GEF

Global Environment Facility

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December 27, 2005

Dear Council Member:

I am writing to notify you that we have today posted on the GEF's website at www.theGEF.org, a medium-sized project proposal from UNEP entitled ***Egypt: Support the Implementation of the National Biosafety Framework***. The GEF will contribute $908,100 towards a total cost of $2,297,100.

The overall goal of the project is that by 2009 Egypt will have a workable and transparent national biosafety framework, in line with its national development priorities and international obligations.

The project proposal is being posted for your review. We would welcome any comments you may wish to provide by January 17, 2006, in accordance with the procedures approved by the Council. You may send your comments to gcoordination@theGEF.org.

If you do not have access to the Web, you may request the local field office of the World Bank or UNDP to download the document for you. Alternatively, you may request a copy of the document from the Secretariat. If you make such a request, please confirm for us your current mailing address.

Sincerely,

Junke Oyewole

Leonard Good
Chief Executive Officer and Chairman

cc: Alternates, Implementing Agencies, STAP

United Nations Environment Programme
برنامج الأمم المتحدة للبيئة • 联合国环境规划署
PROGRAMME DES NATIONS UNIES POUR L'ENVIRONNEMENT • PROGRAMA DE LAS NACIONES UNIDAS PARA EL MEDIO AMBIENTE
ПРОГРАММА ОРГАНИЗАЦИИ ОБЪЕДИНЕННЫХ НАЦИЙ ПО ОКРУЖАЮЩЕЙ СРЕДЕ
UNEP

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TELEFAX TRANSMISSION

To: **Ms. Patricia Bliss-Guest** **Date:** **23 May 2005**
Deputy CEO,
GEF Secretariat

GEF Coordination

Mr. Steve Gorman
Executive Coordinator, World Bank/GEF

Mr. Frank Pinto
Executive Coordinator, UNDP/GEF

Ms. Yolanda Kalabadse
Chairperson, STAP Secretariat

Mr. Hamdallah Zedan
Executive Secretary, CBD Secretariat

From: **Ahmed Djoghlaf**
Director
UNEP Division of GEF Coordination

Subject: **BD:EA: MSP: Capacity Building for the Implementation of the National Biosafety Framework of Egypt**

Please find attached the medium-sized project entitled 'Capacity Building for the Implementation of the National Biosafety Framework of Egypt' for your review and comment.

We would appreciate receiving your comments by 13 June 2005.

Regards.

MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEFSEC PROJECT ID:
COUNTRY: Egypt
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of Egypt
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES): Egyptian Environmental Affairs Agency
DURATION: 48 months
GEF FOCAL AREA: BD
OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: September 2005
IMPLEMENTING AGENCY FEE: US $ 146,000

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	908,100
PDF A*	
Sub-Total GEF	
GEF Agency	
Government	1,389,000
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	1,389,000
Total Project Financing:	2,297,100
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

The project was endorsed on the 9th June 2004 , with a letter signed by the Operational Focal Point of Egypt, Dr. Mohammad Said Khalil, Chief Executive Officer, Egyptian Environmental Affairs Agency, 30 Misr Helwan El-Zerae Road, Maadi, Egypt, P.O. Box 11728. Tele: (202) 525-6452. FAX: (202) 525-6490

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

IA/ExA Coordinator

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Date: December 20, 2005

LIST OF ACRONYMS

ABSP	Agricultural Biotechnology Support Project (MSU)
AIA	Advance Informed Agreement
AGERI	Agricultural Genetic Engineering Research Institute
ARE	Arab Republic of Egypt
BCH	Biosafety Clearing House
CASC	Central Administration for Seed Testing and Certification
CBD	Convention on Biological Diversity
CC	Consultative Council
CCDBL	Coordinating Committee for Drafting the Biosafety Legislation
CB	Cartagena Protocol on Biosafety
COP	Conference of the Parties
EDR	Executive Directive Regulations
EEAA	Egyptian Environmental Affairs Agency
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
LMO	Living Modified Organism
MARL	Ministry of Agriculture and Land Reclamation
MOP	Meeting of the Parties to the Protocol
MOSE	Ministry of State for Environmental Affairs
NBF	National Biosafety Framework
NCA	National Competent Authority
NCB	National Committee for Biosafety
NCC	National Coordinating Committee
NEA	National Executing Agency
NPC	National Project Coordinator
PA	People's Assembly
SCIRGEPE	Supreme Committee on Intentional Release of Genetically Engineered products into the Environment
UNDP	United Nations Development Programme
WB	World Bank

A. PROJECT SUMMARY

1. Egypt hosts one of the oldest agricultural communities in the world and is **among the centres of origin/diversity for important crop plants.** Egypt has a total land area of one million km^2 with a limited area of irrigated farmland (3% of the total area of Egypt) and a total population of about 70 million with an annual increase of 2.2%. In recent years, only 15% of agricultural commodity products have been exported as consequence of an increased domestic demand.
2. In its quest for increasing food production, overcoming significant constrains of agricultural productivity and releasing pressure on natural ecosystems, the country embarked on the development and application of relevant biotechnologies as well as acquisition of biotechnologies and biotechnology products developed elsewhere. This induced the Ministry of Agriculture and Land Reclamation (MARL) to issue two Ministerial Decrees, namely
   - the Ministerial Decree No. 85 (January 25, 1995) establishing a Biosafety Committee (BC) to regulate the research and contained field testing, introduction, and release of crop plants developed through modern biotechnology and
   - Ministerial Decree No. 136 (February 7, 1995) which adopted the guidelines on the structure, composition, roles, and responsibilities of the NBC and the establishment of Institutional Biosafety Committees (IBC).

   Because of wide implications, the BC was re-designated in 1997 as the National Biosafety Committee (NBC) and its membership expanded to include representatives from a variety of institutions as specified in section C2.B1. In 1996, the Ministry of Scientific Research and Technology approved and supported financially a **National Strategy for Biotechnology and Genetic Engineering**, with the explicit purpose of encouraging research leading to exploiting modern biotechnology commercially in 4 areas of application: health care, agriculture, industry and environment. The strategy addresses biosafety and the main actions to be taken in order to set up a biosafety framework. Research activities relating to LMOs release, use, and commercialisation will be extremely important and Egypt is providing significant support in this respect. To date the National Strategy for Biotechnology Development in Egypt alone disburses 54 Million Egyptian Pounds for research activities, but while little has been specifically earmarked for biosafety research, each project sponsored under it includes a clearly stated biosafety component.
3. However, since the NBC was established by a decree of MARL under the Seed Certification Act and not by a national law, its scope is restricted and does not necessarily apply to the handling of GMOs not intended for seed certification, and even to laboratory research and field testing of seeds if there is no declared intention to apply for seed certification. The decree is also not sufficiently comprehensive with regard to procedures and does not mention penalties for not abiding by the decree. As a result, the vast majority of r-DNA research and testing in Egypt does not report to the NBC and IBCs exist only in some, not even in all, MALR institutions. In addition, in Egypt there is still no law, including Law 4 /1994 on Environment and the law on Intellectual Property Rights of 2002, which contains a legal definition and/or reference to LMOs,.
4. In this context, a major obstacle towards the transfer and application of biotechnology is undoubtedly the lack of a comprehensive regulatory regime, which covers the use, transfer ,release, and commercialization of living modified organisms (LMOs) into the environment. Since Egypt ratified the Cartagena Protocol on Biosafety in December 2003 , it is now attempting and endeavouring to meet requirements/obligations as Party.

   The first step towards a fully operational National Biosafety Framework (NBF) is the finalisation and approval of the Draft Biosafety Law on use, handling, release and placing on the market of all genetically engineered organisms and products into the environment (Annex A), irrespective if they are locally produced or imported. The Law was formulated under the GEF-funded enabling activity "National Biosafety Framework for Egypt", successfully completed in

August 1999. This was adopted as a result of the eleven technical reports prepared during the execution of the activity and of the four workshops carried out . these workshops addressed 1) existing biotechnologies and status of safety in Biotechnology applications including review and assessment of Biosafety 2) existing national, bilateral, and multilateral cooperative programs in R & D and application of biotechnology 3) existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation 4) of the extent and impact of release of LMOs and commercial products.
The Draft Biosafety Law sets out basic rules as well as implementing structures and broad outlines of procedures in relation to LMOs, details of which will be elaborated in Executive Directive Regulations to be decreed by the Prime Minister.

The draft biosafety Law is currently being reviewed by a coordinating committee, constituted in 2003 by the competent authority , namely the Ministry of State for Environmental Affairs (MOSE), which is also in charge of revising the draft law and bring it in conformity with the Protocol in consultation with the relevant stakeholders. The final result of the Committee will be a legislative bill agreed by the different categories of stakeholders in view of presentation to the Prime Minister's Office before submission to the People's Assembly for promulgation.

The Overall Goal of the project is that by 2009 Egypt has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations.

The immediate objectives

A. To assist Egypt to have a fully functional and responsive regulatory regime in line with CP and national needs**.**

B. To assist Egypt to have a functional national system for handling requests, performing risk assessment, decision-making, performing administrative tasks, handling, storing and exchanging information in line with the BCH requirements.

C. To assist Egypt to have a functional national system for "follow-up", namely monitoring of environmental effects and enforcement.

D. To assist Egypt to have a functional national system for public awareness, education, participation and access to information

Project Outcomes

A. Egypt has a fully functional and responsive regulatory regime in line with CP and national needs

- Draft Biosafety Law on use handling release and placing on the market of locally produced or imported genetically engineered organisms and products into the environment adopted and in place; Executive Directive Regulations drafted, finalised, adopted and in place; ministerial decrees related to biosafety revised and reviewed; analysis on how best to regulate the contained use and confined release of genetically modified organisms is carried out and regulations for legal actions described.
- Increased national competence on regulatory issues is available and equipped with tools for related additional capacity building

B. **Egypt has a functional national system for handling request for permits for LMOs**

- Administrative processing, risk assessment and decision-making of LMOs are set and operational
- Increased national competence on handling of request is available and equipped with tools for related additional capacity building

C. Egypt has a functional national system for "follow-up" actions

- Procedures for monitoring of environmental effects and enforcement actions are defined and in place
- Technical means for monitoring and inspections are in place
- Increased national competence on monitoring and inspection is available and equipped with tools for additional capacity building

D. Egypt has a functional national system for public awareness, education, participation, access to information

- Increased public education and participation
- Increased national awareness on public information and participation

Indicators for outcomes: See attached log frame, Annex D

12. Budget (in USD) :

GEF:	US $ 908,100
Co-financing:	US $ 1,389,000 (in-kind by Egypt)
TOT:	US $ 2,297,100

Information on Project proposer:

Department of Nature Protection, Egyptian Environmental Affairs Agency, Cabinet of Ministers.
Contact Person: Dr. Mostafa Fouda, Director
7th Floor, 30 Misr Helwan El-Zerae Road, Maadi, Cairo Egypt
(P.O.Box 11728), Tel. and email (2) 012 228 3890, (202)524 8792, foudamos@link.net

B - COUNTRY OWNERSHIP

B1. Country eligibility

Egypt is a Party to the CBD since 02/06/1994 and ratified the Cartagena Protocol on Biosafety on 23 December 2003.

B2. Country Drivenness

Egypt prepared the first draft of its **National Environmental Action Plan for 2002 – 2017** placing high priority to biodiversity and biosafety. **Annex B presents** the relevant sections of the National Environmental Action Plan 2002-2017. In particular, section 2 specifies that Egypt has to :

- *conform to obligations under international law and to avoid conflicts with Egypt's trade partners.*
- *protect biological diversity from possible risks due to intentional release of GMOs and their products into the environment, and hence promote the participation of Egypt in safely harvesting the fruits of modern biotechnology.*
- *protect the health of people without unnecessarily hindering the application of modern biotechnology products safely in the environment, and to promote the safe use of modern*

biotechnology in environmental management

The following activities are envisaged to achieve these objectives:

1. Outlining and implementing a series of actions so that Egypt can make use of funding and facilities made available to Members of the Protocol – especially in the areas of capacity building and interaction with the Biosafety Clearing House mechanism.

2. Review and analysis of legislation and regulations on which the intentional environmental release of GMOs would have an impact, and of the report of the EEAA on the Biosafety Framework and the Cartagena Protocol on Biosafety. Identification of elements of the Framework which need to be further polished in light of current state of the art on the subject, the provisions of the Cartagena Protocol on Biosafety, and the OAU suggested legislation.

3. Outlining and implementing a series of actions which would lead to a consensus on the draft national legislation (law, executive directive regulations and related laws, decrees and regulations)currently being formulated by *the EEAA, especially through circulation to stakeholders* for *opinions and views, through involvement of the Media, through public hearings and possibly through specialized workshops.*

4. Establishing the necessary instruments for implementation of the proposed legislation, including training of necessary human resources and provision of reference laboratories capable of backing proper implementation of the legislation.

