PROJECT BRIEF

1. IDENTIFIERS:

PROJECT NUMBER	PIMS 2182
PROJECT NAME	**Capacity Building for Implementation of Malaysia's National Biosafety Framework**
DURATION	3 years
IMPLEMENTING AGENCY	United Nations Development Program in co-ordination with UNEP and UNIDO
EXECUTING AGENCY	Ministry of Science, Technology and the Environment
REQUESTING COUNTRY	Malaysia
ELIGIBILITY	Party to CBD on 24 June, 1994 Cartagena Protocol signed 24 May, 2000
GEF FOCAL AREA	Biodiversity, crosscuts the Biodiversity OPs 1,2,3,4 and follows the Initial Strategy adopted by the GEF Council in November 2000.
GEF PROGRAMMING FRAMEWORK	Enabling Activity (EA)

2. SUMMARY:

The project will help consolidate Malaysia's national capacity for the implementation of the Cartagena Protocol on biosafety. This project will address the capacity building needs of the country so as to be able to implement her national biosafety framework.
Specifically, the project will develop the national capacities in biosafety required to: carry out risk assessments with an appropriate scientific and technical level; implement necessary activities for risk management; evaluation and strengthening of legal and regulatory framework; and development of infrastructure for information exchange and data management. The development of national capacities in these areas will consolidate the national framework for biosafety management.

The project builds on the development of the national biosafety framework in Malaysia.

3. COSTS AND FINANCING (MILLION US$):

		Total
GEF	Project	US$ 911,380
	Sub-Total	**US$ 911,380**
Co-Financing	Government of Malaysia	US$ 4,303,175
	Sub-Total	US$ 4,303,175
Total Project Cost		US$ 5,214,555

4. OPERATIONAL FOCAL POINT ENDORSEMENT

Dr. Zulkifli bin Idris,
Director, Conservation and Environmental Management Division,
For the Secretary-General, Ministry of Science, Technology, and the Environment
Date of endorsement: 2 January 2002

5. IMPLEMENTING AGENCY CONTACTS

Tim Clairs, GEF Regional Co-ordinator for Asia and the Pacific
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LIST OF ACRONYMS

AIA	Advanced Informed Agreement
BCC	Biotechnology Cooperative Centre
CBD	Convention on Biological Diversity
CCF	Country Cooperation Framework
CP	Cartagena Protocol
DOA	Department of Agriculture
DOE	Department of Environment
EPU	Economic Planning Unit
GDP	Gross Domestic Product
GMAC	Genetic Modification Advisory Committee
GoM	Government of Malaysia
IBC	Institutional Biosafety Committee
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LMO	Living Modified Organism
MABIC	Malaysian Biotechnology Information Centre
MOSTE	Ministry of Science, Technology and the Environment
NAP3	Third National Agricultural Policy
NBB	National Biosafety Board
NGO	Non Governmental Organisation
NPBD	National Policy on Biological Diversity
PSC	Public Services Commission
RA	Risk Assessment
RM	Risk Management
SC	Steering Committee
TWN	Third World Network
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation

1. BACKGROUND AND PROJECT CONTEXT:

1.1 NATIONAL DEVELOPMENT STRATEGY

1. The Government of Malaysia is showing a high level of commitment to biosafety issues. This is because biotechnology is one of the five core technologies that are expected to accelerate Malaysia's transformation into a highly industrialized nation by 2020 and it has been identified as one of the new sources of growth in the Third National Agriculture Policy (NAP3) for 1998-2010. This sector is gaining importance as the contributions to total agricultural value-added from rubber, cocoa and sawlogs are expected to decline. NAP3 highlights the importance of human resource development in order to "generate highly skilled and innovative manpower in new and emerging sciences such as food, genetic engineering and biotechnology".

2. In the Third Outline Perspective Plan (2001-2010) , it was stated that efforts would be made to increase the Gross expenditure on research and development (R&D) from the current level of 0.4% of GDP to at least 1.5% . This will involve restructuring the present research structures, encouraging more private sector R&D as well as increasing research funds available through the competitive Intensified Research Priority Areas (IRPA) mechanisms.

3. Under the 8th Malaysian Plan (2001-2006) the Government has proposed the setting up of three National Biotechnology Institutes. These Institutes will act as hubs for the development of biotechnology and associated companies leading to the formation of the Malaysian Biotechnology Clusters or Bio-Valley. The Bio-Valley is expected to create a conducive environment for the introduction and synergistic expansion of biotechnology services and integrate the various aspects of development of the biotechnology industry. Besides that, it will be located in the Multimedia Super Corridor (MSC), where an "integrated environment" brings together smart cities, multimedia industries, R&D center among others. This will help ensure that the Bio-Valley would be well supported in terms of Information and Communications Technology (ICT).

1.1.2 National Focal point on Biosafety

4. Until such time that the National Biosafety Board is established, MoSTE is the National focal point on biosafety.

1.2 BIOSAFETY FRAMEWORK IN MALAYSIA

1.2.1 Government Commitment

5. The Government of Malaysia has shown its commitment to biosafety issues by working on a biosafety framework since the mid 1990s. The task force for the drafting of the biosafety bill had even produced several drafts before Malaysia signed the Cartagena Protocol.

1.2.2 Institutional context

6. Primary responsibility for environmental management and legislation falls under the purview of MoSTE, but many other ministries and government bodies are also involved in issues related to the environment. This includes the Ministry of Health (mainly under its Department of Public Health), the Ministry of Agriculture, the Ministry of International Trade and Industry (for matters pertaining to trade and the environment) and the Ministry of Primary

Industries (under which fall the Forestry Department as well as research centers focusing on commercial crops such as the Malaysian Palm Oil Board and the Malaysian Rubber Board).

Genetic Modification Advisory Committee (GMAC)

7. Up to present, the Genetic Modification Advisory Committee (GMAC) is the only body bringing together scientists working on biosafety. This national advisory body was established administratively within the ambit of the National Committee on Biodiversity of MoSTE. GMAC provides technical advice to MoSTE as well as to private bodies. It is responsible for establishing guidelines for the importation, research, testing, release and utilization of LMOs and to promote public awareness in biotechnology and biosafety. The Secretariat of the GMAC is housed in MoSTE, and its members are scientists from different research universities and relevant government agencies who volunteer their time and expertise. Representatives from civil society, such as the Third World Network (TWN) are also included in the GMAC. Members of GMAC are appointed by the Secretary General of MoSTE on the recommendation of the Chairman of GMAC. The Chairman of the current GMAC is the Deputy Vice Chancellor of the Universiti Kebangsaan Malaysia (UKM).

8. In 1996, the GMAC published the National Guidelines for the Release of GMOs into the environment, which was developed from existing principles and documents including the UNDP International Technical Guidelines on Safety in Biotechnology, 1996 and the UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment 1991.

National Biotechnology Directorate (Biotek)

9. The National Biotechnology Directorate (Biotek) of MoSTE is responsible for strengthening and developing the biotechnology industry towards commercial orientation. One of its main activities is the Intensification of Research in Priority Areas (IRPA) Programme, which has so far allocated US$ 6.68 million for 16 approved research and development projects in biotechnology over a five-year period. Under the 8th Malaysian Plan, the Treasury is allocating US$ 7.8 million to Biotek for their eight Biotechnology Cooperative Centers (BCCs). This allocation will mainly be for enhancing laboratory equipment as well as funding research projects of the BCCs. No work directly on biosafety issues is scheduled to be carried out by the BCCs, although the Food BCC (FBCC) did hold a workshop on risk assessment and regulations for food safety in November 2001.

Chemistry department

10. The Chemistry Department is one of the Departments under MoSTE. It is formed by a network of multipurpose laboratories made up of 10 laboratories around the country which provide scientific services (analysis, investigation, and consultation) to MoSTE as well as to other ministries. The GMO laboratory is one of the laboratories in the Environmental Health Division. The establishment of the GMO laboratory is to fulfil the needs arising from the proposed amendments to the Food Regulations 1985, which plan to make mandatory labelling of GMOs found in food.

Research institutions

11. Research institutions such as the Malaysian Agricultural Research Development Institute (MARDI) and the Malaysian Palm Oil Board (MPOB), formerly known as the Palm

Oil Research Institute (PORIM) also play a key role in the local biotechnology industry and hence are an important part of the national biosafety framework. For example, the Advanced Biotechnology and Breeding Center of MPOB works mainly on genetic engineering and molecular genomic, with the aim of developing tools and technology to create value added palm oil and other products with greater precision. MPOB has successfully transformed oil palm with marker gene to make it resistant to the herbicide "Basta" and is also working on the production of high oleic unsaturated oils.

Universities

12. Many local university academics are well informed on biotechnology and biosafety issues. As mentioned in paragraph 7, the Chairman of GMAC is a professor at the National University of Malaysia (Universiti Kebangsaan Malaysia, UKM). The UKM Center for Gene Analysis and Technology which was formed in December 1996 aims to bring scientists together to identify and characterize novel genes and gene families through the application of molecular cloning techniques, DNA sequence analysis and computational biology. Its main roles are to focus on advanced molecular biology as a basis for understanding the role of genes in normal physiology and pathological states, to provide state-of-the-art facilities for research, education and technology development at the university and national levels and to create a collaborative and cooperative environment with other institutions of higher learning, research institutes and industries at national and international levels.

