private-sector rather than public-sector (e.g., IFC projects), elements of effective country ownership/driveness that demonstrate the interest and commitment of the local private sector to the project may include:

- The number of companies that participated in the project by: receiving technical assistance, applying for financing, attending dissemination events, adopting environmental standards promoted by the project, etc.
- Amount contributed by participating companies to achieve the environmental benefits promoted by the project, including: equity invested, guarantees provided, co-funding of project activities, in-kind contributions, etc.
- Project's collaboration with industry associations

**Stakeholder Participation/Public Involvement** consists of three related, and often overlapping processes: information dissemination, consultation, and "stakeholder" participation. Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the GEF-financed project. The term also applies to those potentially adversely affected by a project.

Examples of effective public involvement include:

Information dissemination

- Implementation of appropriate outreach/public awareness campaigns

Consultation and stakeholder participation

- Consulting and making use of the skills, experiences and knowledge of NGOs, community and local groups, the private and public sectors, and academic institutions in the design, implementation, and evaluation of project activities

Stakeholder participation

- Project institutional networks well placed within the overall national or community organizational structures, for example, by building on the local decision making structures, incorporating local knowledge, and devolving project management responsibilities to the local organizations or communities as the project approaches closure
- Building partnerships among different project stakeholders
- Fulfillment of commitments to local stakeholders and stakeholders considered to be adequately involved.

**Sustainability** measures the extent to which benefits continue, within or outside the project domain, from a particular project or program after GEF assistance/external assistance has come to an end. Relevant factors to improve the sustainability of project outcomes include:

- Development and implementation of a sustainability strategy.
- Establishment of the financial and economic instruments and mechanisms to ensure the ongoing flow of benefits once the GEF assistance ends (from the public and private sectors, income generating activities, and market transformations to promote the project's objectives).
- Development of suitable organizational arrangements by public and/or private sector.
- Development of policy and regulatory frameworks that further the project objectives.
- Incorporation of environmental and ecological factors affecting future flow of benefits.
- Development of appropriate institutional capacity (systems, structures, staff, expertise, etc.) .
- Identification and involvement of champions (i.e. individuals in government and civil society who can promote sustainability of project outcomes).
- Achieving social sustainability, for example, by mainstreaming project activities into the economy or community production activities.
- Achieving stakeholders consensus regarding courses of action on project activities.

**Replication approach**, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated or scaled up in the design and implementation of other projects. Replication can have two aspects, replication proper (lessons and experiences are replicated in different geographic area) or scaling up (lessons and experiences are replicated within the same geographic area but funded by other sources).

Examples of replication approaches include:

- Knowledge transfer (i.e., dissemination of lessons through project result documents, training workshops, information exchange, a national and regional forum, etc).
- Expansion of demonstration projects.
- Capacity building and training of individuals, and institutions to expand the project's achievements in the country or other regions.
- Use of project-trained individuals, institutions or companies to replicate the project's outcomes in other regions.

**Financial Planning** includes actual project cost by activity, financial management (including disbursement issues), and co-financing. If a financial audit has been conducted the major findings should be presented in the TE.

**Effective financial plans include:**

- Identification of potential sources of co-financing as well as leveraged and associated financing<sup>1</sup>.
- Strong financial controls, including reporting, and planning that allow the project management to make informed decisions regarding the budget at any time, allows for a proper and timely flow of funds, and for the payment of satisfactory project deliverables
- Due diligence due diligence in the management of funds and financial audits.

Co-financing includes: Grants, Loans/Concessional (compared to market rate), Credits, Equity investments, In-kind support, Other contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries. Please refer to Council documents on co-financing for definitions, such as GEF/C.20/6.

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<sup>1</sup> Please refer to Council documents on co-financing for definitions, such as GEF/C.20/6. The following page presents a table to be used for reporting co-financing.

*Leveraged resources* are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector. Please briefly describe the resources the project has leveraged since inception and indicate how these resources are contributing to the project's ultimate objective.

**Cost-effectiveness** assesses the achievement of the environmental and developmental objectives as well as the project's outputs in relation to the inputs, costs, and implementing time. It also examines the project's compliance with the application of the incremental cost concept. Cost-effective factors include:

- Compliance with the incremental cost criteria (e.g. GEF funds are used to finance a component of a project that would not have taken place without GEF funding.) and securing co-funding and associated funding.
- The project completed the planned activities and met or exceeded the expected outcomes in terms of achievement of Global Environmental and Development Objectives according to schedule, and as cost-effectively as initially planned.
- The project used either a benchmark approach or a comparison approach (did not exceed the costs levels of similar projects in similar contexts)

**Efficiency:** Was the project cost effective? Was the project the least cost option? Was the project implementation delayed and if it was then did that affect cost-effectiveness? Wherever possible the evaluator should also compare the cost-time vs. outcomes relationship of the project with that of other similar projects.