The output of these activities will be a legislative instrument capable of maintaining biosafety of biotechnology products along with mechanisms for its enforcement. The outcome will be enabling of Egyptian participation in safely harvesting the fruits of biotechnology and be a partner in safe international trade in GMO products without jeopardizing its biodiversity, ecological equilibrium and the health of its people.

In order to meet its obligations as Party to the Protocol, Egypt is finalising its draft Biosafety Law on use handling release and placing on the market of locally produced or imported genetically engineered organisms and products into the environment. Executive Directive Regulations for the implementation of mentioned Law will be drafted under this project.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private sector stakeholders."

It is therefore most relevant to the implementation of GEF Operational Programs 1-4 and 13.

C2. PROJECT DESIGN

C2.A Background and context

1. In 1997, responding to the third Conference of the Parties to the Convention which called for GEF to provide the necessary financial resources to developing countries for **capacity building in Biosafety**, the GEF Council approved a US$ 2.7 million Pilot Biosafety Enabling Activity Project.

   The Pilot Project involved 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, **Egypt**, Hungary, Kenya, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda, Zambia, Malawi) and consisted of the following two components:
   A *National Level Component* aiming at assisting the eighteen countries to prepare National Biosafety Frameworks (US$ 1.9 million), and
   A *Global Level Component* aiming at facilitating the exchange of experience at regional levels through the convening of 2 workshops in each of four regions and involving a very large number of countries (US$ 0.8 million).

   In order to design a **National Biosafety Framework**, each country that participated in the National Level Component was required to:

   - Assess the existing national capacity and roles in environmental release of LMOs and their products;
   - Develop methods, techniques, standards, guidelines, indicators for assessing and monitoring the environmental risks, and control and regulatory measures for those risks likely caused by the transportation, release, commercialisation and application of LMOs;
   - Facilitate the national capacity building for biosafety management and formulate a package of needs;
   - Promote the establishment of institutional arrangements and operational mechanisms for biosafety management;
   - Develop human resources for biosafety management through formulating and implementing a series of training plans to upgrade expertise in this field;
   - Undertake publicity activities at the national and local levels to increase the understanding ofthe public and major decision makers on the potential benefits and risks of biotechnology application;
   - Enhance international co-operation and communication on scientific research, legislation, information exchange and personnel training in the field of biosafety.
   -

A summary of the results of this project in Egypt is reported in Annex A.

2. The Cartagena Protocol on Biosafety was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity in Montreal, Canada, on 29 January 2000. It was opened for signature in Nairobi, on 24 May 2000 and as of June 2004, 100 countries have already ratified or acceded the Protocol. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements of LMOs.

3. In November 2000 the GEF Council approved the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety" (GEF/C.16/4). The main objectives of the strategy are to a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and sub-

regional level, and c) promote collaboration with other organizations to assist capacity-building for the Protocol.

5. In December 2001, the GEF Council approved 12 demonstration projects to support countries in the implementation of their national biosafety frameworks. Two projects (Malaysia and Mexico) are implemented by UNDP, eight projects are being implemented by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and two projects (India and Colombia) are being implemented by the World Bank.

6. The Cartagena Protocol on Biosafety entered into force on September 11, 2003, on the 90th day after the date of deposit of the fiftieth instrument of ratification or accession. As of December 2004, 110 countries, including Egypt , are Parties to the Protocol .

7. The seventh Conference of the Parties to the Convention, serving as the first Meeting of the Parties to the Cartagena Protocol, was held in Kuala Lumpur, Malaysia in February 2004. The Conference focused on setting up an operational framework for the effective implementation of the Protocol and approved Decision VII/20 on Further Guidance to the financial mechanism . The decision invites the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.

   The COP/MOP-1 decision specifically calls upon the GEF to "provide additional support for the development and/or strengthening of existing national and regional centres for training; regulatory institutions; risk assessment and risk management; infrastructure for LMO detection, testing, identification and long-term monitoring; legal advice; decision-making; handling of socio-economic considerations; awareness-raising and technology transfer for biosafety." This project fulfils these criteria.

8. Finally, *Decision on Agenda Item 9,Institutional Relations,* of the Joint Summary of the Chairs of the GEF Council, held 19-21 of May 2004, states in par 27: "*The Council welcomes the guidance of the Conference of the Parties to the CBD inviting the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries*."

C2.B Current situation (in the country with respect to the NBF)

C2.B1 System in place since 1995[1]

Regulatory regime

The current Egyptian system (the National Biosafety Committee system) has a limited scope and legal validity as it applies only to seed certification and was instituted by two ministerial decrees (MALR) in early 1995. A summary of some of the existing Egyptian ministerial decrees impacting on biosafety is presented in Annex C.

The system touches on several ministries, organizations, and/or government agencies involved with the importation, exportation, and local production of natural products. Within the MALR, the CASC- Central Administration for Seed Testing and Certification- controls, tests, and registers new plant varieties. In the Ministry of Health, the Supreme Committee for Food Safety ensures the safety

[1] Part of the information reported in the following section is extracted from the ISNAR COUNTRY REPORT 62, Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt, 2000.

of food production and consumption and permits for controls food imports. The National Organization for Drug Control and Research oversees pharmaceutical quality control. The Ministry of Trade and Supply controls the import and export of products. In the Ministry of Industry, the Egyptian Organization for Standardization and Quality Control sets the standards for all food and industrial products irrespective whether they are imported or locally produced. The Ministry of Environment, through the Egyptian Environmental Affairs Agency (EEAA) ensures implementation of the Environment Protection Law No 4 of 1994 in Egypt.

The MARL published Biosafety regulations and guidelines of the NBC system in draft form in January 1994. Research materials from the ABSP-AGERI collaboration were nearing completion of greenhouse tests, providing impetus to move forward with developing biosafety policy and procedures for conducting GMO field tests. The first guidelines were adopted under the CAS by Ministerial decree No. 136 The guidelines were intended to describe the modalities of testing of GMOs intended for seed certification; they address laboratory practices, greenhouse containment, and small-scale isolated field testing.

The guidelines describe the structure, composition, roles, and responsibilities of the NBC. NBC duties include formulating, implementing and updating biosafety guidelines; conducting risk assessments; issuing permits for conducting research and controlled trials; coordinating with national and international organizations; providing training and technical advice; and, reporting to governmental authorities. Being complementary to the seed certification act, the guidelines do not touch on the commercialization of commodities or any other products of biotechnology.

The guidelines are basically focused on laboratory and isolated field testing of GMOs and thus call for establishment of an Institutional Biosafety Committee (IBC) at all institutions conducting recombinant DNA (r-DNA) research. The IBC is responsible for establishing a facility inspection program; assembling a set of appropriate institutional guidelines that comply with the NBC guidelines; assessing facilities, practices, and procedures; periodically reviewing r-DNA research being conducted in the institute; adopting emergency plans for accidental spills and personnel contamination; periodically reviewing containment measures; overseeing IPR matters as they apply to the institute; and reporting annually to the NBC. Since the NBC was established by MALR decree under the seed certification act (and not by a national legislation), it is not legally binding to the handling of GMOs not intended for seed certification, even with respect to laboratory research and field testing of seeds if there is no announced intention to apply for seed certification. In addition, it is not sufficiently comprehensive with regard to procedures and does not mention penalties for not abiding by the decree. As a result, the vast majority of r-DNA research and testing in Egypt does not report to the NBC and IBCs exist only in some, not even all, MALR institutions. Universities and research institutions are largely unaware of the existence of a NBC.

Egypt's National Biosafety Committee is the official body responsible for ensuring that biotechnology products are used safely in research laboratories and contained trials.. The Chair, the Minister of Agriculture and Land Reclamation , appoints members of the NBC. The initial committee consisted of 10 members; subsequent appointments have expanded it to 30. Current members include: seven representatives, in personal capacity, from the Ministries of Agriculture, Health, Environment, Industry, and Commerce, the Egyptian Academy of Science and Technology; 12 members from academic institutions; an attorney; eight people from government research institutes; and a seeds expert. Based on area of expertise, members are appointed to one of three subcommittees specializing in agriculture (crops), environment (bio-pesticides, bio-fertilizers, agents for bioremediation), and health (pharmaceuticals, human and veterinary vaccines) but these subcommittees hardly hold any activities or meet. The NBC does not meet regularly and on the average meets about once a year

IBCs are to be composed of people with expertise in r-DNA technology, biological safety and physical containment, policies and applicable law, and a biological safety officer (BSO). The BSO reports to the IBC regarding follow-up duties, which include enforcing approved policies and regulations; ensuring that all facility standards are rigorously followed; ensuring safety of all facility work and prevention of the accidental escape of GMOs; maintaining data on all aspects of biosafety related to mandated crops; checking and advising on biosafety issues on a day-to-day basis; and monitoring worldwide biosafety requirements for r-DNA technology. In practice, BSOs rarely communicate with the NBC.

Handling of requests for seed certification under the NBC system

A standardized Permit Application form (see later) is used to request NBC approval of a proposed greenhouse study or field test. Upon submission of the application, all members of the appropriate subcommittee are expected to be given copies and one member is designated the Principal Investigator. The Principal Investigator, who may consult with other subcommittee members, is assigned to thoroughly review the application, visit the field test location, inspect the facilities, and submit a report to the NBC. The proposed release is then discussed at a meeting of the full NBC, where a decision is made to issue or deny the requested permit. Where a Committee member is the applicant or had been involved in the research leading to the GMO to be considered, that member does not vote on the application. The vast majority of applications come from institutions of the MALR or from members of the NBC itself. This picture reflects the need for a more rigorous system which gives confidence to both producers and consumers in the safety of biotechnology products, safeguards the environment, gives greater assurance to trade partners and conforms to obligations under the Cartagena Protocol .

Approval may stipulate certain conditions or practices during field tests that the NBC deems appropriate to the proposed release. For approved tests, the Principal Investigator advises institutional staff regarding standard and specific biosafety practices and techniques. Because of lack of a secretarial arrangement, the applications are in practice submitted directly to the NBC.

For varieties produced within Egypt, the process is as follows:

I. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, and other relevant information. The applicant also provides data from food and feed safety studies and evidence supporting a determination of "low or negligible environmental risk". Where applicable, the applicant provides documents indicating approval of similar GMOs for release in "their country of origin".
2. The application form is submitted to the NBC, which, after examination and approval, forwards it to the Seed Registration Committee (SRC) for their preliminary approval to proceed with standard field trials conducted at several locations. The SRC assigns a team of qualified inspectors drawn from relevant Agricultural Research Center units (even if the applicant is an ARC unit) and/or private certified laboratories (which the decree did not designate yet) to supervise cultivation, ensure adherence to any biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.
3. The NBC has the right to confirm the nature of the genetic modification by taking samples from the field for molecular analysis, but refernece laboratories have not yet been designated.
4. After successful completion of the field trials and submission of a report to the NBC, the NBC authorizes the applicant to submit an application to the Seed Registration Committee for final approval to "commercially release" the new variety presumably for cultivation. Pending this, three years or seasons of agronomic performance trials are conducted under the supervision of the SRC in order to confirm that the new variety is at least 15% agronomically superior to

existing ones (this requirement in fact is applied to all new varieties whether GMO or not). So far no application for a locally produced or an imported LMO has reached this stage and thus the system has not been tested in practice. However, the MALR decided that appropriate labelling must be instituted.

The process for securing "commercial" release approval for crops genetically engineered outside of Egypt has an added step. The applicant must first obtain a permit for importing the initial seed material from the Supreme Committee for Food Safety, Ministry of Health. Their are no set procedures or regulations at that Committee specifically focused on GMOs. The EEAA is not involved in the process. The permit is then presented to the NBC and the Seed Registration Committee, after which the seed is imported into the country. From this point forward, the remaining steps in the approval process are exactly the same as for GMOs developed within Egypt.

Data from local and external field tests, findings reported in the scientific literature, reports from risk assessment studies, and proceedings from conferences and workshops are among the potential sources of feedback to the biosafety system. Currently, acquisition of this information is an individual activity on the part of some applicants and biosafety committee members. Although the NBC could require environmental risk assessment to be conducted and putting environmental risk management plans into force.

Monitoring and inspections under the NBC system

In Egypt, approval by the NBC to conduct a field test does not require the applicant to submit a report at its conclusion. During seed registration trials, an appointed team of inspectors carries out monitoring. As the purpose of the trials is to evaluate variety performance, monitoring is conducted primarily to ensure compliance with biosafety requirements.

Public information and participation under the NBC system

There is no official strategy to inform the public about GMO and biosafety.

However, a new approach has been taken with the new Law , where preparation and formulation have involved all the stakeholders, including civil society. Details on involvement of civil society during the decision-making process are presented in section C5 .