Private corporations

13. As the Cartagena Protocol mainly covers the transboundary movement of LMOs, multinational companies which are present in Malaysia will be stakeholders in the biosafety framework. In fact, the first application which GMAC Malaysia had to undertake concerned risk assessment exercise for the import of transgenic glyphosate-tolerant Roundup Ready soybeans (GTS), line 40-3-2 into Malaysia in 1998. Owing to constraints of expertise and facilities, that risk assessment was primarily based on scientific evidence provided by the proponent (Monsanto).

14. It should be pointed out here that most local companies, including the bigger plantation companies, focus their R&D efforts on tissue culture and micro propagation techniques, rather than on biotechnology R&D.

1.2.3 Legal context

15. Malaysia is a signatory to the Convention on Biological Diversity. Under the CBD, through Article 8(g), the Government is committed to establish or maintain means to regulate, manage or control risks associated with the use and release of LMOs resulting from biotechnology that are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biodiversity. On May 24th, 2000, Malaysia signed the Cartagena Protocol.

16. Malaysia is constituted as a federation of thirteen states, with a separation of legislative and executive powers between federal level and federated state level in relation to certain subject matters. The separation of powers is detailed under the federal, state and concurrent

lists in the Constitution. The Federal list gives the Federal government control over areas such as trade, commerce and industry (including imports and exports and the establishment of standards of quality of goods manufactured in or exported from the country), scientific and technical research and health. The Federal government has the responsibility of general environmental protection and control of pollution. The State governments have jurisdiction over forests and other natural resources. Concurrently, both Federal and State may legislate on the protection of wild animals, national parks and town and country planning. Biosafety is a federal issue, and the development of the national biosafety framework has been at federal level.

17. Present capacity for enforcing general environmental regulations lies within the Department of Environment (DOE). DOE was set up in 1974 to administer and enforce the Environmental Quality Act (1974) and part of the Economic Exclusive Zone Act, 1984. Its mission is to ensure that the "uniqueness, diversity and quality of the environment are preserved towards maintaining health, prosperity, security and well-being for the present and the future". It streamlines its activities according to the Environmental Policy Objectives, which are to "achieve a clean, safe, healthy and productive environment for present and future generations; conservation of the country's unique and diverse cultural and natural heritage, with effective participation by all sectors of society, and sustainable lifestyles, patterns of production and consumption". There are also enforcement divisions on federal and state levels in the other Ministries, for example within the Ministries of Health and Agriculture respectively.

Biosafety Bill

18. In order to fulfill the obligations under the Cartagena Protocol, MoSTE has drafted a Biosafety Bill. The Biosafety Bill will serve as an "umbrella act" and will include the setting up of the National Biosafety Board (NBB) as well as legal and institutional provisions tailored to comply with the Cartagena Protocol. The Bill is scheduled to come into force by 2002. The Bill, which is mirrored on the Cartagena Protocol, will constitute the national legal and institutional base of the Biosafety Act in Malaysia.

19. In 1997, a core team of GMAC members drew up the National Guidelines for the Release of Genetically Modified Organisms into the Environment. These Guidelines set a regulatory framework for biotechnology and shows the importance the country has been giving to biosafety issues. However, these Guidelines only cover the general scientific and technical aspects of the release of GMOs into the environment. It is stated in the Guidelines that as a starting point in their implementation, existing institutional mechanism, such as the Plant Quarantine Act 1976 will be utilized. However, the Guidelines are only administrative in nature and unaccompanied by legislation to ensure compliance.

20. The purpose of the Bill is to regulate the import, export, deliberate release, contained use and marketing of GMO-related products in order to protect human, plant and animal health, the environment and biodiversity, the principle of sustainable development, and ethical and cultural norms. The Bill contains articles pertaining to 1) Control and Licensing 2) Risk assessment and risk management 3) Institutional structure and 4) Enforcement.

21. The competent authority for the purposes of administering the Bill will be the National Biosafety Board (NBB). The other specific powers and functions of NBB are to determine, formulate and review the biosafety policy. NBB will act upon the advice of the GMAC in

scientific and technical issues. GMAC, which is at present a voluntary body, will be given legal recognition under this Bill. NBB, in consultation with GMAC may establish ad hoc panels of experts to evaluate the risk assessment and risk management report submitted by the applicant. Any institution involved in any activity relating to GMOs will be encouraged to establish institutional biosafety committees (IBC) to ensure control and safety. These committees will report to the GMAC. NBB will designate enforcement competencies to relevant Ministries or local authorities. NBB will first give its approval before the applicant can apply for the required permits from the relevant ministries.

22. In principle, enforcement will be on a sectoral basis. Within the Ministries of Agriculture and Health, enforcement mechanisms already exist to implement legislation such as the Pesticides Act, 1974, Plant Quarantine Act 1976 and the Food Act. Under the Pesticides Act, there are Guidelines on Application for Permit to Import Pesticides for Educational or Research Purposes The Crop Protection and Plant Quarantine Division of the Department of Agriculture (DOA) is responsible for the prevention, control and of agricultural pests. The Plant Quarantine Act 1976 and the Plant Quarantine Regulations 1981 provide the DOA with the legislative power to carry out preventive and eradicative measures to safeguard the agriculture industry. The Plant Quarantine Regulations 1981 stipulate the requirements which must be met for the importation of plants, plant products, growing media/rooting compost, beneficial organisms, plant pests and carrier of plant pests into Malaysia. Phytosanitary certificates are issued to exporters when required by the importing country. The phytosanitary certificates verify that the products have been inspected, treated and are pest and disease free.

23. In the absence of enforcement clauses in the sectoral acts (for example, in food or in agriculture), delegated authority will be prescribed. In general, provisions will be in the Biosafety Bill for MoSTE to act. However, at present, no division within MoSTE has the capacity to do so. MoSTE will be requesting the Federal Public Service Commission to create approximately 35 posts to provide support to the NBB, 20 of which would be for enforcement officers, who would also be involved in sampling activities, documentation for compliance and other secretariat work at NBB. As capacity in biosafety does not presently exist on the managerial or enforcement level, MoSTE will have to train its newly recruited officers in areas related to biosafety.

Public Health

24. The proposed amendment to the Food Act (2001) includes mandatory labelling for foods which contain a percentage of GM products. The safety threshold of 5% has been proposed.

1.2.4 Environmental context

25. Malaysia is one of the 12 mega-diversity countries in the world today. Around 58% of the country is still under natural forest cover (Masran et.al. 1994). The Government has long realized the direct and indirect importance of biodiversity, in economic terms and also in other aspects such as that of medicinal plants and food supply, as well as the global significance of the country's biodiversity.

26. Malaysia launched the National Policy on Biological Diversity (NPBD) in 1998, following extensive consultations with stakeholders. The policy has the main objective of preserving the country's biological resources for economic, social and physical well-being.

MoSTE is also drafting the Access to Biological Resources and Benefit Sharing Bill to regulate access to the country's biological resources, as well as their collection, protection, utilisation and export. However, Malaysia faces several challenges in implementing the NPBD, especially in the field of enforcement of environmental legislation. There is also a need to improve the scientific knowledge base. At the base of these two challenges lies the need for more trained personnel in the field of biodiversity and biotechnology.

1.2.5 Public information

27. The Malaysian Biotechnology Information Centre (MABIC) was set up to fill the gap between information available from research institutions needs of the public for non-technical information about biotechnology and biosafety. It has a three-year funding from the International Service for the Acquisition of Agri-biotech Applications (ISAAA). Its mission is to develop a biotechnology information centre that is recognised to be a resource based on sound science to the public and policy makers and by doing so, to support the GoM's efforts to develop biotechnology as a tool for national development. MABIC is also a country node of ISAAA's Global Knowledge Center and depends on a scientific advisory committee that consists of local biotechnology scientists. One of their three advisors is also a member of the GMAC. Activities of MABIC include the organisation of seminars to create public awareness on issues concerning biotechnology (an example being a public forum on "Assuring the safety of Biotechnologically-produced foods" in September 2001) and workshops on risk communication targeted at biotechnology researchers (November 2001), so they can present their research work in a more effective way to the media and the public to enhance the understanding of biotechnology and LMOs in general.

28. In September 2001, the Ministry of Science, Technology, and the Environment (MoSTE) organised a public consultation on the proposed National Biosafety Bill. The participants were from NGO, government, agro-industry, scientific and academic communities and were invited to voice their views about the draft bill before it is sent to Parliament. It is rare in the Malaysian process of legislation to hold such public consultations with the scheme of the proposed law made available to the public in advance to allow for comments and it is a recognition of the importance of public consultation in the field of biosafety and shows the commitment of the Government in viewing the public as important stakeholders in the field of biosafety.

1.3 BASELINE CAPACITY AND IDENTIFIED GAPS:

1.3.1 Institutional

29. At present, there is no scientific and technical capacity within MoSTE to implement regulations on biosafety. MoSTE has to fall back on the Genetic Modification Advisory Committee (GMAC) for such expertise. MoSTE will set up the secretariat of the NBB and to do so, it will be submitting a request to the Federal Public Services Commission (PSC) to employ about 35 people, comprising enforcement officers, managers, lawyers and scientists in 2002. Approximately US$ 263,160 has been requested by MoSTE in its year 2002 budget to carry out the planned recruitment. As an interim measure, staff from other departments within MoSTE would be seconded to the new NBB structure.

Chemistry Department

30. Under the 8th Malaysian Plan (2001-2006), a supplementary allocation of US$ 530,504 has been made available during the next two years to equip the new GMO laboratory of the Chemistry Department of MoSTE, of which US$ 371,353 will be for the purchase of hardware and the remaining US$ 159,151 for the purchase of chemicals and other consumables. The Chemistry Department will also hire 2 scientific officers and 3 assistant scientific officers so as to be able to carry out risk assessment tests for LMOs. In the long term, MoSTE would like to set up a laboratory for NBB, but it realizes that first, more capacity among local scientists has to be developed.