The evaluation of relevancy, effectiveness and efficiency will be as objective as possible and will include sufficient and convincing empirical evidence. Ideally the project monitoring system should deliver quantifiable information that can lead to a robust assessment of project's effectiveness and efficiency. Since projects have different objectives assessed results are not comparable and cannot be aggregated. To track the health of the portfolio project outcomes will be rated as follows:

Highly Satisfactory (HS): The project had no shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Satisfactory (S): The project had minor shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Satisfactory (MS): The project had moderate shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Unsatisfactory (MU): The project had significant shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Unsatisfactory (U) The project had major shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Highly Unsatisfactory (HU): The project had severe shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Relevance and effectiveness will be considered as critical criteria. The overall outcome rating of the project may not be higher than the lowest rating on either of these two criteria. Thus, to have an overall satisfactory rating for outcomes a project must have at least satisfactory ratings on both relevance and effectiveness.

The evaluators will also assess positive and negative actual (or anticipated) impacts or emerging long term effects of a project. Given the long term nature of impacts, it might not be possible for the evaluators to identify or fully assess impacts. Evaluators will nonetheless indicate the steps taken to assess project impacts, especially

impacts on local populations<sup>2</sup>, local environment (e.g. increase in the number of individuals of an endangered species, improved water quality, increase in fish stocks, reduced greenhouse gas emissions) and wherever possible indicate how the findings on impacts will be reported to the GEF in future.

### Assessment of Sustainability of project outcomes

The GEF Monitoring and Evaluation Policy, 2006, specifies that a TE will assess at the minimum the “likelihood of sustainability<sup>3</sup> of outcomes at project termination, and provide a rating for this.” The sustainability assessment will give special attention to analysis of the risks that are likely to affect the persistence of project outcomes. The sustainability assessment should also explain how other important contextual factors that are not outcomes of the project will affect sustainability. Following four dimensions or aspects of sustainability will be addressed:

- **Financial resources:** Are there any financial risks involved in sustaining the project outcomes? What is the likelihood that financial and economic resources will not be available once the GEF assistance ends (resources can be from multiple sources, such as the public and private sectors, income generating activities, and trends that may indicate that it is likely that in future there will be adequate financial resources for sustaining project’s outcomes)?
- **Sociopolitical:** Are there any social or political risks that can undermine the longevity of project outcomes? What is the risk that the level of stakeholder ownership will be insufficient to allow for the project outcomes/benefits to be sustained? Do the various key stakeholders see that it is in their interest that the project benefits continue to flow? Is there sufficient public / stakeholder awareness in support of the long term objectives of the project?
- **Institutional framework and governance:** Do the legal frameworks, policies and governance structures and processes pose any threat to the continuation of project benefits? While assessing on this parameter also consider if the required systems for accountability and transparency, and the required technical know-how is in place.
- **Environmental:** Are there any environmental risks that can undermine the future flow of project environmental benefits? The TE should assess whether certain activities in the project area will pose a threat to the sustainability of the project outcomes. For example, construction of dam in a protected area could inundate a sizable area and thereby neutralizing the biodiversity related gains made by the project.

On each of the dimensions of sustainability of the project outcomes will be rated as follows.

Likely (L): There are no risks affecting this dimension of sustainability.

Moderately Likely (ML). There are moderate risks that affect this dimension of sustainability.

Moderately Unlikely (MU): There are significant risks that affect this dimension of sustainability

Unlikely (U): There are severe risks that affect this dimension of sustainability.

All the risk dimensions of sustainability are critical. Therefore, overall rating for sustainability will not be higher than the rating of the dimension with lowest ratings. For example, if a project has an Unlikely rating in either of the dimensions then its overall rating cannot be higher than Unlikely, regardless of whether higher ratings in other dimensions of sustainability produce a higher average.

Project monitoring and evaluation system will be rated as follows on each of the dimensions:

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<sup>2</sup> Impacts are positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended. *Glossary of key terms in evaluation and results based management*. OECD, Development Assistance Committee. For the GEF, environmental impacts are the main focus.

<sup>3</sup> Sustainability will be understood as the likelihood of continued benefits after the GEF project ends.



Highly Satisfactory (HS): There were no shortcomings in the project M&E system.

Satisfactory(S): There were minor shortcomings in the project M&E system.

Moderately Satisfactory (MS): There were moderate shortcomings in the project M&E system

Moderately Unsatisfactory (MU): There were significant shortcomings in the project M&E system

Unsatisfactory (U): There were major shortcomings in the project M&E system

Highly Unsatisfactory (HU): The Project had no M&E system.