C2.B2 System currently under approval (to be implemented under this project)

**** Please note the distinction between the current institutional structure , the National Biosafety Committee (NBC) , and the new institutional structure proposed in the Law under approval , the Supreme Committee on Intentional Release of Genetically Engineered products into the Environment (SCIRGEPE)***

In November 2003 , the People Assembly approved ratification of the Cartagena protocol and mandated MOSE to review the draft biosafety legislation proposed within the framework elaborated by the Egyptian Environmental Affairs Agency (EEAA) in 1999 with assistance from UNEP/GEF, bringing it up to date and in conformity with the CPB for presentation to the People's Assembly during the same Session (2003/2004).

The MOSE constituted a coordinating committee to revise the draft biosafety legislation in conformity with the Protocol and coordinate broad consultations with the relevant stakeholders. The final result of the Committee is an agreed legislative bill ready for final presentation to the People's Assembly.

The Committee has 13 senior experts, all acting in their personal capacity, in various fields of application of biotechnologies (health, industry, agriculture and environment) including three legal and legislative experts. The Committee held 12 meetings and two consultative workshops during 2004

where the following bodies were invited to consider both the Protocol and the Draft Legislation in view of the implications on their activities, to express their observations in writing and to appoint a liaison officer with authority from the organization to the committee, including possible direct consultations and/or participation in the deliberations of the committee:

1. Ministry of Health and Human Settlements: Supreme Committee of Food Safety, Food Control Administration, Laboratories Department, Central Administration for Preventive Health, National Organization for Drug Control and Research, National Laboratory for Sera, Vaccines and Blood Products,
2. Ministry of Industry: Egyptian Organization for Standardization, Egyptian Codex Alimentaris
   Committee
3. Ministry of Foreign Trade: Export and Import Control Administration, Department of International Trade Agreements
4. Ministry of Foreign Affairs: Department of Research and International Agreements, Department of Environment and Sustainable Development, Department of Economic Relations
5. Ministry of Agriculture and Land Reclamation: Department of Feed, Committee on Registration of Seeds, National Biosafety Committee, Institute of Agricultural Genetic Engineering, National Gene Bank
6. Ministry of Supplies: Commodities Administration
7. Ministry of State for Scientific Research: Academy of Scientific Research and Technology
8. Ministry of Higher Education: Supreme Council for Universities
9. Ministry of Justice: Legislative Sector
10. State Council
11. Ministry of Finance: Customs Department
12. Union of Industries: Chamber of food Industries, Chamber of Drug Industries
13. Egyptian Chamber of Commerce

Through the two consultative workshops, representatives of various NGOs, consumer groups and scientific experts who have aired views on the issues under consideration during the previous year in the media expressed their views on the NBF Draft Legislation. In addition, the Union of Industries and the Egyptian Chamber of Commerce were encouraged to take into consideration the views of the private and public sectors involved in the placing on the market and trading in biotechnology products. The two one day workshops, each lasting for 6 hours, were thus organized for invited participants from a broader spectrum of stack holders for information dissemination and gathering and exchange of views.

The Committee also made an attempt to survey all relevant legislations, which may impact, or being impacted upon by the biosafety legislation.

The Committee reviewed and settled conflicts and contentious issues on the draft legislation by going through each article of the legislation. The basic approach and orientation of the legislation was also agreed upon. This was concluded on 26 June 2004 and it was then decided to form 2 small drafting groups, one for the body of the legislation and one for definitions. Given the complexity of the task, the mandate of the Committee was extended till end of September 2004.

Handling of requests, monitoring and inspections under the Law being approved

Under the new Law, the procedure for handling requests is structured as follows:

- Applicant deposits the application with the Secretariat of the Committee**.** The information to be submitted is specified in the law. Fees to be paid are to be specified in the Regulations. Communications of decisions to applicant are provided within 270 days in one of the following forms:

a- Approval, with specified labelling, packaging, handling, monitoring, and risk management procedures
b- Request for additional information or studies specified in the Regulations, including the need for risk assessment studies and for public hearings. Time of delivery of information and for conducting further RA studies and public hearings are not counted in the 270 days time limit.
c- Rejection of the application with defined reasons.

Applicant could appeal the decision and Secretariat has 90 days to give a final decision, which is subject to judicial procedures at the State Council only.

If RA studies are required, the applicant deposits the cost, to be calculated according to rules specified in the Regulations, with the Secretariat in advance.

Committee examines the dossier of information, including any results or approvals made during the research and contained field trials stage, and decides on:

a- Approval based on information available, applying confirmed scientific facts, the precautionary approach and results of previous studies and in conformity with the provisions of the CPB
b- Refer the dossier of information to the relevant competent authority/authorities for examination and recommendations
c- Request additional information to help make a decision
d- Decides on the need for RA studies, cost the studies and commission it if payable by the applicant
e- Request a special meeting with participation of other bodies not represented in the Committee, including consumer and environmental groups, industry and trade interests in the private and public sectors, and/or specialized experts from the Roster of Consultants.
f- Refer specific material to Reference Laboratories for certification of information.
g- Any mix of b through f in an appropriate sequence.
h- Reject the application giving specified answerable legal reasons for rejection.

Committee publishes resume on applications and progress of proceedings and decisions on its website and encourages public involvement.

Monitoring for environmental effects and inspections

Committee designates the competent authority for monitoring, inspection and enforcement for the product and reporting back to the Secretariat as outlined in the Regulations.

Committee examines reports on monitoring submitted by the applicant and by the relevant competent authority for needs to amend or cancel the permit and procedures pursuant to a possible amendment or cancellation

Committee examines requests for further investigation on the basis of additional information, which requires amendment, or cancellation of permits and informs the applicant and follows the matter with consideration of appeals and/or procedures to follow decision

Committee decides on referring a proposed penalty to the relevant authority for implementation.

Committee publishes a final report on the product after the permit expires.

Public information and participation

The Biosafety Law currently under approval foresees different ways of public information and involvement, namely

- the participation of civil society (including consumer protection representatives) to the biosafety committee on a case by case basis ,
- pro- active behaviour of NGOs that can report on any violation and the
- call for public hearings once the biosafety committee so decides and on specific applications.

Under this project , additional mechanism and tools will be developed and defined under a specific plan for public information and participation .

Structure of the draft law currently being approved

The proposed law comprises four sections:

Objectives and scope (5 articles, covering the handling, use and intentional release of LMOs into the environment including exemptions for products in transit, products for research and contained trials; labelling, post release monitoring; use of unique identifiers; liability and redress; socio-economic and traditional communities considerations; national sovereignty on national resources; compliance with the CPB; equal treatment for similar products regardless of origin)

Permit procedures (10 articles, including information required in the application; the law being a pre-requisite step to application of other laws relating to bio-products; the establishment of an inter-ministerial-cum-experts committee for examination of applications, with a chair , a general secretary and an administrative secretariat; referral to sectoral bodies and taking decisions; an roster of experts for technical support; inviting representatives of other relevant bodies, consumer societies, industries to meetings; decisions on RA studies; decisions on adequacy of information; referral to reference laboratories; decisions on public inquiries; decision on inquiries on religious, ethical and security bodies; monthly meetings as a minimum; decision within 270 days excepting time required for procuring additional information; decision on traceability and labeling requirements and on monitoring procedures and required RM protocols)

Constitution of the Supreme Committee on Intentional Release of Genetically Engineered products into the Environment (SCIRGEPE) , its responsibilities and procedures (9 articles including appointment by the Prime Minister for 3 years; one member will be nominated by each of the relevant Ministries - Environment, Health, Agriculture, High Education, Scientific Research and Technology , Justice, Foreign Affairs , Industry, Foreign Trade, and Consumer Commodities -plus a chair and an executive secretary both nominated by the MOSE plus 8 experts in personal capacity,; the committee could invite representatives of any institution that is not represented in the committee as well as the civil society and consumer groups to specific meetings on a case by case basis with no voting rights, the committee may refer specific applications to members of an open ended roster of consultants for advise and may require a risk assessment study at the expense of the applicant if they feel it necessary , a fee system covers the real costs of permit processing, a public site for the committee on the internet; refusal of applications requires explicit reasons; consideration of unequivocal scientific information and the precautionary approach; amendment or cancellation of a permit based on additional information and its consequences including the right of appeal; procedures for appeal of decisions; treatment of confidential information). The committee is to meet at least monthly. Acknowledgment of application will be decided in the executive regulations; decisions must be issued within 270 days unless additional information becomes necessary. Permit holders as well as the relevant government bodies must monitor the implementation of the substance of the permit. The budget for the Committee will be incorporated within the budget of the EEAA The Executive Directive Regulations will define procedures for referral of applications to relevant government body(s) for examination but permits can only be issued by the Committee and LMO products must be first approved by the Committee before application of other laws or regulations.

Penalties (5 articles including penalties for violation of the law by applicants, non-applicants and government officials; penalties for submission of inaccurate or incomplete information; penalties in case the violation results in loss of human life; authorization of inspectors, the rights to report violations extended to civil society)

C2.B RATIONALE AND OBJECTIVES

It is likely that crops and products imported into Egypt or produced locally may contain some transgenic components, though , as already mentioned , it is difficult to estimate the volume since existing legislation (including the environmental Law 4/1994) does not demand such identification and the system currently in place applies only to seed certification (and only when certification is requested).

The government is well aware of the importance of the adoption of the framework Law, currently in final draft, as a key instrument to enable the country to benefit of the potential of biotechnologies without posing risks to biodiversity, ecosystems and human health. Therefore it has worked hard to bring together the many interests that influence biosafety despite paucity of financial resources.

The purpose of this project is to support Egypt in its current effort to conform as Party to the Cartagena Protocol. This means formalising and implementing the drafted regulatory regime as well addressing the major needs of building capacity on legal, administrative and technical matters. The project builds on the recommendations of the GEF-funded enabling activity completed in August 1999 and complement the BCH project, approved in March 2004, which will be run in parallel.

The MoU of the BCH project for Egypt is currently under negotiation. Under the BCH project, a website will be established to facilitate the rapid exchange of information between stakeholders and to provide regular updates on significant developments in biosafety. The BCH project will also assist the country in:

a. Purchasing and setting up of the equipment required for the national BCH;
b. National-level training workshop(s) on the use, maintenance and access of the national BCH, and fulfilment of national obligations in relation to the Cartagena Protocol on Biosafety;
c. Access to regional advisers to assist in the design and development of the national participation in the BCH. The regional advisers could assist in several ways:
    - Assist in making the country's choice for national participation in the BCH;
    - Conducting training workshop(s) with national counterparts to train up to 20 participants in the use and access of the BCH;
    - Assist in setting-up and making the national BCH components operational

As per country need, the project activities have been grouped in four components , namely *regulatory regime , handling of requests, monitoring and inspections and public information and participation* **.** The activities are described in detail in section C2.F

In the absence of GEF contribution, the baseline scenario is as follows:

a. Implementation of the protocol

The Egyptian government- Party to the Protocol as of March 2004- has devoted special attention to issues of biosafety despite paucity of financial resources

The proposed GEF project has been designed as a key activity in a range of those that are addressing biosafety issues. This intervention and its financial contribution is in fact assuring that the biosafety framework worked out during the Pilot Project phase can quickly become fully operational, playing an important role in launching the biosafety management in Egypt in the Middle East and North Africa.

b. Economic , Environmental and Development Viewpoint

Despite significant increases in per capita agricultural production in Egypt over the last decades, the challenge of producing sufficient food remains daunting given the increasing population growth, reduced availability of water and limits to agricultural land expansion.

In this respect, biotechnology applications, if properly integrated into production systems, offer new opportunities to increase production and productivity and release pressure on natural resources and hence their degradation. The country is in the process of acquiring biotechnologies and biotechnology products and has plans for the release and commercialization of living modified organisms (LMOs) into the environment. Egypt has already established the Agricultural Genetic Engineering Institute (Agricultural Research Centre), the Biotechnology Centre (Cairo University), the Research Institute of Biotechnology and Genetic Engineering (Mubarak City for Scientific Research), over 60 government financed research projects under the National Strategy for Biotechnology and Genetic Engineering and is developing disease resistant and stress tolerant crop varieties, as well as a number of biotechnology-based therapeutic, diagnostic, industrial and environmental products for release and application. It is recognized that some LMOs are now treated internationally as commodities and their transboundary movements into and out of Egypt is inevitable. However, while potential benefits of these developments are well recognized, the relative limited experience with such organisms makes it necessary that they should be developed and applied in a precautionary and judicious manner

However, a comprehensive regulatory regime and the full implementation of the national biosafety framework drafted for addressing questions of potential risk to the environment and human health has been hampered by inadequate financial resources and expertise and by limited regional and international cooperation.