GMAC

31. From the institutional point of view, the Genetic Modification Advisory Committee (GMAC) is presently a voluntary body, without any paid staff. As a purely advisory body, GMAC decisions are not legally binding. This will change under the proposed Biosafety Bill where the status of the GMAC as the scientific advisor to the proposed National Biosafety Board would be backed up by legal and regulatory powers. MoSTE sees that it is necessary to employ full-time personnel and also to especially when a greater workload is generated through more field release applications. MoSTE is making provisions to implement the hiring of personnel within their overall institutional framework and with their own budget. However, there will still be a need for training, especially for risk assessment and risk management.

32. It is also expected that under the proposed Biosafety Bill, the membership of GMAC be extended to include representatives of other ministries. While this will hopefully result in broader participation from different sectors when it comes to implementing the Bill, it also means that there will be increased need for capacity building, at least for raising awareness among participating government officers.

Enforcement

33. Under the proposed Biosafety Bill, enforcement will be sectoral-based where food and agriculture is concerned. Even though the Ministry of Health and the Ministry of Agriculture have enforcement units, these units are not prepared to handle the scope of the Biosafety Bill. The same can be said for the Customs officials in charge of border control. To be able to effectively implement the Biosafety Bill, and hence fulfill the obligations under the Cartagena Protocol, customs officials must be able to have full knowledge that GMOs will be crossing the country's national boundaries.

Research

34. Even though Malaysia spends about 0.4% of her annual Gross Domestic Product (GDP) on research and development, only a small fraction goes to support research in biodiversity and biosafety. This does not mean that biosafety issues occupy a low rank on the Government's priority, but more because at present there are only limited capabilities and a small number of researchers working on this subject.

35. In addition, most research funds are now channelled through the Intensification of Research in Priority Areas (IRPA) mechanism of competitive bidding. Research proposals are presented to one of the nine sectoral panels. At present there is no panel to address biosafety

issues. Even though research projects on biotechnology have been approved, they are not oriented towards biosafety and risk assessment. In addition, given the multidisciplinary nature of a comprehensive risk assessment, it is envisaged that it will be difficult for researchers to apply for a multisectoral research grant. Research funding through the National Biotechnology Directorate (NBD) is channelled to the Biotechnology Cooperative Centers, which do not specifically focus on biosafety issues.

36. Besides that, it is also felt that there are not enough researchers in Malaysia who work on the interface between different disciplines, for example between environment and medicine. The baseline scenario thus suggests that inadequate research will be carried out to assess potential risks of LMOs. For example, to date, no field release has been conducted in Malaysia.

37. While the government has been making progress on the biosafety front this progress is largely scientific and technical based. In the baseline scenario, little attention seems to be given to the study of other aspects of biosafety, such as the socio-economic impacts of risks of the potential adverse effects on biotechnology. This is all the more so important in a country like Malaysia, whose economy is reliant on the export of commodity crops.

Stakeholder awareness and participation

38. MoSTE plans to allocate an annual US$ 16,448 grant to each of the thirteen federated Malaysian States for biosafety public awareness programmes. In addition, MoSTE will channel funds directly to an NGO to also carry out public awareness programmes. It will allocate US$5,263 per State per year for this purpose. However, it will also need to rapidly undertake activities such as the production of education kits, flyers and posters for different target groups (consumers in general, school children etc) as well as documentary films.

39. MoSTE plans to hold an awareness workshop in 2002 to familiarize stakeholders from government, research organizations, media and NGOs on main issues covered in the Cartagena Protocol.

40. Although MoSTE has declared that it will undertake the development of public awareness, it does not have the capacity at hand to promote awareness within policy makers and enforcement officers. For the moment, little provision has been made for activities targeted at raising awareness among members of private sector.

1.4 Barriers to Fully Implement the Cartagena Protocol

41. A number of significant barriers preventing the full implementation of the CP in Malaysia have been identified and are described below:

1.4.1 Systemic level

42. The proposed legal framework for biosafety is broad and not sufficiently well detailed to be completely operational. However the legislation has evolved to be a general act, under which details for implementation will be mostly captured in the regulations, to allow MoSTE more flexibility should the need to adapt to changing needs arise.

1.4.2. Institutional level

43. At present there is insufficient institutional capacity, in research capabilities as well as management systems.

1.4.3. Individual level

44. MoSTE and other government agencies remain ill-equipped to successfully implement the Biosafety Bill as there are insufficient capacities, in terms of numbers and skills, in risk assessment and risk management, administrative systems, enforcement and legal implementation.

2. GEF ALTERNATIVE COURSE OF ACTION:

45. A GEF intervention would complement baseline activities in Malaysia by ensuring that key required capacities for implementation of the Cartagena Protocol would be developed. The current process of development of a national legal framework on biosafety will be capitalized on, to ensure that the legal instruments are used effectively and that effective and coordinated enforcement can be carried out.

2.1. PROJECT OBJECTIVES:

Development objective:

46. The development objective of the 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.

Immediate objective:

47. The immediate objective is that at the end of the three year capacity building project, 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 biosafety framework with the necessary regulations, enhanced technical capacity and enforcement and monitoring capacities as well as a well managed information and coordination network.

2.2. PROJECT STRATEGY

48. In the GEF initial strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety (November 2000), although it is mentioned that GEF assistance might best be channelled to countries which have already ratified the Protocol, in the interest of gaining experience in the immediate future, it is proposed that GEF financing be provided in the form of a "limited number of country-based demonstration projects".

49. As the Government is focussing its resources to the areas of biotechnology development and public communication, this can be taken to mean that in the baseline scenario, skills in areas such as risk assessment, which is essential for importing countries to be able to make informed decisions under the Advanced Informed Agreement (AIA) under the Cartagena Protocol, would not be developed. Furthermore, without external assistance, capacity in risk management would be slower and Malaysia would not be able to effectively manage risks to the conservation and sustainable use of biodiversity within her territory.

50. The main activities of the project are focused on the identification, regulation and management of the risks derived from the trans-boundary release and utilisation of LMOs, that might present adverse risks to the conservation and sustainable use of biological diversity, taking also in account potential risks to human health. This national approach to capacity building contemplates risk assessment and management, monitoring and evaluation, legal and regulatory reform/strengthening, broad social participation and a dissemination strategy in the context of the Advanced Informed Agreement.

51. GEF is requested to participate in strategic elements of this approach over the medium-term horizon (3 years) that will permit the longer-term consolidation of the strategy. The GEF-financed portion of the project includes training and risk management components that will ensure sustainability and information exchange over the long-term.

52. The anticipated activities and outcomes are for each component are summarised below:

Component 1: A legal and regulatory framework that permits the effective evaluation, management and monitoring of GMOs (GEF: US$ 89,375; COFIN: US$ 682,890)

53. While the process of tabling the Biosafety Bill is well underway, the regulations are still being drawn up. The regulations will be drafted using national resources. It is essential that those responsible for drawing up these regulations be up to date on the best practices and lessons learnt from the experiences of other countries.

54. Government resources have been budgeted so that the key policy makers and lawmakers to attend international meetings on issues related to biosafety (e.g. ICCP Nairobi-October 2001, ASEAN biosafety meeting-November 2001). This will ensure expose to international best practices and lessons learnt from other countries.

55. In addition, GEF resources will be used to allow for cross-project learning with the other UNDP and UNEP capacity building demonstration projects. Staff from NBB will visit at least two other demonstration projects.

56. GEF resources shall be used to further strengthen the legal and regulatory framework. Short courses for lawmakers and policy decision makers will be made available to these key personnel to be able to better integrate the obligations under the Biosafety Bill into the existing legal framework, and to put in place mechanisms to strengthen the coordination of the existing implementation and monitoring capacity of different government agencies while taking into account the federal-state division of responsibilities in the Malaysian system.

57. A consultant will be hired for 2 person months to work with the in-house expertise within MoSTE to formulate these regulations while transferring and building capacity. This is consistent with the GEFSEC comments which state that “project activities could include the further development of specific rules and regulations within the national biosafety framework, if relevant to the Protocol”. Part of the consultant’s terms of reference would include acting as the key resource person in a workshop after the proposed regulations have been drafted. This workshop aims to bring together experts from different departments, the private sectors and enforcement agencies to discuss the operational aspects of the regulations. It is proposed that the workshops continue on an annual basis after the first year of the project.

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

(GEF: US$ 105,505; COFIN: US$ 1,423,906)

58. This component will be achieved through the development of capacity in the following areas: analysis of risks to conservation and sustainable use of biodiversity, analysis of risks to human health and to food security posed by effects to biodiversity and the analysis of ecosystem effects of the introduction of LMOs. These outcomes will contribute towards the identification and understanding of potential risks of LMOs and also the production of biological information needed for risk assessments in local environments.

59. Expert support and training courses to develop capacity of local scientists in the preparation of field release application, the selection of the correct release site, the selection of barriers (physical, biological or temporal) and monitoring of environmental impacts. Training also needed for the modeling of the probable impacts on the environment of the risks related to the release of LMOs. Results of these field release capacity building, modeling and Components from research should be inputted to an information system (cf. Component 5).

60. As mentioned earlier, the Chemistry Department will be equipping and staffing a National GMO Laboratory.

61. The participation of scientific officers of the GMO lab of MoSTE's Chemistry Department in the following areas will be supported with GEF resources:

- Theory of modern molecular genetics
- Detection of genetically modified organism in foods.
- Quantification of GMO using Real Time PCR.
- Accreditation, Proficiency testing and Quality Assurance .
- Sampling and statistical analysis.