“M&E plan implementation” will be considered a critical parameter for the overall assessment of the M&E system. The overall rating for the M&E systems will not be higher than the rating on “M&E plan implementation

## Annex 2

### Consultant's Itinerary

<b>Date</b>	<b>am</b>	<b>pm</b>
27 May 2012		Arrive in Malaysia; Review documents
28 May 2012	Review documentation	Review documentation
29 May 2012	Meet with DOB at NRE	Review documentation
30 May 2012	Stakeholder interviews	Stakeholder interviews
31 May 2012	Stakeholder interviews	Review documentation
1 June 2012	Document review	Draft report
2 June 2012	Review financial information	Review financial information
3 June 2012	Draft report	Draft report
4 June 2012	Meet with DOB	Draft report and presentation
5 June 2012	Present draft findings to stakeholders	Revise draft; Stakeholder interview Depart Malaysia

### Stakeholder interviews

Ms. Jasbeer Kaur  
Senior Scientific Officer  
Department of Chemistry Malaysia  
Ministry of Science, Technology and Innovation

Dr. Noor Zaleha Awang Saleh  
Head, Biotechnology Section  
Department of Chemistry Malaysia  
Ministry of Science, Technology and Innovation  
Project Steering Committee Member

Dr. Anika  
Scientific Officer  
Department of Chemistry Malaysia  
Ministry of Science, Technology and Innovation

Mr. Adrian Abdul Ghani  
Vice President, Policy & Regulatory Engagement  
Malaysian Biotechnology Corporation  
Project Steering Committee Member

Dr. Cheong Weng Chung  
Manager, Regulatory Affairs  
Malaysian Biotechnology Corporation

Dr. Maria Alina Ahmad  
Manager, Regulatory Affairs  
Malaysian Biotechnology Corporation  
Project Steering Committee Alternate Member

Lim Li Ching  
Researcher, Third World Network  
Project Steering Committee Member

Dr. Shahnaz Murad  
Director, Institute of Medical Research  
National Biosafety Board Member

Ms. T.S. Saraswathy  
Senior Research Officer  
GMAC Member and Applicant

Mr. Bambang Irawan Syah (by telephone)  
Cerca Insights Sdn. Bhd.  
Pulau Pinang.  
IBC member and applicant

Mahaletchumy Arujanan  
Executive Director  
Malaysian Biotechnology Information Centre  
(MABIC)

## **Annex 3**

### **Stakeholder feedback on the Department of Biosafety**

- The DOB has built a good relationship with the stakeholders.
- The staff members are accessible and professional.
- They are open to ideas and suggestions from stakeholders.
- DOB staff have discussed issues and dealt with them in a knowledgeable and helpful way.
- The DOB has been good at keeping stakeholders informed and engaged.
- While some provision such as products are difficult, the DOB has made the Biosafety Act workable.
- DOB managed the handling of applications well and made an effort to be inclusive in training activities.
- DOB is accessible to the extent that a regulatory agency can be.
- Personal relationships help access to the DOB.
- Focused outreach to specific stakeholders and affected parties worked very well for the mosquito application.
- DOB staff members were very helpful with the completion of application forms.
- The DOB, GMAC and NBB made their decision in the documented timeframe.

## Annex 4

### Stakeholder suggestions for the way forward:

- Expect detection requirements to increase when the labelling regulation is implemented. Need to establish a sustainable mechanism to carry out regulatory detection.
- Expand the guideline on contained use to include scale up for commercial production in contained facilities.
- Streamline the handling of LMOs across the many regulatory agencies, especially those that fall under several jurisdictions.
- More needed on interdepartmental co-ordination, including outreach to state governments, as land issues are dealt with at this level.
- Would like to review the law, especially the regulation of products.
- Need to build onto progress, and not just repeat what was done before.
- Continue to increase the number of people with biosafety capacity and the quality of the existing expertise.
- Dedicate a working group to look at how other countries have reviewed their biosafety laws and then plan a review process for the Biosafety Act.
- Look at building sustainability in the DOB: efficiency and institutional memory. Also, consider how to keep regulatory expertise in the DOB. How will DOB be financed once the co-funding dries up? What is a practical with respect to numbers and size of biosafety bodies and the core staff?
- Would like to expand the source of regulatory resource people to use more than the OGTR in Australia.
- NBB members need a mechanism to consult with their ministries and agencies on the decisions.
- Implement enforcement of the law.
- Continue to widen awareness of biosafety among stakeholders and the general public.
- Establish a mechanism to address socio-economic issues in decision making.
- Steering Committee is very large, but managed to meet regularly. Government members kept changing and were not up-to-date on the project. Is there a way to create institutional memory in a body such as this?
- Need to discuss ratification of the Supplementary Protocol on Liability and Redress.
- Need guidance in other areas of the Act.
- It is possibly too early for a review, but a gaps analysis would determine what needs to be done through additional regulations, or a review and revision of the existing Act and/or regulations.
- Investigate mechanisms for doing biosafety research and identifying issues that could be addressed with biosafety research.

- Create an email list of biosafety interested parties to notify them of new applications or calls for input and participation.
- Create a listserv on the website for notifying interested stakeholders of new updates or information.
- Timelines are long from a research and business point of view. It is hoped that these will become shorter with experience.
- Apply experience to streamline processes and improve on aspects of the biosafety system.