C2.E Expected project outputs

Outcome A **Egypt has a fully functional and responsive regulatory regime in line with CP and national needs**

Outputs *Survey of the current status of relevant existing laws and regulations, research and trials and release of LMOs and products thereof in Egypt carried out; Legal translation of the Biosafety Law into English carried out; One four-day workshop organised for 24 technical, administrative and legal experts to examine the Biosafety Law and provide draft Executive Directive Regulations based on an outline of options; One four-day consultative workshop carried out for 25 government stakeholders (representatives of the nine ministries involved in biosafety, legal experts) to discuss the first draft Executive Directive Regulations of the Biosafety Law and the revision of the existing ministerial decrees; one four day-workshop organised for 25 legal, technical and trade specialists, legislators, managers and administrators to discuss, advise and provide inputs to the second draft Executive Directive Regulations and its administrative structure; Finalisation of the Executive Directive Regulations and its administrative structure and the revision to the existing ministerial decrees relating to biosafety for presentation to Prime Minister for approval; Executive Directive Regulations are translated into English; four day training workshop carried out for 24 legal officers/experts on the application and implementation of the biosafety law and the executive directive regulations; Analysis on the legal steps to be taken to regulate the interaction of the Biosafety Law with the contained use and confined release of potentially hazardous genetically modified related organisms is carried out and steps for legal actions indicated*

Outcome B **Egypt has a functional national system for handling request for permits for LMOs**

Outputs *A five-day technical workshop for 8 specialists carried out to draft and finalise implementation procedures for risk assessment and risk management for LMOS*

organised; technical guidelines on methodologies for RA/RM protocols drafted and published; an internal "Manual on procedures for handling requests of LMOs in Egypt prepared; two five-day training courses organised for 30 participants/course (members of the NBC, Ministries, including representatives of civil society and private sector) on handling requests for permits, including RA/RM; two five-day training courses organised for 30 administrative officers/course from the biosafety office and relevant Ministries, on the administrative processing related to the handling of requests (including administrative aspects related to monitoring and inspections, a training manual is published)

Outcome C **Egypt has a functional national system for "follow-up", namely monitoring of environmental effects and inspections**

Outputs *Manual on procedures/ methodologies for monitoring of environmental effects and inspections prepared finalised and published ; survey of existing facilities at universities and research centres for designation of operational reference laboratories carried out; criteria/procedure for the selection and certification of two reference laboratories established; additional equipment purchased for the laboratories certified for LMOs detection, including post-release monitoring and enforcement, a training guide for LMOs detection in laboratories, including sampling and analysis drafted finalised and published, Two senior scientist trained for 10 days at a well established laboratory in procedures for analysis and detection; two training programs (2 weeks each) for 10 selected staff of the two reference laboratories in LMO detection carried out; a five-day training course organised for 40 custom officials and inspectors on LMOs investigation and inspection techniques; a guide for legal personnel on enforcement, settlement of disputes and handling of court cases is produced; two two- day training workshops for 8 selected judges held*

Outcome D **Egypt has a functional national system for public awareness, education, participation and access to information**

Outputs *Public education and involvement plan prepared and approved; OUTREACH materias on biosafety prepared and disseminated; the biosafety committee web site set up and data entry protocols formulated and operational; two two-day information workshops organised for 40 local administrators on public awareness education and involvement in biosafety; two one-day workshops organised for 35 participants, including parliamentarians, media and NGO representatives on the Legislation and its implementing Directives*

C2.F Activities and Financial inputs needed to enable changes

The estimated additional cost of enabling changes to improve the baseline scenario is :

Component A: Regulatory Regime (TOT: 146,600; GEF: 98,600)

As first step, a large-scale investigation will be initiated to provide basic information on the actual environmental release, commercial release and transboundary movement of LMOs in Egypt. In fact, still to date , information on LMOs and responsibility for protecting biodiversity and ensuring the safe use of biotechnology is spread amongst many Government Departments, research institutions and universities. Many institutions undertaking research and development of biotechnology and/or implementation of regulations belong to different ministries and departments and are governed by different ministerial decrees. The extent of such regulations and their details must be made transparently available to the national project committee at project start .The National Biosafety Committee has been operational in Egypt since 1994 under the Seed Certification Act and has been concerned with biosafety aspects of research and of trials for LMO seeds. It has been receiving applications and issuing permits for such research and trials but has not been involved with commercial releases or with enforcement. It has nevertheless accumulated considerable information and experience, which would be collected and made available to the Project Coordinating Committee PCC. A consultant will be recruited for each of the three surveys to collect data, make personal visits and interviews and will present a final report to the PCC.

Upon approval of the Biosafety Law currently being formulated, it will be translated into English. The first step will be for two consultants to draw an outline of available options for the content of the Executive Directive Regulations (EDR) which best serves the Egyptian Biosafety Law, based on background working papers covering modalities for implementation of well-established biosafety regulatory systems in key developed countries. These will be reviewed by a 4-day workshop of 24 legal and technical experts who would give guidance on formulating a draft structure for the EDR, taking into consideration current practices and regulations in Egypt as well as the requirements of the Egyptian Biosafety Law. The draft will be considered by a 4-day consultative workshop of 25 relevant stakeholders representing potential implementing bodies. Based on the views of the workshop, a second draft of the EDR will be formulated by the PCC with assistance of the two consultants. The views of stakeholders on the second draft will be sought and a second draft will then be presented to a second consultative 4-day workshop of 25 representatives of implementing bodies for review. On the basis of this workshop, the EDR will be finalized and put in legal form for presentation to the Prime Minister's Office for approval, along with any required amendments for other decrees. It will then be translated into English. The Regulations will cover the following:

- Institutional arrangement and mechanism for the implementation of the biosafety framework;
- Responsibilities for implementation
- Guiding requirements for implementation
- Procedures for permits and approvals
- Procedures for amendment of risk assessment and risk management protocols
- Procedures for amendment of definitions of LMOs, scope and coverage
- Methods, procedures and designation of institutions for testing
- Procedures for penalty application, liability and compensation and settlement of disputes
- Procedures for inspection and enforcement
- Specifications for packaging, unique identification and handling
- Management in the import and export of LMOs:
- Packaging and identification of LMOs
- Procedures for Advance Informed Agreement for transboundary movement of LMOs
- Regulations and procedures for environmental monitoring of LMOs

The PCC, with the assistance of two resource persons, will follow up the process of amendments to existing decrees with comments or inputs from different interest groups. In parallel, an analysis of the legal steps to be taken to cover the legal vacuum on the current work of the NBC in the area of research and contained trials of biotechnology products which are not covered by the Biosafety law , will be started. The PCC will finalize the final report and recommend action with the assistance of a consultant

Finally, a four-day training workshop will be held for 24 potential implementing officers on interpretation and application of the Biosafety Law and related Executive Directive Regulations and a training guide serving that purpose will be prepared and published.

Activity A.1 Survey of:

- Relevant existing laws and regulations which need to be adjusted to conform with the currently proposed draft legislation
- Current status of trials and releases of LMO material in closed and open environments in Egypt
- Current practices of the National Biosafety Committee and its impact on biosafety in Egypt

Activity A.2 Legal translation of the Egyptian Biosafety Law into English

Activity A.3 A four day workshop for 24 technical and legal experts on guidance towards the drafting of the Executive Directive Regulations based on an outline of available options for the contents of the EDR (first draft of the EDR as output**)**

Activity A.4 One four-day consultative workshop for 25 government stakeholders (representatives of the nine ministries involved in biosafety, legal experts) to discuss the first draft of the Executive Directive Regulations of the Biosafety Law and revision of the existing ministerial decrees**.**

Activity A.5 Four-day consultative workshop for 25 stakeholders (legal, technical and trade specialists, legislators, managers and administrators) to review and comment on the second draft of the Executive Directive Regulations for the Biosafety Legislation of the ARE (including statutory forms for applications) and amendments to the existing ministerial decrees before finalisation

Activity A.6 Final drafting of the EDR, along with the required amendments to current decrees of relevance, in proper legal language to be presented to the Prime Ministers Office for approval and translation in English

Activity A.7 Four day training workshop for 24 officers from implementing bodies on the application and implementation of the biosafety law and the Executive Directive Regulations. Publication of a training guide on regulatory issues

Activity A.8 Analysis on the legal steps to be taken to examine the interaction with the Biosafety Law, and to regulate the contained use and confined release of potentially hazardous genetically modified organisms is carried out and indication of steps for legal actions.

Component B: Handling of requests (TOT: 185, 100 ; GEF: 117,100)

Many of those who will be in charge of implementing the National biosafety framework of Egypt (managers, customs officials, law-making persons, decision makers in a court of law, inspectors, analysts, media personnel and the general public) are short of knowledge and experience in biosafety . In particular with respect to risk assessment, the professionals in charge will need to be provided with the capacity and tools to carry out their tasks and adequately assess the safe use, import or export of any LMOs.

Therefore, the first step will be to formulate technical methodologies for risk assessment and risk management for LMOs through a highly specialised meeting of 8 local scientists, 2 local consultants and an international expert. The protocols will be drafted by 2 consultants who will also write a local "Manual on procedures for handling requests of LMOs in Egypt". The protocols will contain indicators and monitoring methods for environmental risk assessment of LMOs, methods of identification, estimation, prediction and comprehensive benefit analysis for LMOs, revision and testing of Technical Guidelines for Risk Assessment and Risk Management of LMOs, drafting final risk assessment and risk management protocols for consideration by the PCC. These are needed to implement the Legislation. The guidelines will cover the following aspects:

Objective and scope of risk assessment;

a. Principles and procedures of risk assessment;
b. Classification and determination of risk levels and types;
c. Information requirements for risk assessment of various LMOs;
d. Analytical methods for risk/benefit analysis;
e. Risk management for laboratory research, environmental release, commercial release, and transboundary movement of LMOs.

The guidelines will also comprise the following elements:

- The development of an information inventory of environmental risk ;
- The development of indicators and monitoring methods for environmental risk assessment ;
- Methods of identification, estimation, prediction and comprehensive benefit analysis for risk due to LMOs, including determination of unique identifiers:
- The development of technical measures and methods for risk management of environmental releases.

During the four year implementation period , two series of training courses (5 days for 30 technical persons each) will be carried out for different audience , i.e . members of the NBC, ministries, including representatives of civil society and private sector. A similar set of training courses will be organized for administrative officers. A training manual will be also published. To test the efficiency of the various components of the regulatory regime for biosafety, two separate mock applications, respectively for notification and for approval processes for the use of an LMO, accompanied by the required information documents will be submitted to the national competent authority in the last year of the project. The timeliness of their response as well as the quality of decision will help to indicate how successful the capacity building activities have been.

Activity B.1 One 5-day workshop led by national/international consultants for 8 specialists to discuss and draft protocols for risk assessment and risk management for LMOs

Activity B2 Draft technical guidelines on Risk Assessment and Risk Management protocols

Activity B.3 Preparation of an internal "Manual on procedures for handling requests of LMOs in Egypt"

Activity B.4 Organisation of two five-day training courses for 30 participants/course (members of the implementing bodies, including representatives of civil society and private sector) on handling requests for permits, including RA/RM

Activity B.5 Organisation of two five-day training courses for 30 administrative officers/course from the biosafety office and relevant Ministries, on the administrative processing related to the handling of requests (including administrative aspects related to monitoring and inspections)

Component C Systems for follow-up, namely monitoring of environmental effects and inspections (TOT: 1,484,100 ; GEF: 391,100)

In order to tackle all the aspects to be considered in monitoring for environmental effect and inspections, including specific tasks and responsibilities, a manual on monitoring and enforcement will be prepared. In parallel, a survey of the existing laboratories and facilities in universities and research institutes will be carried out so as to have a clear picture of the current situation in the country and of candidates for the position of reference laboratories. Based on the results, there will be a call for applications to act as reference laboratories, which basic criteria will be independence, expertise and availability of physical facilities. The PCC with the assistance of selected consultants will draw appropriate criteria, review applications, make site visits and interviews and make recommendations on selection, areas of strengths and weakness for each candidate laboratory including specifying additional equipment and training needs which would qualify the facility as a reference laboratory – for the Minister to issue the necessary decree as required by the Biosafety Law.

An agreement will be signed between the implementing body and the institution on the support to be provided in terms of equipment and training of personnel, the commitment of the designated laboratory/ies for continued operation and use of its existing equipment for the purpose, commitment for additional resources to be made available through the institution as a national reference laboratory/ies and proposed modality of operation for testing and certification. The equipment component to be provided through the project aims at complementing, strengthening, up-grading the facilities of the selected laboratories, focusing it on the duties required by the Biosafety Law and represents a maximum which would be made available. Details will be determined by the consultant's report depending on available equipment existing in the selected laboratories.

In the meanwhile, a training guide for LMO detection and certification in laboratories will be compiled and used as background material for the two training programs that will be run over the four year period for selected staff of the reference laboratories the provision of information on the Laws, regulations and procedures of biosafety management at home and abroad; introducing basic theories and methods for risk assessment and risk management as well as monitoring technologies; visiting pilot sites with transgenic organisms.