	Course	Duration	Participants	Number of participants	Location	Total (US$)
1	GMO analysis	2 weeks	Scientific Officer and Assistant Scientific Officer	2	Overseas	7958.00
2	Modern molecular genetics	5 days	Scientific Officer and Assistant Scientific Officer	2	In-country	1326.00
3	Seminar and Workshop on Food Safety Risk Assessment	1 week	Scientific Officer	2	Overseas	5305.00
4	Quality Assurance in GMO analysis	2 weeks	Scientific Officer and Assistant Scientific Officer	2	Overseas	7958.00
5	Detection of genetically modified organisms in foods.	2 weeks	Scientific Officer and Assistant Scientific Officer	2	Overseas	7958.00

56. It is expected that the officers who have benefited from the training courses will be then able to contribute towards developing training packages on risk assessment together with local researchers to be able to train other scientists involved in risk assessment, specifically to be able to review and audit the information they receive from the risk assessments submitted by applicants.

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

(GEF: US$ 208,500; COFIN: US$ 1,087,650)

57. This will be achieved through the implementation of the Biosafety Bill. A request will be submitted to the Public Services Commission of Malaysia to recruit 35 persons needed to staff the secretariat of NBB.

58. Activities need to be developed to build awareness among the staff of the NBB, enforcement agencies, the private sector as well as NGOs so that they are familiar with the risk management regime and their obligations under the Biosafety Bill.

59. GEF resources will be used for the supporting and implementing of training activities to the representatives of different ministries and the Customs Board, who will then become trainers themselves in their respective ministries (as part of a programme of training the trainers). This will concern officers who in their enforcement duties will have to have some basic knowledge of identification of LMOs, AIA procedures and risk management. Besides the staff of NBB secretariat, this would also include :

- Medical officers of health and health inspectors of the Ministry of Health;
- Fisheries officers of the Department of Fisheries, Ministry of Agriculture;
- Port officers;
- Police officers; and
- Custom officers.

60. The training courses will be on the identification and handling of LMOs at points of import and the capacity to monitor, enforce and report on non-compliance

PRIVATE SECTOR

61. The private sector has been identified as one of the key stakeholders of the national biosafety framework and hence this capacity building project. Opportunities for technology transfer within the private sector should also be studied during the project. Participation by the private sector is an essential component of the implementation of the Biosafety Bill and as a cooperative importing/exporting private sector will reduce the need for policing and sanctions.

62. Dialogues will be held with the members of private sector both potential applicants as well as private laboratories to familiarize them with the procedures and processes under the national biosafety framework as well as their legal obligations. Preliminary discussions have been held with a leading international biotechnology company over the possibility of their sharing experiences on application dossiers especially on risk assessment studies and the possibility of other forms of collaboration. This will be followed up on during the initial stages of the project.

63. GEF funds will be used to produce a manual, and user-friendly handbook for the private companies, which detail their obligations under the Biosafety Bill.

Component 4: Developed capacity for long-term regime building maintenance

(GEF: US$ 165,700; COFIN: US$ 168,000

64. Long-term regime building maintenance will be crucial for the country to be able to monitor, review and report on the effectiveness of risk management programme, including legal, regulatory and administrative mechanisms.

65. GEF resources will be used for building scientific capacity to monitor longer-term environmental and health impacts, as well as longer-term impacts on biodiversity. Specific activities would include training courses both for managers and for scientists on:

- Monitoring, reviewing and reporting on the effectiveness of risk management programmes,
- Monitoring longer-term environmental impacts of release of LMOs,
- Establishment of environmental reporting systems.

66. GEF resources will also be used for reviewing the effectiveness of the risk management programme.

67. These activities would also be linked up to activities under Component 5.

Component 5: Better institutional coordination and sharing of information

(GEF: US$ 55,600; COFIN: US$ 72,000)

68. This Component will be achieved through the development of capacity for information sharing mechanisms. Inter-ministerial coordination would be mostly ensured through the National Biosafety Board (NBB), which will comprise of representatives of different ministries. The Secretariat of the NBB will provide administrative support in coordinating this inter-ministerial information sharing.

69. GEF resources will be used to support training courses for the information technology specialist of the secretariat of NBB in setting up and maintaining the database which is to be linked to the Biosafety Clearing House containing the information required by the Cartagena Protocol (applications for permits, laboratory and field trials, approved permits for the release of LMOs, products containing LMO).

70. Resources will be used to establish and update a list of exemptions to the AIA procedure. The exemption list will be both proactive and reactive. A consultant will be hired to assist MoSTE or NBB with drawing up the initial ("proactive") list of exemptions, based on international best practices and. A significant part of the consultant's work would be the transfer of knowledge and skills to NBB in-house expertise. As with the consultancy under Component 1, a workshop would be organised with the consultant as a key resource person to discuss with national scientists and policy makers on the choice of products exempted from the AIA procedure and how to constantly update the exemption list.

71. Training course on data management skills will be held for the information technology specialists from the different enforcement agencies.

72. Training courses to increase awareness among officers in different ministries will be carried out to increase the effectiveness of NBB.

73. Workshops will be held on an annual basis so that enforcement agents from different agencies and ministries can exchange experiences and share best practices.

Component 6: Public awareness relative to the transboundary movement of LMOs and participation of stakeholders

(GEF: US$ 59,700; COFIN: US$ 846,729)

74. Government resources will be used to hold biosafety public awareness programmes through the grants made by the Federal government to each of the 13 federated states. GEF resources will complement these efforts in the preparation of education kits, flyers and posters for different target groups.

75. Activities should also address the issue of participation of civil society. NGOs could play the role of auditor to keep the system transparent without crippling the procedures of the biosafety regime. Dialogues or workshops could be held periodically so that the different States can share their experiences of implementation among each other and also with the different Ministries.

76. MoSTE has plans to create a website which will be accessible by the public and will be a forum for the public to voice their concerns. The website will be designed and maintained by the in-house Information Technology expertise of NBB. Training will be provided to the IT staff on the specificity of biosafety topics, what information should be disseminated to the public while maintaining the confidentiality of certain information which has been guaranteed by NBB to applicants .

3. RISKS AND SUSTAINABILITY

3.1 SUSTAINABILITY

77. This capacity-building project is designed to form the first part of a longer-term national effort to consolidate the biosafety framework. Each of the proposed activities addresses gaps or barriers that have been identified during the project preparation process. Capacity building activities have been designed to strengthen not only the capabilities of the competent authority to the CP, but also of key federal line ministries, and awareness and decision-making support activities will ensure cross sector and cross government synergies.

78. UNDP will provide technical, financial and administrative backstopping to the entire process.

79. The project would be sustainable after its completion by having successfully achieved the following:

- Enhanced management capacity at national level;
- Implementation of the national risk management regime;
- Enforcement of laws and regulations under the Biosafety Bill;
- Better coordination between different enforcement agencies;
- Better cooperation and partnerships between public and private sectors and civil society;
- Increased capacity for focused research in biosafety;

- Increased capacity in risk assessment, for implementation and enforcement of a national risk management programme, as the officers trained under this proposed project would be able to train others in their respective fields; and
- Increased awareness and understanding on biosafety issues among government officials and policy makers as a result of the capacity building activities.

80. An effective indicator that this project has fulfilled its objectives and will hence be sustainable is by verifying that the personnel involved in the national biosafety framework are able to handle obligations under the Cartagena Protocol in a timely manner, for example, with reference to the time frame for notification and decision procedures under Articles 8 – 10.

3.2 RISKS

81. The justification behind this project as a demonstration project on the implementation of the Cartagena Protocol depends on the commitment of the Government to ratify the Protocol.

82. There is a risk of lack of communication and coordination between Federal and State level agencies. It is hoped that the role of NBB as coordinator of activities pertaining to biosafety will be able to attenuate this risk. In addition this issue can be addressed during the training courses and workshops of Component 5.

83. The role of the private sector needs to be defined more clearly. This will be done in the initial stages of the project.

4. STAKEHOLDER PARTICIPATION AND IMPLEMENTATION ARRANGEMENTS

4.1 STAKEHOLDER PARTICIPATION

4.1.1 Federal and state government agencies

84. Federal ministries (such as those listed below) and enforcement agencies at State level are the main stakeholders.

- Ministry of Science, Technology and the Environment, Conservation and Environmental Management Division as well as GMAC and NBB.
- Economic Planning Unit (EPU), Regional Economics and Environment Section;
- Ministry of Agriculture, Plant Quarantine Section of the Crop Protection Branch (Department of Agriculture)
- Ministry of Health, Department of Public Health;
- Ministry of Primary Industries;
- Ministry of International Trade and Industry;
- Ministry of Domestic Trade and Consumer Affairs; and the
- Ministry of Finance, Royal Customs and Excise Department.

4.1.2 Research institutes

85. Research institutes such as the Malaysian Rubber Board (MRB) formerly known as the Rubber Research Institute of Malaysia (RRIM), the Malaysian Agricultural Research and Development Institute (MARDI), the Malaysian Palm Oil Board (MPOB), the Forest Research Institute of Malaysia (FRIM), Department of Genetics and Plant Breeding Universiti Kebangsaan Malaysia, Center for Genetic Analysis (Universiti Putra Malaysia) and other research institutes in local universities.

4.1.3 Private sector

86. Biotechnology companies, plantation companies and other companies dealing or trading in biotechnology products.

4.1.4 Civil society

87. Representatives from civil society, including NGOs such as the Third World Network, whose international secretariat is based in Malaysia. TWN aims to promote scientific understanding on biosafety issues and also to share information and experiences in the area of biosafety policies and laws as they are developed at the international, regional and national levels. Another objective of TWN is to improve the flow of information on these issues especially to policy makers, scientists and NGOs in developing countries, all the more so in view of the need for implementing the Biosafety Protocol at national level.

88. Environment NGOs such as the World Wide Fund for Nature Malaysia (WWFM) and the Malayan Nature Society (MNS) are also key stakeholders as are other NGOs such as Federation of Malaysian Consumers Associations (FOMCA).

4.2 Implementation arrangements and project management

89. The Project will be executed by the Government of Malaysia, with the support of the UNDP- Malaysia Country Office. Until such time the NBB Secretariat is established and fully staffed, MoSTE will be responsible for project execution.

4.2.1 Project Advisory Body

90. The Genetic Modification Advisory Committee (GMAC) will act as the advisory body to the project.

4.2.2 Project Steering Committee

91. MoSTE will establish a Steering Committee (SC). The SC will be chaired by a senior officer from MoSTE and will comprise senior representatives from relevant Federal Ministries and Departments, including:

- Ministry of Science, Technology and the Environment, Conservation and Environmental Management Division as well as representatives from the Genetic Modification Advisory Committee (GMAC) and the National Biotechnology Directorate;
- Economic Planning Unit (EPU), Regional Economics and Environment Section;
- Ministry of Agriculture, Plant Quarantine Section of the Crop Protection Branch within the Department of Agriculture;

- Ministry of Health, Department of Public Health;
- Ministry of Primary Industries (including representatives from research institutes under the Ministry, such as the Malaysian Palm Oil Board, the Forest Research Institute of Malaysia and the Malaysian Rubber Board);
- Ministry of International Trade and Industry;
- Ministry of Domestic Trade and Consumer Affairs; and the
- Ministry of Finance, Royal Customs and Excise Department.

92. In addition, the Steering Committee will include representatives from State Governments (including State Departments of Environment and Departments of Agriculture) as well as representatives from UNDP.

93. SC members will be expected to promote awareness of the project and of biosafety issues in general within their respective agencies and to facilitate consultations within their agency's jurisdiction.

94. Travel and associated costs incurred by Government representatives in attending SC meetings will be included as part of the Government's in-kind contribution.

95. UNDP, UNEP and UNIDO will meet every year to discuss project implementation and to review institutional commitments and support for the project.

4.2.3 Project Co-ordination Unit

96. A project co-ordination unit will be created and supported within MoSTE to administrate the project. Tasks will include overall project management, co-ordination efforts amongst the different line agencies. The PCU will also prepare work plans, budgets, and terms of reference for sub-contractors and consultants, and will be responsible for maintaining financial accounts and records according to UNDP guidelines for nationally executed projects. The PCU will consist of a Project Co-ordinator and a Project Administrative assistant.

5. INCREMENTAL COSTS AND PROJECT FINANCING

5.1 INCREMENTAL COSTS

97. In the baseline scenario, that is, even without this project, Malaysia would continue to develop her biosafety framework based on the obligations under the Cartagena Protocol. MoSTE has requested for additional funds from the federal budget for additional personnel dedicated to the NBB secretariat. The federal government has allocated funds to the Chemistry Department and will also make provisions for State grants for public awareness activities.

98. There are still barriers to fully implementing the Cartagena Protocol and the alternative scenario addresses these barriers.

99. The total costs of the GEF alternative are estimated at US$ 5,194,555 of which GEF is requested to provide US$ 891,380 as agreed full cost funding, or 17.2% of the project cost. The Government of Malaysia will fund a total of US$ 4,303,175 through MoSTE. The GEF-financed activities of the project are expected to be completed by year 3.

100. The project will be financed through agreed full cost funding with the GEF, with significant counterpart funding. Detailed incremental cost analysis is presented in Annex A.

5.2 BUDGET IN US DOLLARS

Component	GEF	GoM	Total	% GEF of total
Legal and regulatory framework	89,375	682,890	772,265	11.6
Risk assessment	105,505	1,423,906	1,529,411	6.9
Risk management	208,500	1,087,650	1,296,150	16.1
Long term regime maintenance	165,700	168,000	383,700	49.7
Information sharing and coordination	55,600	72,000	127,600	43.6
Stakeholder awareness and participation	59,700	846,729	906,429	6.6
Project Management	207,000	22,000	229,000	90.4
Monitoring and Evaluation	20,000	0	20,000	0.4
TOTAL	911,380	4,303,175	5,214,555	17.5

6. MONITORING, EVALUATION AND DISSEMINATION

101. The project will be monitored and evaluated according to standard UNDP rules for nationally executed projects. In line with UNDP procedures, the project will be subject to annual tripartite review (TPR). The tripartite review (TPR) is a policy-level meeting of the parties directly involved in the implementation of a project. The participants include the Government (MoSTE and EPU), UNDP (Country Office and GEF), and project management (Steering Committee Chair, and Project Coordinator). On these occasions, the Project Coordinator will submit an updated workplan (if required) and the latest Annual Project Report (APR), and formulate recommendations for eventual adjustments of strategies and activities. A draft APR shall be prepared at least two months in advance of the TPR to allow review by UNDP prior to the meeting. The TPRs can be scheduled to take place back-to-back with other meetings, such as Steering Committee meetings.

102. Due to recent changes in reporting requirements by the GEF Secretariat, the APR will serve as the basic document for the PIR. Based on future bilateral discussions between UNDP/GEF and the GEF Secretariat, specific minor additions to the APR may be required to ensure consistency with the GEF's reporting requirements. As per GEF guidelines, UNDP Malaysia is responsible for submitting quarterly operational reports (QORs) to the UNDP-GEF Task Manager.

103. A final project evaluation will be conducted at the end of project implementation. It focuses on relevance; performance (effectiveness, efficiency and timeliness); issues requiring decisions and actions; and initial lessons learned about project design, implementation and management as well as identifies early signs of potential impact and sustainability of results,

including the contribution to capacity development and the achievement of global environmental goals. It should also provide recommendations for follow-up activities.

104. Periodic Status Reports would be prepared at the request of the Steering Committee for presentation at key meetings associated with the Project.

7. COMPLEMENTARITIES WITH OTHER GEF INTERVENTIONS

105. This project is one of the ten demonstration projects, and one of the two GEF projects in Asia Pacific on capacity building for the implementation of national biosafety frameworks that seek to implement the Cartagena Protocol. As stated in the GEF Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety, the experience gained through these demonstration projects should assist the Parties in determining guidance to the financial mechanism once the Protocol enters into force. The GEF Secretariat will ensure that lessons learned will be shared and that methodologies and experiences are transferred to other Parities as they later receive assistance pursuant to the guidance of the Parties of the Protocol."

8. LESSONS LEARNED

106. The process of drafting the Biosafety Bill has been a highly consultative one, both within the government agencies and ministries as well as with the public. Public consultations on draft legislation are rare in Malaysia, but in this case, the drafters of the Bill and the Ministry of Science, Technology, and the Environment have recognized the importance of public opinion and a wide participation of stakeholders in issues relating to biosafety. This commitment to public involvement will continue during the implementation of the national biosafety framework.

107. The process of project design has helped to prioritize the federal government's strategic actions for the implementation of the national biosafety framework. This improved communication and coordination will be capitalized upon during the capacity building process.

108. The process of project design has also promoted wider dialogue between the different agencies and other stakeholders. This improved co-ordination and dialogue is a key aspect of the proposed capacity building activity with the GEF.

9. LINK TO UNDP CCF AND REGIONAL INITIATIVES

9.1. UNDP INITIATIVES

109. This project is consistent with the Country Cooperation Framework (CCF) of UNDP Malaysia, which identifies two major areas for development cooperation for the current cycle (1997-2001), namely, human development and the environment.

110. The proposed project complements the GEF portfolio in Malaysia, which includes a capacity building project to enhance the country's human resource and technical capability for developing national responses to climate change as well as a successfully completed project which assisted MoSTE to publish and disseminate its National Biodiversity Strategy and Action Plan and to prepare its first national report to the Conference of the Parties to the CBD.

9.2 REGIONAL INITIATIVES

111. The experiences gained during the development of this project as well as project activities themselves will be invaluable to other countries in the Asia Pacific region. As yet there has not been a regional Asia Pacific mechanism for sharing information on biosafety or on the development of biosafety frameworks. We understand that such an effort will be undertaken on a regional level next year by the IUCN Colombo office. Malaysia will then be in a position to share her experiences from this project with other countries in the region.