Finally, because of paucity of experience in this area of biosafety, inspectors, custom officials and enforcement officers will be trained to ensure compliance to the regulatory regime through two national training (for 10 scientists for 2 weeks each course and for 2 senior scientists for 2 weeks each) to improve their capacity/expertise in tracing and investigating on GMOs and one 5-day local training course for 40 customs officials and inspectors from various implementing bodies will be conducted.

The related issue of expertise in legal enforcement, dispute settlement and handling of court cases will be covered by two 2-day training workshops for 8 selected judges each, with a training guide prepared and published for the benefit of the judiciary.

In the last year of the project, mock import documents will be submitted to the custom officers and inspectors to test the efficiency of the 'follow-up' systems and to evaluate the success of the training courses, which had been conducted.

Activity C.1 Preparation of a manual on procedures/methodologies for monitoring of environmental effects and inspections

Activity C.2 Survey of existing facilities at universities and research centres

Activity C.3 Define the criteria/procedure for the selection and certification of two reference laboratories

Activity C.4 Providing additional equipment for laboratories to be certified for LMOs detection, including post-release monitoring and enforcement

Activity C.5: Training guide for LMOs detection in laboratories, including sampling and analysis

Activity C.6 A training for 2 senior scientists from the reference laboratories to improve their capacity/expertise in investigating on GMOs

Activity C.7 Two national training courses programs (2 weeks each) for 10 selected staff of the two reference laboratories in LMO detection

Activity C.8 Organisation of a five-day training course for 40 custom officials and inspectors on LMOs investigation and inspection techniques.

Activity C.9 Two 2-day training workshop for 8 judges on enforcement, dispute settlement and handling of court cases. Preparation and publication of a training guide on enforcement, dispute settlement and handling of court cases

Component D Public information and participation (TOT: 138,300 ; GEF: 69,300)

Decision-making in biosafety depends upon accurate and sufficient information. Article 23 of the Cartagena Protocol requires parties to promote and facilitate public awareness and participation concerning the safe transfer, handling and use of LMOs. The project will strengthen Egyptian capacity for public information and participation by first preparing a public information, participation, and education plan. Based on this, outreach material will be produced and widely disseminated in the country. This will involve production of easily accessible pamphlets, brochures, and abridged versions of the Law and the Regulations and other technical matters by target audience (government institutions, scientists, NGOs, the media, the general public, etc). Within the context of the plan for public education and participation , of a series of training workshops will be carried out , namely one for parliamentarians, media and NGOs representatives on the Law and its Executive Regulations and related provisions (and tools) for public involvement in decision making and two for local administrators in charge of educational issues .

Finally , a specific official web site will be set up for the biosafety committee where all the deliberations will be placed and a data entry protocol will be prepared. The website will be managed by the permanent secretary , who receives applications and confirms their receipt For reasons of transparency, independency and accountability , this website will be different from the main biosafety website to be set up under the BCH project, but linked to it. The website will also contain information on the committee members , consultants in areas biotechnology biosafety and links/information on reference laboratories .

Activity D.1 Preparation of public education and involvement plan

Activity D.2 Preparation and dissemination of outreach materials on biosafety

Activity D.3 Setting up the web site and preparation of a data entry protocol

Activity D.4 Organisation of two two-day information workshop for 40 local administrators each on public awareness education and involvement in biosafety

Activity D.5 Organization of a two-day workshop for 35 participants, including parliamentarians, media and NGOs representatives on the Law and its Executive Regulations with specific focus on public involvement

C3. SUSTAINABILITY

Institutional sustainability

Egypt has officially committed itself to guaranteeing sustainability by ratifying the Cartagena Protocol on Biosafety on 23 December 2003. This commitment will be strengthened by the approval and enactment of the Biosafety Law (as well as the EDRs) which will institutionalise the Supreme Committee on Intentional Release of Genetically Engineered products into the Environment (SCIRGEPE) as well as the mechanism for handling of requests.

Operational sustainability

Once completed, the project will be self-sustainable. In fact , by the time the project will be finalised the biosafety management structure developed will be translated into a legislative framework that, once officially approved, will be binding to the government and the people. The Executive Directive Regulations (EDR) will be covering modalities for implementation of the biosafety system according to the biosafety law and therefore set up the frame to guarantee the operability of the system .

Operational sustainability will be further addressed by ensuring that adequate capacity is built through training workshops and the development of tools (as manuals and training guides) aimed at creating additional capacity beyond the life of the project. In fact, this project has been designed to focus on capacity building for all those involved in the biosafety-related activities, i.e. decision-makers, customs-officials, inspectors and scientists. It is strongly believed that it will guarantee a solid basis for setting up a good biosafety management. However, it will need as well further development and updating through further training activities, workshops and national/international meetings. It is no doubt that the implementation of the Draft National Biosafety Framework for Egypt will have a wider effect at global level than that one strictly limited to the country itself: Egypt will be a major counterpart for any forthcoming activity on biosafety and this guarantees its involvement in all the major activities carried out in the sector worldwide.

Financial and political sustainability

The Biosafety Law being approved stipulates that the budget necessary for implementation will be incorporated into the budget of the EEAA and that a fee system is established to defray the cost of operation (details of the fee system will be set in the executing directive regulations) .

Environmental sustainability

Given the growing expansion of the LMOs market and the strong economic potential that it offers in economic terms for Egypt as well as for many other countries, it will be extremely important to guarantee that the legal framework keeps on reflecting the market/commercial realities. This legal framework will therefore be constantly updated and revised based on emerging scientific evidence associated with the risk of any new LMOs being used/commercialised in and outside the country.

Accordingly, the indicators and monitoring methods selected and adopted for the risk assessment and management as well as the technical protocols developed in order to provide guidance in the implementation of the Biosafety Legislation of the ARE will be continuously updated too.

Risks: The risks associated with the implementation and successful outcome of this project can be described in the following general categories: need to face a rapid expansion of the LMOs market; need to update current legislation;; capacity building; knowledge and information.

Mitigation measures : These risks will be reduced by the approval and implementation of a comprehensive regulatory regime , by setting up of a mechanism for revising legislation when and how needed , by strengthening legal and technical capacity and developing tools that to guarantee capacity building beyond the life of the project .

C4. REPLICABILITY

The project benefits of a « replicability » effect generated by the experience gained through the demonstration projects and will produce a similar effect (by for example further developing training material and methodologies, producing risk assessments or environmental reviews of LMOs generated by regulatory processes, taking final decisions on import or release of LMOs, etc.) so as to be used in other areas of the world and different contexts.

So as to guarantee sharing and dissemination of information and amplify the replicability potential of national projects to other countries in the world, documents, reports, findings of the demonstration projects are posted and regularly updated on the web. A meeting of the national project coordinators of the demonstration countries was carried out in January 2004 and in March 2005 and -given the success in terms of 1) getting insight to other countries day-to-day practices , 2) promoting exchange of information and 3) sharing of lessons learned - another similar initiative is being considered for 2006. These activities would be extended to this project.

The Monitoring and Evaluation plan of the project will include indicators to measure potential of replication.

C5. STAKEHOLDER INVOLVEMENT

Stakeholder identification and participation

The main stakeholders within and outside the government were identified during the Pilot Project and they actively participated in drafting the Framework and later the Biosafety law currently being approved. In fact the resulting Draft Legislation, and later the Biosafety law currently being approved anticipated that final decisions on specific releases may be suspended pending the holding of public hearings to monitor public sentiments. It also makes clear reference to socio-economic impacts. Its preamble clearly promotes the use of biotechnology products for the welfare of people but anticipates that such promotion must be safe for present and future generations and anticipates this as feasible and realistic. In the proposed demonstration project this approach will be maintained and expanded. The consultative workshop, which is the major fact finding mechanism and consensus-making mechanism in the project will include many representatives of the public, including NGOs, consumer groups and the media. Media interaction aims at enhancing public interest in biosafety issues and to encourage feedback, which will be monitored by the PCC. Transparency is a cardinal principle governing project activity.

An information network will be established as part of the project activities and a web site will be established. Both will be designed to be publicly accessible and feedback from this mechanism will be taken seriously into consideration by the PCC. The legislative package sought through the project focuses on the need to obtain broad consent and support from the broadest range of stakeholders. Considerable reliance on independent scientific expertise is built into project activities. The involvement of the Academy of Scientific Research and Technology and its strong Specialised Council, as well as the National Specialised Councils of the President's Office will be exploited to the fullest – these being the national think tanks with the most experienced independent senior scientists in the country.

It is also anticipated to involve key legislators and the judiciary in many project activities and to keep them informed of progress made.

The project will provide the interested parties with needed information and analyses on various issues related to project activities. This will not be limited to access and interaction with the clearing house and the website but will also spill into the distribution of training material and of public awareness material produced. A limited distribution project newsletter will be produced and made available to participants in various project activities after these are concluded to maintain and foster interest and feedback. Finally, as part of the project, public opinion polls may be held occasionally to gauge public interest in project activities.
Harmonisation with EEAA activities in genetic resources conservation, maintenance of gene banks and eco-tourism will be put to use in project implementation.

The project is addressing policy-makers, government departments and all the institutions (including research centres and universities) involved in the biosafety management system in Egypt. Their involvement will ensure broad acceptance of the on "Biosafety Legislation of the Arab Republic of Egypt" whose Biosafety Law is due to be approved by the People`s Assembly during the development of the project. At present, in fact, Egypt`s National Biosafety Committee is concerned with biosafety in research and field trials but does not address commercialization of LMOs and an Integrated biosafety regulatory structure at national level is still lacking. Customs-officials, inspectors, managers and scientists, who are to be involved in:
1) The provision of general information, laws, regulations, policies, guidelines, trade patterns and practice of domestic and foreign biosafety management;
2) Introducing the procedures for the application and approval of LMOs,
are going to be important stakeholders as well. Their pro-active participation in all the capacity building activities planned in the project and their direct involvement in different phases of the biosafety management system (inspection, custom clearance, application of the existing regulations, etc.) will guarantee the needed support for the Biosafety Law and its executive directive regulations to be effectively implemented.
The access of the general public to biosafety related information and ongoing activities is also considered a key issue: besides mass media, a user-friendly website will be set up and the Clearing House Mechanism established.

The EEAA, the executive arm of the Ministry of State of Environmental Affairs (MOSE), being constitutionally responsible for biodiversity and the environment in Egypt will be the executing agency. The EEAA has a track record as a coordinating body, having previously been linked to the Cabinet Office and enjoys the trust of all ministries. It has a tradition of cooperation with various sectoral authorities in Egypt. Its linkage to the MOSE 8 years ago has given it a permanent specialized voice within the Cabinet. It also has strong links to the scientific community, components of the civil society, consumer groups and the media. It is thus best suited to lead national efforts in biosafety. The EEAA is also well experienced with implementation if international projects.

Table 1 Stakeholders and roles

Stakeholders	Type of Involvement
Ministry of Health:	Central Laboratories: analytical work including unique identifier Supreme Committee on Food Safety: quality for human consumption within the food chain, role in food chain, food inspection National Organization for Drug Control and Research: analytical work, quality of therapeutics and diagnostics, authorization of release of therapeutics and diagnostics Preventive Medicine Administration: role in general human health VACSERA Organization: analytical work, quality of immunologicals, biological products and pharmaceutical biotechnology products
Ministry of State for The Environment (competent authority)	National Biodiversity Unit: impacts of LMOs on national biodiversity, implications on obligations under international environmental agreements; implications on the National Environmental Action Plan and the National Biodiversity Strategy, alien and invasive species, implications on traditional communities and knowledge National Protectorates Sector: implications on the integrity of biodiversity in protected areas; implications on the National Biodiversity Strategy and obligations under international agreements National Pollution Unit: implication on environmental pollution, the inspection system
Ministry of Agriculture and land Reclamation	Seed Certification Committee: role of crop seed certification for growing, inspection system for crop seeds Central Laboratory for Animal Feed: analytical work, matters relating to farm animal safety and nutrition The Agricultural Research Center: analytical work, certification of unique identifiers; examination of breeding history of LMOs Fisheries Department: implications on biodiversity of aquatic animals for human consumption, certification of breeding history of LMOs
Ministry of Scientific Research and Technology	National Research Center, Mubarak Scientific Research City and the specialized research institutes: analytical work, determination of unique identifiers, examination of parental origin, issues related to intellectual property rights, issues related to national souvergnty on national biodiversity Executive Committee on the National Strategy for Biotechnology and Genetic Engineering: issues related to biosafety as a component of the National Strategy
Ministry of Higher Education	Universities and Higher and Graduate Institutes: analytical work, scientific elements in implementation of the biosafety law and its regulations including technical backup, socio-economic studies and public involvement
Ministry of Industry	General organization for Standardization and Quality: settings standards for products of biological origin, industrial products, food, feed and the Environment
Ministry of Foreign Trade	Export Development Authority: implications on viability of