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ANNEXES

Required Annexes

ANNEX A: Incremental Cost Matrix

ANNEX B: Log Frame Matrix

ANNEX C: STAP Roster Technical Review

ANNEX C1: Response to STAP review

ANNEX D: Letter of endorsement and Co-financing Confirmation from the Operational Focal Point

Other annexes

ANNEX E: Suggested Workplan

ANNEX F: Matrix of the relationship between the proposed activities, provision in the Cartagena Protocol and provision in the national biosafety framework

ANNEX A

INCREMENTAL COST MATRIX

Project Components	Baseline	Alternative	Increment
Component 1: A legal and regulatory framework that permits the effective evaluation, management and monitoring of GMOs	MoSTE officers will also continue to participate in international meetings on biosafety and biotechnology. Work will continue to go on the biosafety bill. Cost = US$ 478,023	MoSTE will send relevant personnel from GMAC to study tours overseas. Cross project learning with other GEF capacity building projects. Strengthening of regulations. Training on legal aspects of biosafety Cost: US$ 772,625	The biosafety legal and regulatory framework will be strengthened and harmonized with other existing sectoral frameworks according to international best practices. Cost: US$ 204,227 (GOM) US$ 89,375 (GEF) Total: US$ 294,602
Component 2: Enhanced scientific, socio-economic and institutional capacities for risk assessment	In order to fulfil the country's obligations under the Cartagena Protocol, the GMO lab under the Chemistry department of MoSTE will be established. In the baseline situation, MoSTE would have continued to rely on voluntary services by researchers in universities and GMAC. Cost = US$ 1,400,000	GMAC members to be remunerated and costs of additional local meetings borne by MoSTE Staff will be trained in courses on risk assessment. MoSTE's capacity to carry out field releases enhanced through training. Cost: US$ 1,529,411	Risk assessment capacities developed. US$ 23,906 (GOM) US$ 105,505 (GEF) Total: US$ 129,411

Component 3: Increased capacity for developing and implementing a risk management programme	NBB to be established. GMAC members would be volunteering their time and expertise. Local GMAC meetings to continue. Cost = US$ 1,013,650	Training courses for trainers to be carried out. Partnerships built with private sector. Cost: US$ 1,296,150	Risk management resources and capacities to be developed. US$ 74,000 (GOM) US$ 208,500 (GEF) Total: US$ 282,500
Component 4: Developed capacity for long-term regime building maintenance	MoSTE will recruit personnel within the NBB as monitoring staff. Cost = US$ 160,000	Training will be carried out and monitoring equipment purchased. The effectiveness of RA and RM regime will be reviewed and recommendations made to further improve on them in the future. Cost: US$ 333,700	LT regime building maintenance strengthened and monitoring skills developed. US$ 8,000 (GOM) US$ 165,700 (GEF) Total: US$ 173,700
Component 5: Better institutional coordination and sharing of information	Recruitment of NBB staff for website development and data management Cost = US$ 68,000	The exemption list will aid institutional information sharing. Workshops to be held to learn best practices across different enforcement agencies Database to be developed by NBB staff. Cost: US$ 127,600	Improved institutional coordination on biosafety issues. US$ 4,000 (GOM) US$ 55,600 (GEF) Total: US$ 59,600
Component 6: Public awareness relative to the transboundary movement of LMOs and	Federal grants to be provided to states for public awareness activities	Public awareness on biosafety to be increased through website and other awareness activities.	Biosafety mainstreamed in state government awareness programmes.

participation of stakeholders	Cost = US$ 840,729	Cost: US$ 906,429	US$6,000 (GOM) US$ 59,700 (GEF) Total: US$ 65,700
Project management		Cost: US$ 229,000	US$ 22,000 (GOM) US$ 207,000(GEF) Total: US$ 229,000

ANNEX B

LOGFRAME MATRIX

Project Components	Activities	Success indicators	Means of verification
Strengthening the legal and regulatory framework	A. Increasing exposure to international best practices 1. Travel to meetings and technical tours 2. Travel to UNDP/UNEP capacity building projects	25 Government officials gained exposure and knowledge of best practices through technical tours.	Mission reports
	3. Training course on legal aspects of biosafety	2 legal experts to be trained on harmonisation of biosafety legislation with existing legislation	Course participation certificates
	B. Strengthening regulations 1. Finalising of regulations 2. Holding expert group meeting on standards and regulations	Draft regulations available and finalised during expert group meeting. Regulations approved by year 1	Regulations approved and signed by the Minister
		Expert group meeting on regulations and related operational issues to take place every year	Wide representation of experts from different sectors (at the very minimum experts should represent members of the project steering committee) Minutes of meetings

Building capacity in risk assessment	A. Hiring of GMO lab scientific officers 1. Hiring of GMO lab scientific officers 2. Hiring of GMO lab assistant scientific officers B. Development of GMO lab	2 Officers hired by the middle of Year 1 3 assistants hired by the middle of Year 1 GMO lab equipped by the middle of Year 1	Performance reviews by Chemistry Department officials
	C. Training for GMO lab scientists Training - GMO analysis Training - Modern molecular genetics Training - Quality assurance in GMO analysis Training - Detection of GMO in foods Attendance of seminar and workshop on food safety risk assessment	Scientific officer and assistant scientific officer trained by the end of year 1	Course participation certificates
	D. Enhancing expertise in field releases Training on the preparation of field releases Site testing	Site releases to be carried out in Years 1, 2 and 3	Testing reports from scientists
	E. Increasing capacity for impact-monitoring Training on potential impacts of gene flow Training on potential risks on human health	Two courses to be held annually	Course participation certificates.

Building capacity in risk management	A. NBB secretariat in operation Local meetings of GMAC members and NBB staff Operations and maintenance of NBB secretariat	Meetings held on a regular basis, at least one meeting per quarter	Minutes of meetings Regular activity reports from NBB
	B. Training 1. Training of trainers at federal level AIA procedures Detection of LMOs	30 government officials trained at federal level	Reports on courses. Feedback from participants gathered through evaluation forms.
	Identification of LMOs at entry points Reporting on non-compliance Handling & transportation of LMOs Procedures for disposal of LMOs Other specialised courses to be determined In-house training for enforcement agencies	Government officials trained within their respective agencies as part of the in-house training (number to be determined at Steering Committee meeting and submitted to the Project Coordination Unit)	Reports on courses. Feedback from participants gathered through evaluation forms.
	C. Partnerships with the private sector Manual for industry developed Workshop held with private sector	Production of manual in first year, updated in second year	Number of manuals made available to private sector.

Building capacity for LT regime maintenance	A. Staffing Recruitment of monitoring staff in NBB B. Development of scientific capacity Purchase of monitoring equipment Training courses on LT monitoring of environment impacts of LMOs C. Development managerial capacity 1. Strengthening of reporting systems Evaluation of current reporting system Training on reporting system D. Review of the effectiveness of RA and RM	7 monitoring officers hired by the middle of Year 1 Equipment in operation by end of Year 1 Progress reports	Number of officers recruited GMO lab equipped with monitoring equipment Progress reports received
Improving institutional coordination and information sharing	A. Development of the exemption list B. Strengthened institutional coordination 1. Workshops held Awareness workshop Best practices workshop C. Development of the database Training on setting up the database Purchase of equipment Data mgt training	Exemption list drawn up and published on website as well as in other public awareness material Equipment purchased IT expert of NBB trained IT officers of the 5 enforcement agencies trained	List available for public. Consultant report Workshop reports (on annual basis) Course participation certificates

Increasing stakeholder awareness and participation	A. Increased public awareness on biosafety 1. Development of awareness materials Preparation of education kits Production of flyers and posters B. Website 1. Development of site Training	Public awareness material prepared and regularly updated. Website for public developed.	Number of kits produced and distributed. Number of flyers and posters produced and distributed Consultant's report Number of visitors on website

ANNEX C

STAP ROSTER TECHNICAL REVIEW

PROJECT NAME	**Capacity Building for Implementation of Malaysia's National Biosafety Framework**
REQUESTING COUNTRY	Malaysia
REVIEWER	A. H. Zakri
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KEY ISSUES

PREAMBLE

Biotechnology can be defined as the application of our knowledge and understanding of biology to meet practical needs. It is as old as the growing of crops and the making of soy sauce, tempe, cheeses and wines. What is new in modern biotechnology, largely identified with applications in medicine and agriculture, is its dependence on our understanding of the genetic code. Various terms have been used to describe this form of biotechnology including genetic engineering, genetic transformation, transgenic technology, recombinant DNA technology, and genetic modification technology.

One of the most prominent developments, apart from the medical applications, has been the production of novel transgenic crop plant varieties. Millions of hectares of transgenic soybean, cotton, tobacco, potato and corn have been grown annually mainly in the USA and Canada, but significantly in developing countries like China and Argentina. It has been suggested that in the current 21st century, with the impending threat of overpopulation and shrinking land area for cultivation, biotechnology is seen as an emerging technology that has the potential to alleviate world hunger. However, despite its potential benefits, the technology has its perceived risks to the environment, in particular to biodiversity, and also to human health.

Against such a backdrop, and as a follow-up to Article 19(3) of the Convention on Biological Diversity which calls for the Parties to the Convention 'to consider the need for and modalities of a Protocol setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any LMOs resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity', the Cartagena Protocol on Biosafety was adopted on 29 January 2000 in Montreal. Currently, the Protocol has 103 signatories with 7 States having ratified it.

The Cartagena Protocol on Biosafety addresses the safe transfer, handling and use of LMOs that may have an adverse effect on biodiversity, taking into account human health, with a specific focus on transboundary movements. The Protocol establishes an advanced informed agreement (AIA) procedure for imports of LMOs for international introduction into the

environment. It also incorporates the precautionary principle and mechanisms for risk assessment and risk management. The protocol further establishes a Biosafety Clearinghouse (BCH) to facilitate information exchange, and contains provision on capacity building and financial resources with special attention to developing countries and those without domestic regulatory systems.

The task for Parties to the CBD and signatories to the CPB, in particular those with little experience and expertise in biotechnology – mainly those in developing countries, is very onerous indeed. In the case of Malaysia which is somewhere in between in terms of its capacity in biotechnology, some external assistance would provide a big boost to its effort in strengthening its national biosafety capabilities. The ability to implement the CPB depends on no small measure on the preparedness of each country at the systemic/national, institutional and individual levels to handle the biosafety issue. In that respect, GEF intervention in the form of the above project is both timely, relevant and constructive.

2.SCIENTIFIC AND TECHNICAL SOUNDNESS OF THE PROJECT

The background and project context is comprehensively written, taking into account the niche where biotechnology is placed in terms of the National Development Strategy.These include its role in the Third National Agricultural Policy (1998 – 2010), the Third Outline Perspective Plan (2001 – 2010) and the 8th Malaysia Plan (2001 – 2006). An up-to-date description of the national biosafety initiatives is also provided. However under 7.2, in particular 7.2.2 (Institutional context), it is felt that there should be a wider elaboration of the role of research institutions like MARDI, PORIM or FRIM in using genetic modification technology to improve food crops, oil palm or forest species respectively. A reference should also be made to research in molecular biology taken, or the lack of it, by major plantation groups in Malaysia such as Guthrie, Golden Hope or FELDA.

One gap that needs filling up is the role of the universities in Malaysia in carrying out R & D in molecular biology and genetic engineering .If there is one active and fairly well-informed group about the scientific and technical aspects of biotechnology and biosafety in the country it has to be the academics in UKM, UM, UPM, USM or UNIMAS. In fact the high level of awareness and activities on this new technology is still mainly confined to this group of stakeholders. This also explains the leadership and make-up of GMAC, Malaysia which at present is academically-based.

Since one of the thrust areas of the Cartagena Protocol on Biosafety is on the safe transfer and transboundary movements of LMOs, there should also be a reference to the activities and/or interest of multinational companies like Monsanto, Cargill etc in Malaysia or in the region. A case in point is the application of Monsanto to the Malaysian government/ GMAC to introduce transgenic herbicide-resistance soybean several years ago.

Under 7.2.4 line 2, there may be a typo by including a citation to one of the statements, in this case a reference to the country's forest cover. If it is done here, it should be done in other parts of the report too.

The second paragraph in Enforcement (7.3.1) which refers to the socio-economic impacts of biotechnology should not belong under ENFORCEMENT but should be more appropriately placed under RESEARCH in the subsequent paragraph. Indeed an argument should be made

why research on socio-economic impacts of biotechnology is important for a country like Malaysia e.g. the displacement of cocoa or palm oil which has the potential to be replaced by similar products produced through genetic engineering in laboratories/fields in advanced and highly-industrialized countries.

In discussing 7.4 (Barriers to fully implement the Cartagena Protocol), preferably the concept of capacity-building (In current GEF- UNDP parlance, it is better known as CAPACITY DEVELOPMENT) should be stratified into three levels, namely SYSTEMIC (refers to legal or policy framework at the national level); INSTITUTIONAL (refers to the institutional capacity e.g. laboratory or research capabilities) and INDIVIDUAL (refers to human expertise e.g. scientific, technical or legal).

Both the development and immediate objectives spelt out in 8.1 are reasonable and achievable within the timeframe. The six Components enumerated and described are pragmatic enough and if judiciously implemented over the course of the project would provide added-value to the efforts of the Malaysian authorities in implementing its national biosafety framework.

3.IDENTIFICATION OF THE GLOBAL ENVIRONMENTAL BENEFITS AND /OR DRAWBACKS OF THE PROJECT

One of the biggest constraints in the governance of biosafety today is the lack of capacity, in particular in developing countries. As rightly pointed out in this proposal, capacity-building involves policy-planning, drafting of legislations, enforcement of laws, ability to carry out risk assessment and risk management on the best available scientific basis. All these elements are almost in place in Malaysia. What is lacking is the refinement of all these processes e.g. learning from the best practices of other countries; updating on the latest techniques and methodologies; sharing and dissemination of information. Therefore, among the benefits of the proposed project are filling up these gaps. One could envisage that without GEF funding, efforts to build up the country's capabilities in biosafety would continue. However this project would accelerate the commitment and interest of the government and the other stakeholders on utilizing the potentials of biotechnology. Despite the perceived risks of this emerging technology, one needs to acknowledge its enormous potentials, as argued in the 2001 Human Development Report of the UNDP.

The project has been well- conceived. If properly carried out and monitored, there will be minimal drawbacks. However, efforts must be taken to ensure that this project is carried out in the most transparent manner, and where appropriate , to involve the maximum number of stakeholders comprising not only government officials but also academics, the private sector and civil society. Recent experience in the development of biosafety guidelines by GMAC, Malaysia and the drafting of the Biosafety Bill had shown that an open consultative process has been very constructive. In a highly- charged subject like the GMOs, it is very easy to be sidetracked by unwarranted views which could be detrimental in the long-term economic development of a country.

4. HOW THE PROJECT FITS WITHIN THE CONTEXT OF THE GOALS OF GEF, AS WELL AS ITS OPERATIONAL STRATEGIES, PROGRAMME PRIORITIES, GEF COUNCIL GUIDANCE AND THE PROVISIONS OF THE RELEVANT CONVENTIONS

This project fits well with the goals of GEF as the Financial Mechanism of the Convention on Biological Diversity and its Cartagena Protocol on Biosafety. As one of the leading developing countries in the negotiations of these two treaties and eventually in their implementation , GEF support for this project in Malaysia would be favorably received.

5. REGIONAL CONTEXT

The lessons learnt from implementing this project would be very useful, in the first instance to countries in the ASEAN region, in which a lot of similarities exist. On a broader scale, Malaysia also represents one of the megadiversity countries of the world where there is still limited experience in the handling of GMO/LMOs, in particular their impacts on centers of origin/diversity of staple food crops and exotic tropical organisms

6. REPLICABILITY OF THE PROJECT

The comments in (5) above also applies here. However beyond the project on biosafety itself, this endeavour encompasses a multisectoral approach i.e. involving the participation of numerous ministries and government departments, the private sector, academia and civil society. This is the order of things in environmental governance today – the so-called "interlinkages approach."

7. SUSTAINABILITY OF THE PROJECT

Given the strong commitment of the Malaysian government in terms of in-kind support as well as funding in several biotechnology-related projects, and as well as the core expertise available in-country, this project is undoubtedly sustainable.

SECONDARY ISSUES

LINKAGES TO OTHER FOCAL AREAS

This project is one of several GEF-supported programmes in the Asia- Pacific region and in line with the UNDP- Country Cooperation Framework in Malaysia

DEGREE OF INVOLVEMENT OF STAKEHOLDERS IN THE PROJECT

It appears that the full-spectrum of stakeholders that need to be brought in in Malaysia are included. One word of caution – among the NGOs, even though the Third World Network is one of the premier activists in biosafety issues in the developing countries, others in Malaysia should also be consulted e.g. WWF Malaysia, The Malaysian Nature Society, FOMCA etc

CAPACITY-BUILDING ASPECTS

There is tremendous scope for capacity-building at various levels i.e. ranging from policy-makers, administrators, scientists, media specialists and NGOs.

CONCLUDING REMARKS

I fully endorse this proposal which is well-conceived and very timely in light of recent developments in biosafety.

ANNEX C1

RESPONSE TO STAP TECHNICAL REVIEW

Issue	Response
There should be a wider elaboration of the role of research institutions like MARDI, PORIM or FRIM in using genetic modification technology.	Paragraph 11 on "research institutions" has been added to the brief under Section 1.2.2 on the Institutional Context, elaborating on the activities of PORIM (now known as the Malaysian Palm Oil Board)
A reference should also be made to research in molecular biology taken, or the lack of it, by major plantation groups in Malaysia such as Guthrie, Golden Hope or FELDA.	Paragraphs 13 and 14 on "Private corporations" have been added to the brief. Paragraph 14 in particular refers to the lack of research activities on genetic engineering of plantation companies.
One gap that needs filling up is the role of the universities in Malaysia in carrying out R & D in molecular biology and genetic engineering.	Paragraphs 12 on "universities" has been added to the brief.
There should also be a reference to the activities and/or interest of multinational companies like Monsanto, Cargill etc in Malaysia	Paragraph 13 has been added. It makes a reference to the application of Monsanto for the import of transgenic Roundup Ready soybeans into Malaysia. This was the first application received by GMAC Malaysia but due to lack of capacity, the risk assessment was mainly based on the scientific evidence provided by Monsanto.
Under 7.2.4 line 2, there may be a typo by including a citation to one of the statements, in this case a reference to the country's forest cover. If it is done here, it should be done in other parts of the report too.	Selected references have been added at the end of the brief, on page 21.
The second paragraph in Enforcement (7.3.1) which refers to the socio-economic impacts of biotechnology should not belong under ENFORCEMENT but should be more appropriately placed under RESEARCH in the subsequent paragraph	The said paragraph (under Section 1.3.1 with the new numbering) has been placed as per the reviewer's suggestion.
An argument should be made why research on socio-economic impacts of biotechnology is important for a country like Malaysia	Research on the socio-economic aspects of biotechnology and biosafety is essential as the Malaysian economy is heavily reliant on the export of commodity crops and of their products.