	exports and trade balance The WTO Unit: implications on foreign trade, imports and obligations under international trade agreements, including intellectual property rights
Ministry of Consumer Commodities	General Organization for Provisions and Commodities: implications on provision of major consumer commodities
Ministry of Finance	Customs Authority: impact on regulations and procedures for release, labelling requirements, handling, packaging, inspection, sampling, identity preservation Department of the Budget: financial implications and costing
Ministry of Justice	General Directorate for Legislation: conformity with current legislation applicability of the legal language, need for specialized courts
Ministry of Foreign Affairs	Department of The Environment and Sustainable Development: conformity with national policies on environment and sustainable development and on national foreign policy, impact on relations with other countries and on regional obligations and coordination procedures Department of International and Regional Agreements: conformity with National obligations under international and regional agreements and with international law
The State Council	General Administration for Legislation: conformity with constitutional obligations, conformity with current legislation, applicability of legal language
Civil society Agricultural Syndicate of Egypt Society for Consumer Rights Watch guard, Society for Protection of the Environment of the Red Sea, Medical Syndicate of Egypt, Pharmaceutical Syndicate of Egypt , Scientific Syndicate of Egypt , Syndicate of Journalism and Audio-Visual Media	Reflecting public opinion, environmentalists and consumers, involvement in public information activities. Reflects the professional views of the relevant Professional Syndicates on issues being considered
Private Sector Union of Egyptian Industries, National Chamber of Commerce	These two bodies are the official representatives of both the public and private manufacturing and trading establishments. Each is composed of an extensive sub-structure based on sectoral specialization. Thus, as an example, the Union of Egyptian Industries has specialized section on food, on pharmaceuticals, on textile industries, on chemical industries etc. Similarly, the National Chamber of Commerce has chambers of Food, feed, pharmaceuticals, fibres, general chemicals, fine chemicals etc. Both were heavily involved in consultations which led to the current draft of the Biosafety Law being approved. Within the sub-structures distinction between publicly and privately owned enterprises is not made.
Media	Reflecting public opinion and sentiments, public awareness

Scientific community Cairo University Biotechnology Center, Cairo University viral molecular biology lab , Ain Shams University biotechnology Center , Ain Sham University Total Containment laboratory Mansoura University Biotechnology Unit , Assyut University fungal research lab , Cairo University Faculty of Medicine Molecular biology Unit , Academy of Scientific Research and Technology , Executive Committee for the National Strategy of Biotechnology, National Research Center , Institute of Biotechnology and Genetic Engineering, Mubarak City for Scientific Research , Agricultural Genetic Engineering Institute , National Gene Bank , Ministry of Health Central Laboratories , Supreme Committee on Food safety of the Ministry of Health , National Biosafety Committee , National Authority for Standardization of the Ministry of Industry, National Organization for Drug Quality and Research , National Organization for Sera and Vaccines , National Authority for Control on Exports and Imports , National Crop Seed Certification Committee , Genetic Engineering Committee of the National Specialized Councils , Alexandria Library	Sources of individual expertise, resource persons and consultants (and attend also meetings of the biosafety committee on a case by case basis). These structures will also be the source of the Roster of Experts on which the SCIRGEPE will settle issues and provide advise on a case by case basis. They are also the sources of scientific backing for the Reference Laboratories.

C.5 d Information dissemination and consultation

Under the project, a specific plan for public information and participation will be prepared and will include an information dissemination and consultation strategy. As part of the project as per section D , beyond the preparation of outreach material, specific training workshops for local administrators are planned to sensitize and activate these crucial nodes of information at Governorates level as well as training workshops for parliamentarians , media and NGOs in terms of general overview of the biosafety system , with a focus on modalities for public information and participation .

C.6 MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This process will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs (Annex E, C.6 a) and project impact (Annex E, C6.b) will be measured according to the indicators developed in the project log frame (Annex D), and using this specific Monitoring and Evaluation Plan. The Plan is based on the general and specific objectives of the project, and the list of its planned outcomes.

The project coordinator, with the assistance of the NCC, will be in charge of the monitoring and evaluation component of the project and will take action whenever needed so as to guarantee that the M&E activities of the project and related indicators adequately reflect the needs of the project.

The Monitoring and Evaluation plan is detailed in Annex E. The monitoring and Evaluation plan includes Table 2 Indicators and Means of Verification, Table 3 reporting and monitoring responsibilities, Table 4 information on reporting requirements, and Table 5 a summary of project activities by project component is presented in.

The matrix on key indicators, baseline and methods of data collection is attached in Annex E.I.

D – FINANCING

D1. Incremental Cost Assessment

The following table provides a summary of baseline and incremental costs by output/component as well as information on GEF financing and national Co-funding. A detailed incremental cost analysis, and global and domestic benefits and related schematic representation are presented in Annex F together with an incremental cost matrix. The total baseline expenditure amounts to US $ 2,105,000, which main components relate to monitoring (of which around 80% devolved to laboratories equipment and consumables, personnel and around 20% to training) and regulatory issues (in terms of preparation of legislation, meetings, training). The increment has been estimated at US $ 2,297,100. The national contribution in kind amounts to 1,389,000, of which 1,000,000 of contribution in laboratories equipment, consumables and infrastructure as well as personnel The 26% of the remaining 389,000USD, namely 111,000USD, is on project management and coordination, while the rest is distributed over the other NBF components as detailed by component in the table below (and detailed per activity in the budget, Annex G). The remaining total cost of US $ 908,100 is requested from GEF.

Table 6. Summary incremental cost analysis

Activity	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing (in kind contributions)
National Biosafety	600,000	746,600	146,600	98,600	48,000

legislation					
Handling of requests	5,000	190,100	185,100	117,100	68,000
Monitoring of environmental effects and inspections	2,500,000	3,984,100	1,484,100	391,100	1,093,000
Public awareness and participation	---	138,300	138,300	69,300	69,000
Project management	---	273,000	273,000	162,000	111,000
Technical support	---	70,000	70,000	70,000	----
TOTAL	2,105,000	3,402,100	2,297,100	908,100	1,389,000

D2. BUDGET (including national co-financing)

The detailed budget of the project is shown in Annex G. A summary of the budget by components with co-financing details and the staff costs are shown in Tables 7 and 8 respectively (below). A sum of US $ 70,000 has been included for technical support.

Table 7: Project Budget by Components

	Component	GEF (US $)	Government in-kind (US $)	Total (UD $)
1	Regulatory regime	98,600	48,000	146,600
2	Handling applications	117,100	68,000	185,100
3	Monitoring and Inspection	391,100	1,093,000	1,484,100
4	Public participation and information	69, 300	69,000	138,300
5	Project coordination	162,000	111,000	273,000
6	Technical support	70,000		70,000
	TOTAL	908,100	1,389,000	2,297,100

E-1 Staff costs – not directly linked to a specific activity

A Project Co-ordination Committee (PCC) will be constituted from a small number of eminent scientists in personal capacity, headed by a project coordinator (PC) and served by a one person secretariat which together with the responsible officer at the EEAA will be the Management Committee. The PCC will meet at least monthly to plan, review, assess and adjust activities. The project coordinator will be responsible for preparation for the committee meetings and for following the activities planned.

Table 8: Project Staff

Personnel	GEF	National Co-financing	TOTAL
National coordinator of the project (part time)	48,000	48,000	96,000
One project assistant (full time)	48,000	12,000	60,000
Administrative assistant (part time)	4,000	2,000	6,000

TOTAL	**100,000**	**62,000**	**162,000**

The total personnel cost for the project is therefore 162,000 USD of which 100,000-USD (requested from GEF and 62,000 US$-provided by the government.

E-2 Equipment and operating costs:

The equipment and operating costs budget (USD) covers the purchase of computers, software upgrades, maintenance etc and includes stationery and communications costs.

Total cost: US$ 59,000, cost to GEF: US$ 24,000, contribution in –kind : US$ 35,000

Project Monitoring

Table 9: Staff costs related to project monitoring

Monitoring	**GEF**	**National co-financing**	**TOTAL**
National Coordination Committee Meetings	24,000	12,000	36,000
Administrative assistant (part time)	4,000	2,000	6,000
Auditing	8,000	---	8,000
TOTAL	36,000	14,000	50,000

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out over four years. The implementation plan is associated to the budget provided in Annex G

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on an UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the CP-carried out through the development and implementation of National Biosafety Frameworks respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in Egypt where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

E2. CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IMPLEMENTING AGENCIES, EXECUTING AGENCIES, AND THE GEF SECRETARIAT (WHERE APPROPRIATE)

E2.a National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex h.

E2.b National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, after consultation with UNEP, for the duration of the National Project. The National Project Coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex E.

E2.c UNEP Steering Committee

The Steering Committee provides guidance and direction to the implementation of the project. It is chaired by UNEP, and comprises representatives of the National Executing Agency, two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, whenever technical and scientific issues related to the implementation of the MSP are to be addressed, the representative of STAP as well as experts selected in their personal capacity will be invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

LIST OF ANNEXES

TABLES

Annex A

Summary of the the Biosafety Framework for Egypt

1. EXECUTIVE SUMMARY

Biotechnology is a technology developed during the past 20 years, which promises to revolutionize the patterns of economic development in the 21st Century. The central material of biotechnology are the so called "Genetically Modified Organisms" or GMOs, which are organisms developed in the laboratory, using molecular biology techniques, which break natural barriers between species, genera, families and even biological kingdoms, and hence can not develop in nature. Most non-living processed products of GMOs retain the unique laboratory-developed genetic material and hence may be regarded as equivalent to living GMOs.

Potential applications for biotechnologies are broad: in pharmaceuticals and health care, in food and agriculture, in environmental protection and management, and in industry. Countries, which may fail to exploit the technology, will suffer severely in terms of lost income and export potential. In many cases entire economic systems may collapse and unemployment may soar.

Like any new technology, biotechnology is not without its specific risks. Fortunately, however, consideration of risk took place side by side with the development of the technology. Again fortunately many such risks could be eliminated, or be made acceptable in terms of cost benefit analysis, with proper regulation of the use of biotechnology products and its release into the environment. It is the consensus of the relevant scientific community that biotechnology products would be safe if appropriately regulation. Such regulation should encourage the development and application of the technology while at the same time protecting the environment in which it operates.

The possible risks of the use and release of GMOs and their processed products are focused on risks to the biological diversity in the environment which are often irreversible, on risks to human health, on risks to the socio-economic integrity of a community and on risks to the political sovereignty of a country. Safety is achieved through the provision of transparent information on the product and the process and conducting extensive risk assessment and risk management by the regulatory authority in the receiving environment. This requires a strong scientific base and facilities. It also requires an efficient system for implementation of regulations, along with protection of the intellectual property rights of inventors.

Three cardinal principles govern the regulation system. The first is the application of the *Precautionary Principle* adopted at *the Earth Summit* in 1992 which requires caution in application of actions which could have serious long term impacts on the environment unless there is solid proof of the absence of possible harm. The second is recognition that GMOs are distinct and intrinsically different from natural organisms because they did not develop in harmony with the environment and because their behavior can not be predicted with certainty hence require specific regulation. The third is the right of the community to know the source of the material being made available through appropriate segregation and labeling of GMOs.

Accordingly, the regulation system must be a special legislation to be introduced by the executive structure entrusted with environmental protection. It applies only to GMOs and products thereof, and requires environmental approval before application of other regulatory requirements, which apply to both GMOs and non-GMOs. The framework calls for prohibiting the testing and release of GMOs before being approved by a small special committee established by the Ministry of the Environment in which the ministries of Health, Agriculture, Industry, Trade, Higher Education and Scientific Research and of Foreign Affairs designate members with appropriate expertise. The Ministry of the Environment will designate an equal number of experts in their personal capacity. Applications would be submitted to the Secretary of the committee along with a dossier of specified information, which makes it possible for the committee to take a decision within a specified time frame. The committee refers the application or components thereof to experts selected from a roster of consultants for review and recommendations. If necessary the data in the dossier could be referred to one or more specified reference laboratories for certification and/ or further examination. The committee may request additional information from the applicant and time freezes until the information is provided. It may also decide to hold public hearings in order to take public opinion into consideration in which case too time freezes. The committee also establishes an executing body with the responsibility of following up implementation of the permit and ascertaining adherence to its conditions. The permit is issued to the applicant only and may not be delegated to a second party.