	During the financial and economic crisis of 1998 , exports of commodities were the main source of foreign exchange. In addition, the plantations sector is labour intensive, therefore changes in the production system or in the plantations base itself would also have serious social implications.
In discussing 7.4 (Barriers to fully implement the Cartagena Protocol), preferably the concept of capacity-building should be stratified into three levels, namely SYSTEMIC, INSTITUTIONAL and INDIVIDUAL	In Section 1.4 (7.4 under previous numbering) the barriers to fully implement the Cartagena Protocol have since been classified and presented on the three levels as suggested by the reviewer.
Efforts must be taken to ensure that this project is carried out in the most transparent manner.	As the reviewer also points out, the development of the biosafety framework in Malaysia has already greatly benefited from an open consultative process. Wide stakeholder participation and activities to increase public awareness (funded by GoM grants to States) will ensure transparency. The Project Steering Committee (Section 4.2.2) will include members of the different Government agencies at federal and state level as well as representatives of UNDP.
Other NGOs in Malaysia besides TWN should also be consulted	Several NGOs in Malaysia besides the TWN, such as the consumers' associations and the Malaysian Nature Society are already part of the consultation process. NGOs are also represented on GMAC. Paragraph 88 of Section 4.1 on Stakeholder Participation has been added to clarify that other NGOs will also be involved in consultations as they are key stakeholders.

ANNEX D

LETTER OF ENDORSEMENT AND CO-FINANCING CONFIRMATION FROM THE OPERATIONAL FOCAL POINT

MINISTRY OF SCIENCE, TECHNOLOGY
AND THE ENVIRONMENT, MALAYSIA,
14TH FLOOR, WISMA SIME DARBY,
JALAN RAJA LAUT,
50662 KUALA LUMPUR,
MALAYSIA

Telefon: 2938955
Telex: MOSTEC MA 28154
Telefax: 603-2936006

Our Ref: KSTAS 140.020
Your Ref: P001/004( ).
Date: 2 January 2002

Ms. Maxine Olson,
Resident Representative,
United Nations Development Programme Malaysia,
P.O.Box 12544,
50728 Kuala Lumpur.

Via Fax No: 03-2552870

Dear Ms. Olson,

Project Name: Capacity Building For Implementation of Malaysia's National Biosafety Framework

We would like to refer to the project proposal on the "Capacity Building for Implementation of Malaysia's National Biosafety Framework", which will be submitted for the consideration of the Global Environment Facility (GEF) Council through UNDP. We are pleased to inform that the Ministry of Science, Technology, and the Environment, as the GEF Operational Focal Point, hereby endorses the said project for GEF support and wishes to work with UNDP on the above.

2. The proposed project will be an important contribution to the Government of Malaysia's on-going and future efforts on biosafety. In year 2002, an allocation of RM 2,000,000 (US$ 530,500) has been budgeted for the development of a National GMO Laboratory under the Ministry of Science, Technology, and the Environment, specifically for the analysis of genetic modified organisms and their potential impact on the environment and human health. Over and above that, we were also allocated an amount of US$ 100,000 for activities related to biosafety. This would be used partly for an unscheduled workshop in late February for risk assessment, drawing experts from abroad as trainers. In addition, federal grants will also be channeled to state governments for activities aimed at raising public awareness and encouraging state-level participation on biosafety issues.

ANNEX E

SUGGESTED WORKPLAN

Component	Year 1				Year 2				Year 3			
	I	II	III	IV	I	II	III	IV	I	II	III	IV
Strengthening the legal and regulatory framework												
A. Increasing exposure to international best practices												
1. Travelling to meetings and technical tours												
2. Travelling to UNDP/UNEP capacity building projects												
3. Training on legal aspects of biosafety												
B. Strengthening regulations												
1. Finalising regulations												
2. Holding expert group meeting on standards and regulations												
Building capacity in risk assessment												
A. Hiring of GMO lab scientific officers												
1. Hiring of GMO lab scientific officers												
2. Hiring of GMO lab assistant scientific officers												
B. Equipping the GMO lab												
1. Equipping the GMO lab - development costs												

2. Equipping the GMO lab - consumables	
C. Training for GMO lab scientists	
Training - GMO analysis	
Training - Modern molecular genetics	
Training - Quality assurance in GMO analysis	
Training - Detection of GMO in foods	
Attending seminar and workshop on food safety risk assessment	
D. Enhancing expertise in field releases	
Training on the preparation of field releases	
Site testing	
E. Increasing capacity for impact-monitoring	
Training on potential impacts of gene flow	
Training on potential risks on human health	
Building capacity in risk management	
A. Operating costs of NBB	
1. Staffing of NBB	
Recruitment and staffing	
Local meetings of GMAC members and NBB staff	
Operations and maintenance of NBB secretariat	
Allowance of GMAC members	

B. Training												
1. Training of trainers at federal level												
AIA procedures												
Detection of LMOs												
Identification of LMOs at entry points												
Reporting on non-compliance												
Handling & transportation of LMOs												
Procedures for disposal of LMOs												
Other specialised courses to be determined												
2. In-house training for enforcement agencies												
C. Building partnerships with the private sector												
Developing a manual for industry												
Holding a workshop with private sector												
Building capacity for LT regime maintenance												
A. Staffing												
Recruitment of monitoring staff in NBB												
B. Building scientific capacity												
Purchase of monitoring equipment												
Training courses on LT monitoring of environment impacts of LMOs												
C. Building managerial capacity												

1. Reporting systems												
Evaluation of current reporting system				■								
Training on reporting system				■				■				■
D. Reviewing effectiveness of RA and RM												
Intl expert											■	
National experts							■				■	
Improving institutional coordination and information sharing												
A. Developing the exemption list												
1. Drawing up the initial exemption list	■				■				■			
2. Workshop	■				■				■			
B. Promoting institutional coordination												
1. Holding workshops												
Awareness workshop	■				■				■			
Best practices workshop		■		■		■		■		■		■
C. Developing the database												
Training on setting up the database	■											
Purchase of equipment	■											
Data mgt training			■				■				■	

Increasing stakeholder awareness and participation												
A. Increasing public awareness on biosafety												
1. State grants												
Direct grants												
Grants channelled through NGO												
2. Developing awareness materials												
Preparing education kits												
Preparing flyers and posters												
B. Website												
1. Development of site												
Expert - consultancy												
Training												
Project management												
Setting up the office												
Project Coordinator												
Project Administrative assistant												
Monitoring and evaluation												

ANNEX F

MATRIX OF THE RELATIONSHIP BETWEEN THE PROPOSED ACTIVITIES,
PROVISION IN THE CARTAGENA PROTOCOL AND PROVISION IN THE NATIONAL BIOSAFETY FRAMEWORK

Project activities	National Biosafety Bill	Cartagena Protocol	
		Article	Description
Strengthening the legal and regulatory framework A. Increasing exposure to international best practices 1. Travelling to meetings and technical tours 2. Travelling to UNDP/UNEP capacity building projects 3. Training on legal aspects of biosafety B. Strengthening regulations 1. Finalising regulations 2. Holding expert group meeting on standards and regulations	Activities to implement legal obligations under the Cartagena Protocol The Minister of Environment, Science and Technology, in consultation with NBB to make regulations.	2(1) 2(2) 2(4)	Take the necessary and appropriate legal, administrative and other measures to implement obligations under the Protocol
Building capacity in risk assessment A. Hiring of GMO lab scientific officers 1. Hiring of GMO lab scientific officers 2. Hiring of GMO lab assistant scientific officers B. Equipping the GMO lab 1. Equipping the GMO lab - development costs 2. Equipping the GMO lab - consumables C. Training for GMO lab scientists Training - GMO analysis Training - Modern molecular genetics Training - Quality assurance in GMO analysis Training - Detection of GMO in foods Attending seminar and workshop on food safety risk	Manner and details of the application for approval or notification Export of GMOs or product thereof	2 Annex III	Undertake risk assessments in a scientifically sound manner

assessment D. Enhancing expertise in field releases Training on the preparation of field releases Site testing E. Increasing capacity for impact-monitoring Training on potential impacts of gene flow Training on potential risks on human health			
Building capacity in risk management A. Operations of NBB Local meetings of GMAC members and NBB staff Allowance of GMAC members B. Training 1. Training of trainers at federal level AIA procedures Detection of LMOs Identification of LMOs at entry points Reporting on non-compliance Handling & transportation of LMOs Procedures for disposal of LMOs Other specialised courses to be determined 2. In-house training for enforcement agencies C. Building partnerships with the private sector Developing a manual for industry Holding a workshop with private sector	Establishment of National Biosafety Board. Establishment of GMAC Manner and details of the application for approval and for notification Accidental release Review and revocation of approval or review of notifications	7 8 12 16 17 18	AIA Notification Review of decisions Risk management, (establishment and maintenance of appropriate mechanisms, measures and strategies to regulate, manage and control risks) Unintentional transboundary movement Handling, transport, packaging and identification
Building capacity for LT regime maintenance A. Staffing	Establishment of NBB	33	Monitoring and reporting

Recruitment of monitoring staff in NBB B. Building scientific capacity Purchase of monitoring equipment Training courses on LT monitoring of environment impacts of LMOs C. Building managerial capacity 1. Reporting systems Evaluation of current reporting system Training on reporting system D. Reviewing effectiveness of RA and RM Intl expert National experts			
Improving institutional coordination and information sharing A. Developing the exemption list 1. Drawing up the initial exemption list 2. Workshop B. Promoting institutional coordination 1. Holding workshops Awareness workshop Best practices workshop C. Developing the database Training on setting up the database Purchase of equipment Data mgt training	The Biosafety Act will apply to all GMOs and product thereof with some exemptions.	11 20	Procedure for LMOs intended for direct use as food or feed, or for processing Information sharing and the Biosafety Clearing House
Increasing stakeholder awareness and participation A. Increasing public awareness on biosafety 1. State grants Direct grants /a Grants channelled through NGO /b	Public participation and public access to information relating to applications	23	Public awareness and participation

2. Developing awareness materials Preparing education kits Preparing flyers and posters B. Website 1. Development of site Expert - consultancy Training			