2. THE PURPOSE OF THE DRAFT LEGISLATION:

To regulate the ***release*** of Genetically Modified Organisms (GMOs) into the environment and thence its impact on ***the environment and human health.*** Its economic value and advantages or disadvantages as compared to traditional strains and varieties is not a concern for biosafety. It is a requirement that is independent of other requirements such as food safety, drug efficiency, agricultural productivity etc. One does not substitute for the other, but one – the biosafety equirement must precede the others**.**

3. COMPONENT OF THE BIOSAFETY FRAMEWORK:

a) Reasons and goals
b) Legal definitions
c) Requirements, procedures, time schedules, information required, penalties, detailed technical annexes and forms covering Information required. etc.
d) Oversight structure: how constituted and reconstituted functions etc.
e) Implementation structure: how constituted, functions .etc
f) Information exchange structure
g) Interaction with other laws

4. THE FUNDUMENTAL NASIS OF THE DRAFT LEGISLATION:

GMOs are different and special hence they require a special independent set of regulations.

4.1 This assumes that organisms produced by "modern biotechnology" – often referred to as *"genetically modified organisms" or GMOs* are fundamentally different from wild or domesticated ones or those produced by classic breeding and genetic methods, including mutation. Non-GMOs contain a natural mix of genes which could evolve naturally and

which are produced by methods with which humankind have long standing experience that may even extends into ancient history. Their products have a long-standing history of predictable safety. On the other hand, GMOs are:

a) New to the environment and have not evolved in harmony with it.
b) produced in the laboratory, using molecular techniques, by breaking natural genetic barriers.
c) contain mixes of genes which would naturally never occur, whose behavior is novel to human kind and can not be predicted with certainty.

Accordingly, the handling and release of GMOs into the environment requires *special regulation if it is to be safe for the environment or for human and animal health*. These are the same arguments, which are presented in order to justify that *GMOs are novel entities, which may be patented under WIPO rules.*

4.2 GMOs require special regulations *for no reason except that they are GMOs.* These regulations state explicitly that *they are additional to any other regulations required of non-GMOs, such as food safety, phytosanitary, drug efficacy etc.* Biosafety in a general sense, such as laboratory, worker, and public health safety are separate regulations, or guidelines, which overlap with biosafety in the release of GMOs only when they involve release into the environment.

4.3 Regulation is entrusted to *a special body referred to as: the National Supreme Committee on the Release of Modern Biotechnology Products into the Environment* under the environment oversight structure. Its "supreme" body is usually small, constituted according to rules specified by the law, of*ex officio* representatives of government offices and scientists in personal capacity. It is assisted by a large body of experts and by reference laboratories to which specific tasks are entrusted.

4.4 The application for consent to release GMOs into the environment is submitted according to carefully designed and detailed application forms and is supported by an extensive dossier of information specified in detail in the annexes to the law. The information required is sufficiently comprehensive to allow the oversight body to make a judgement, often based on deskwork, on the level and affordability of the safety of the release. This information relates to every element of the genetic constituents of the GMO and the expected receiving environment. In Many cases it requires information on the process through which the GMO was developed, with due consideration for protection of the Intellectual Property Rights of the applicant. It should include all what is necessary for conducting a thorough risk assessment of the impact of release.

4.5 Risk assessment and risk management are the most fundamental elements of the system. Although it requires submission of the data of any previous risk assessment and risk management conducted previous to application for release (and reasons for previous denial if such was the case), it also requires that risk assessment and risk management be conducted under local conditions, including information such as: effect on insect population and the expression of the gene *in* different tissues. It also requires specification of the conditions for isolation from other crops or organisms, supply of monitoring information during the release, limitation of the area that could be employed. etc. It also requires adequate information on the receiving environment. All methodologies must be described in detail along with the level of its specificity, sensitivity, accuracy, and reliability. etc.

4.6 Information is also required on whether or not the GMO is approved for release in the country of origin (and the reasons for a ban on release if such is the case), but this does not necessarily influence the decision of whether consent for release is given or withheld.

4.7 Transparency of the information is a cardinal rule. It could include what falls under trade secrets, but the regulatory agency is obliged to protect confidentiality of such information and of the trade competitiveness of the applicant based on such information, even if the consent is denied.

4.8 There is a time limit for the regulatory agency to respond by giving or denying consent, and procedures are specified for requesting review of the decision.

4.9 If the regulatory agency finds reason to request additional information time freezes. The regulatory agency may find it necessary to hold public hearings in order to reach a decision.

4.10 There is a modest fee to be paid by the applicant, but the major cost is that of the extensive dossier of information submitted and the research that it requires.

4.11 In almost all cases *segregation of GMO* from non-GMO is required and the public has the right to be informed that the material being released, or placed on the market is a GMO or its product, through appropriate *labelling*.

5. EXAMPLES OF INFORMATION REQUIRED IN THE INFORMATION DOSSIER ACCORDING TO THE DRAFT LEGISLATION.

5.1 Personnel and training (for those carrying out the release)

5.2 Information on the GMO: characteristics of the donor, recipient and parental organism, including description identification and detection techniques as well as the sensitivity, specificity and reliability of such methods, the potential for genetic transfer and exchange with other organisms, genetic stability, pathogenically, infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, possible activation of latent viruses, antibiotic resistance markers, nature of indigenous vectors, history of previous genetic modifications, etc.

5.3 Characteristics of the vector: sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO, frequency of mobilization and methods of determination, degree to which the vector is limited to the DNA required to perform the intended function etc.

5.4 Characteristics of the modified organism: information related to the modification (e.g. methods used for the modification, methods used to construct and introduce the insert, purity of the insert, sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment etc)

5.5 Information on the final GMO (e.g. genetic traits which may be expressed or no longer expressed, structure and amount of any vector and/or donor nucleic acid remaining in the final construction), stability, rate and level of expression of the new genetic material,

activity of the expressed protein, health considerations, if the organism is pathogenic to humans who are not sufficiently immuno-competent etc)

5.6 Information on the conditions of the release and the environment, including techniques foreseen for the elimination or inactivation of the GMO at the end of the experiment and information and results of any previous release, description of target and non-target ecosystems likely to be affected, and any known or planned developments or changes in land use in the region.

5.7 Information on interaction between the GMO and the environment: e.g. characteristics affecting survival, multiplication and dissemination, behaviour in simulated natural environments, genetic transfer capability, possible post release expression and transfer, methods to verify genetic stability, potential for excessive population increase in the environment and for shifts in biological interactions or in host range, known or predicted involvement in biogeochemical processes

5.8 Information on monitoring, control, waste treatment and emergency response plans:

5.9 If the material is to be placed on the market: e.g. quantity, packaging, storage, handling, labelling, instructions, expected use, measures necessary in case of unintended release or misuse etc.

6. TEXT OF THE DRAFT LEGISLATION.

N.B. This is NOT a formal translation and should not be quoted. The Preamble has been ommitted.

Chapter 2

1- Objectives and Applications

Article 2

This law shall apply to GMO and their fragment with genetic information that may be capable of transfer to other organisms in the environment.

Article 3

This law shall not apply to GMO during transport by the following means: railway, marine, river, air or terrestrial (land) transporting means.

Article 4

This law shall not be applied on the products of GMO that is free from the genetic materials after conducting necessary experimental tests.

Article 5

This law shall not be applied on veterinary or human drugs produced by genetic engineering when proved to be free from the genetic materials.

Article 6

This law shall not be applied on gene therapy in human.

Article 7

This law shall not be applied on the in vitro fertilization in human or animals.

Article 8

This law is not applied on products controlled by a similar law for evaluating assessment and management of the risks of the release into the environment.

2- Licensing procedures.

Article 9

Applications for a proposed release or handling of genetically engineered products should be made to the concerned authority, on the specially prepared forms for the purpose of the permit in accordance with the executive regulation of the proposed law which include:

I- File for all criteria and consideration in Annex 2 focusing on the expected risks, in the near or late future, on the environment or human health, information on methods used for modification and all references related to the transformation of the product.

General information in the qualification and training personnel.

Information on the genetically engineered product.

Information on the expected release of the GMO, the potential. Receiving environment, results of relevant research development in similar ecosystem and assessment of risks of the release into the environment and consequently risks on human health.

Information related to: Conditions of the expected release, methods for use, labeling and all data on the product which are recorded in a special card for each product following roles presented in executive regulations of the law.

Anticipated interaction between the genetically engineered products and the other elements of the receiving environment.

Monitoring procedures, methods of control, waste disposal and emergency procedures during and after the release.

II-Any relevant previous assessment and management of risks on the environment and human health.

III-Any information on a relevant release of the same product especially in cases having been permitted.

IV-the applicant should inform the controlled authority of any changes in the procedures of the intended release, providing the necessary precautions for the protection of the environment and human health.

Article 10

Licensing of a product from the control authority is not considered an alternative to other obligations to the other related laws.

Article 11

The control authority is responsible for registration of the application form at the same day of application, after making sure that all required information are supplied.

Article 12

Decision should be taken within 90 days from applying. Applicant should expect one of the following decisions :

Licensing with or without any modifications.

No Licensing, with given reasons.

No decision, for lack of sufficient information.

Article 13

The control authority has the right to change or to cancel licensing when new information on a possible impact or hazards are expected to occur as a consequences of licensing.

Article 14

The control authority has the right to consult public opinion when there are reasons for that.

Article 15

The applicant is expected to inform the control authority of the detail results of the proposed controlled release focusing on impact to environment and human health.

Article 16

The control authority prepares an open record including all cases of controlled releases, which have been licensed previously.

Article 17

The control authority should provide protection for the intellectual property rights to all information given by the applicant.

Article 18

The applicant is entitled to specify confidential data, providing evidence for risk of undermining business interest. The controlling authority concerned must be given sufficient data to confirm the need for confidentiality. The data should include :

The description of the organism(s) genetically engineered.
Name & address of the applicant.
The aim of the release and its location.
The plan & methods of monitoring the genetically engineered product and the emergency plans required for control.
Assessment of possible risks specially infectivity and environmental disorders.

Article 19

The applicant should not carry on the controlled release before applying and having a written licensing from the control authority.

3-Supreme committee for biosafety in biotechnology products.

Article 20

The Egyptian Environmental Affairs Agency will establish a supreme committee for biosafety in biotechnology. This committee comes under the authority of the minister in charge of environment .It will have an independent budget with head quarters in Cairo.

Article 21

The committee is formed upon the nomination by the minister in charge of the environment through the Prime Minister and approved by the President The committee will include:

The chairman nomination by the minister in charge of the environment.

Seven members nominated by the ministers for health, Agriculture, Foreign Affairs, Commerce, Higher Education and Scientific Research, Industry, and Justice.

Five expert members in the field of biosafety in biotechnology nominated by the minister in charge of the environment.

A full time secretariat general, with expertise in the field of biosafety in biotechnology, nominated by the minister in charge of the Environment.

Article 22

The committee must establish an open register in the field of biosafety in biotechnology for reference as required in connection with applications for licensing the planned controlled release of genetically engineered products.

Article 23

The committee should establish an open register for specialized Egyptian laboratories in the fields of biosafety studies in biotechnology, for reference as required in relation to applications for licensing the planned controlled release of genetically engineered products.

Article 24

The committee should establish through decree by the minister in charge of the environment a permanent secretariat for the following up and implementation. The statuary regulation should specify the mechanisms for the following up and implementation.

Article 25

Licensing application should be addressed to the committee secretary general and the licenses should be issued under the name of the minister in charge of the environment.

Article 26

The committee should hold regular orderly meeting every month and may hold additional meetings as required to examine the licensing applications and following up of implementation on the basis of the presentation by committee's secretariat general.

Article 27

The statutory regulation of the law should specify the value of the phase to be paid with the licensing application.

Article 28

Upon the discretion of the committee and as deemed necessary studies may be carried out for risk assessment before a decision is made for the licenses. The cost of the studies required should be born by the applicant and must be paid in advance of the study.

4-Penalties

Article 29

Violators of the provisions of article 19 of this law shall be fined a minimum of 100.000 pounds or a maximum of one million pounds with the confiscation of all release equipment and facilities including the planned site. Violators will also have to bare the expense of clearing and cleaning the site and removing short and long term environmental effects resulting from that release as well as necessary compensation.
Violators of licensing conditions shall receive the same penalties as well as abrogation of the license.

Article 30

Violators will receive prison sentence of one year at least for presenting false information to the committee in connection of the licensing application. The same penalty will also be imposed for the issue of a decision resulting in unlicensed controlled release of genetic engineered products by the concerned administered authorities.

Article 31

Violators will receive a minimum of ten years prison sentence for committing any of the acts in breach of the provision of this law causing long range harm effect to the environment or human health. If an act resulted in the death of a human being the penalty will be temporary hard labor and if it resulted in the death of more than 3 persons the penalty will be life hard labor.

Concluding provisions

Article 32

Officers of the committee's secretariat appointed by the minister of Justice and the minister in charge of the environment will have judicial powers in establishing violations committed in breach of the provision of this law and related executive decrees.

Article 33

All citizens and societies concerned with the environment are entitled to report all violation committed in breach of this law.

Chapter 3

Definitions for the purpose of this law

Accident: Any event causes unintended release of any genetically engineered products.
Biotechnology: Processes using living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses.
Center of origin of diversity: The place or region where the source of diversity is located.
Contained use: Any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans.
Containment: Prevention of the spread of organisms outside the facilities which may be achieved by physical containment (the use of good work practices, equipment and installation design) and/or biological containment (the use of organisms which have reduced ability to survive or reproduce in the environment).
Controlled release: Deliberate release of organisms where risk management measures are applies.
Deliberate release: Any use of organisms that not a contained use.
Gene replacement therapy: Treating diseases by replacing the defective gene, either by incorporating a normal copy of the gene in the germ cells (egg or sperm), in the embryo (germ line gene replacement therapy), or by supplying copies of the normal gene to be taken up and incorporated into cells of the adult (somatic cell gene replacement therapy).
Genetically modified organism (Organisms with novel traits): Organisms produced by genetic modification and whose resultant genetic make-up is unlikely to occur in nature. These do not include organisms obtained by conventional techniques and traditional breeding methods.
Notification: The presentation of documents containing the requisite information to the competent authorities of a national state. The person making the presentation shall be referred to as the notify.
Organism: Any biological entity capable of replication or transferring genetic material.
Parents: Organisms from which an organism with novel trait(s) is derived.
Pathogen: An organism that can cause disease.
Potential receiving environment: An ecosystem or habitat including humans and animals, which is likely to come in contact with a released organism.
Product: A preparation consisting of or containing a GMO or a combination of GMOs, which is placed on the market.
Use: The deliberate application of a product, which has been placed on the market. The persons carrying out this use shall be referred to as users.
Users: Any persons, institutions or organizations (including companies) responsible for the development, production, testing, marketing and distribution of organisms with novel traits. Any member of the general public who purchases and/or uses an organism is not a user in the meaning of these Guidelines, unless specific conditions are attached to its use.

Appendix 1

The following techniques are not included in the production of genetically modified organism:

1. In vitro fertilization.
2. Microbial reproduction: conjugation, transformation, and other natural methods of reproduction.
3. Polyploidy induction.

4. The following methods without the use of parental or recipient genetically modified organisms: Mutagenesis, Plant cell fusion including protoplast fusion with the possibility to produce the same organisms using traditional methods of reproduction.

Appendix 2

Required information for the purpose of licensing the use of GMO

Some of the following information can not be applied for all products of GMO. Therefore each product will require its own suitable needed information. The applicant should explain the difficulties, if any, to obtain such information. Required information will vary according to the nature and the size of the release. In all cases a full description of the methods used for the release should be provided, referring to other authorities involved in all stages of the production of such product.

A-General Information :

1. Applicant name and address.
2. Training information for personnel involved in the planned release of GMO.

B-Information related to the GMO.

The following information is related to the characteristics of the donor organism (from which the nucleic acids are obtained), the recipient and the parental organisms.

1. Scientific name.
2. Classification (taxonomy) of the organisms.
3. Other names: (common name, strain, variety…etc).
4. The center of origin, when known.
5. Genetic characteristics of the organisms.
6. Taxonomic status of donor, recipient and parental organisms.
7. Description of the traits (Nucleic acid) introduced or modified and characteristics of the organism (GMO), as well as the techniques used for modification.
8. The intended use of the GMO.
9. Numbers / volume of the organisms with novel traits expected to be released.(to be used)
10. Any available information or report regarding risk assessment.
11. Relevant information and reported results for any previous releases in any other country.
12. Relevant information on the effect of a previous release of GMO on the sustainable use of the biological diversity and its effects on the human health in general.
13. Proposed mechanisms or approaches for handling, storage, transport, and use of GMO. Methods used in packaging, labeling, and safe disposal in case of accidents.
14. Regulatory status of the GMO at the country of origin. Reasons for not permitting the release or otherwise, and use of the genetically modified products there.
15. Efficient technology to analyze the information of laboratory & field data, which is also capable to identifying sensitivity, specificity, and significance of these information.
16. Possibility of gene transfer and exchange between different species.
17. Levels and factors affecting genetic stability of the product.
18. Natural habitat and geographic origin of the organism, including natural enemies, predators, parasites, competitors and symbionts.
19. Relevant, etiology and physical characteristics of the organisms involved in the modification including Pathogenic, toxicity, allergenicity, and virulence activity.
20. Resistance to antibiotic used in treatment of some diseases.

21. Roles of the GMO in the ecosystem processes, including, major biochemical cycles, cycling of elements, degradation of organic materials, metabolism…etc.
22. Characteristics of the vector particularly, chemical sequence, mobility, specificity and relevant survival characteristics.
23. Information on previous genetic manipulation.

C-Characteristics of the vector:

1. Identity and origin.
2. Nucleotide sequence of the vector, other non- coding segment used in the modification or production of GMO and the promoter used for gene expression in the recipient.
3. Degree of mobility of the vector, and the frequency of transfer into other organisms.
4. Capacity to transfer genetic material and the ways in which this might occur.
5. Information on the specificity of the insert and the encoded trait

D-Characteristics of the GMO

1- Information on the methods used to induce genetic alteration.
- Genotype description of the structure of the vector, the introduced genes, and the recipient organism.
- Characteristics of the vector and the introduced genes.
- Specificity of the vector and the inserted genes.
- Information on the nucleotide sequences and functions coded by the inserted nucleic acid, sites of modification, activity of the gene products and their possible impact on the environment.

2- Information on the final products of organism with novel traits:
1- Information to indicate whether the genetic alterations can cause the addition or deletion of certain functions and also to indicate that other traits are not affected by this particular alteration.
2- Nucleotide sequences and amount of nucleic acids of a particular trait retained in the modified organism.
3- Persistence of the genetic modification.
4- Precision of Characterization of the genes being manipulated, providing information on regulation of gene expression, properties, activities and fate of the gene products.
5- Function of the encoded gene in the GMO.
6- Methods to verify the genetic alterations and to test their effects in the expression of the genes.
7- Relevant information for any previous release.
8- Relevant health considerations including toxicity, allergenicity of the non-living GMO and its metabolites and infectivity.
9- The mechanisms by which the organism survives, multiplies and disseminates in the environment.

E- Information related to the intended controlled release:

1- Purpose and scale of the release including time and duration of the release, method and frequency of the release.
2- The technology used in the process.
3- Number or volume of organisms to be used.
4- Geographical description of the site prepared for this purpose.

5- Proximity to residences and human activities.
6- Plans for safety of the health of personnel involving in the process.
7- Expected environmental conditions during the release and subsequent treatment of the site and plans for waste management at the end of the process.
8- Relevant information on any previous releases into the environment.

F- Information related to the receiving Environment.

These information are related to the environment into which the GMO may be released.

1- Geographical description and location of the release.
2- Expected environmental conditions during the release.
3- Proximity of the site to humans and to significant biota, and protected areas.
4- Flora, Fauna, and ecosystems that could be affected by the release, including, rare, endangered or endemic species, farm animals, and non-target organisms (migrating species).
5- Population density and economic activities related to the natural resources.
6- Distance to the nearest source of water used for drinking or other environmental purposes.
7- Climatic conditions.
8- Any proposed plans for the future development of the area that may have an effect on the potential receiving environment.

G-Information related to the interaction between GMO and the receiving Environment.

1- Biological mechanisms involved in the survival, multiplication and dissemination of organism into the environment.
2- Expected and/or known environmental mechanisms that may be involved in the survival, multiplication and dissemination of the GMO into the environment.
3- The expected habitat for the new organism.
4- Information on the identity, characteristics, and function of the organism as well as their effects on a small scale controlled environment.
5- The potential gene flow from the released organism to the receiving environments.
6- Potential gene flow from the receiving environments to the GMO.
7- Subsequent natural selection following the release of the GMO which may lead to unexpected gene expression and undesired gene products.
8- Factors affecting genetic stability of the novel trait. Or (Appropriate measures to ensure genetic stability of the novel trait.)
9- Biological methods of dissemination of the organism into the environment.
10- Description of the favorable environmental conditions and ecosystems which may cause the dissemination of the genetically modified organism.

H- Expected potential on the environment:

1- Endemic increase of one species in the environment.
2- Competitiveness of the GMO compared to the recipient and the parental organisms.
3- Identification and characterization of the competitive and non-target species and their interaction with the GMO.
4- Expected subsequent alterations (changes) in the biological activities in the receiving environment.
5- The expected and known potential on the non-target species in the receiving environment, including, competitors, predators, prey, symbionts, parasites, pathogens, and hosts.
6- The expected and known cycling processes of elements in the environment.

I- Monitoring Procedures and Controlled releases:

1. Appropriate measures can be taken to arrive at a judgement concerning characteristics and consequence of release of the GMO products and the likelihood effects in relation to the donor, recipient and parental organisms. Testing the validity, the significance and the specificity of these measures.
2. Procedures or Methods, for monitoring the possible transfer of the induced genetic materials to other organisms.
3. Monitoring intervals and duration.
4. Controlling of the dissemination of the released organisms and controlling access to the release site.

J- Waste treatment and emergency plans:

1. Type and amount of wastes produced and the degree of the expected risks involved.
2. Methods for safe disposal of the wastes.
3. Methods for safe control in case of unexpected dissemination of GMO products.
4. Methods of disposal of GMO from the site of accident.
5. Methods for disposal and decontamination of the plants, soil…etc. involved in the accidental dissemination of the GMO products.
6. Isolation of the area exposed to dissemination of the GMO products.
7. Emergency plans for the protection of human health and the environment in case of undesired and adverse impact related to a previous release of GMO.
8. Effective mechanisms required (or adopted) in case of accidental release or misuse of GMO and or their products.

Appendix 3

Risk Assessment Protocol

Risk assessment should be conducted on scientific basis, taking into consideration transparency and precaution principle.

Risk assessment will be conducted on a case-by-case basis, employing all the available information that may vary from one product to the other.

Lack of information does not mean there is no hazards in association with the release.

An assessment of the risks to human health and the environment associated with the use of GMO should be based on the following considerations.

A – General Principles:

The following parameters should be considered for conducting risk assessments.

1. Coordination of the existing manpower, gathering related scientific information for the assessment of risk.
2. General characteristics related to the organism with novel trait, the recipient, parental, host and the vector that used for the transformation. Information on the genetic transformation and the new introduced character.
3. The intended use of the GMO and the characteristic of the receiving environment.
4. Anticipating effects of the GMO on the environment.
5. Expected hazards of the organisms on human health.
6. International organizations interested in biosafety are good sources of information for risk assessment conducted in other similar situations.

B – information related to characteristics of the donor, recipient and parental organisms:

1. Name and identify of the organisms,

2. Characteristics of the related organisms from which the organism with novel trait is derived.
3. Taxonomy status of: organisms involved in the transformation.
4. Relevant biological characteristics (e.g.): pathogenicity, toxicity and allergenicity in case of microorganisms, it should be noted that there are internationally accepted classification lists for human pathogens, similar lists exist for plant and animal pathogens.
5. Geographical origin of the donor, recipient, and the parental organisms (when known).
6. Natural habitat and the geographic origin of the organism, its distribution, and its role in the environment.
7. Types of mechanisms by which organisms survives multiplies (sexual / asexual) and dormant stages.
8. Date and means for transfer of genetic material to other organisms [donor and recipient organisms] and the organism with novel trait.
9. Important genetic markers.
10. Mechanisms of survival, persistence and dissemination in the environment.
11. Factors influencing gene stability of GMO.
12. The potential of any organism in the receiving environment to receive genes from the released modified organism.
13. Infectivity to human and animal.
14. Virulence, infectivity, and toxicity of these organisms.
15. Known toxicity of metabolites and chemical products of these organisms.
16. The available remedy or therapy for infectious diseases that may be caused by these organisms.

C- Information related to the characteristics of the vector (vectors):

1. Identity and origin of the vector.
2. Genetic map of the vector, site of fusion of genes involved in the transformation. Sequences of coding and non-coding segments, and sequencing of the genetic markers.
3. Potential for pathogenicity
4. Natural habitat and geographical distribution of the vector.
5. Potential for hazards to human health, animal and to the environment.
6. Appropriate measures to avoid adverse effect.
7. Mechanisms of survival and persistence in the environment.
8. Vector-host specificity and stability.
9. Potential for persistence in a non-target hosts and persistence in the environment.

D- Information related to characteristics of GMO:

Analysis of this information should base on comparing the GMO and parental (original) organism, focusing on the following points:

1. Detail description of changes occurred due to the use of gene technology.
2. Detail description of genetic changes and or inserted genes, including gene markers.
3. Objective of the transformation specifying the planned use and needs for it.
4. Methods and techniques employed for the transformation in case of GMO
5. Location of genes (linked or on different chromosomes)
6. Number and structure of the inserted segments and colonization potential.
7. Gene product of the inserted genes and its levels or degree of expression.
8. Gene stability of the inserted gene.

9. Metabolic processes and the concomitant biochemical changes in the genetically modified organism compared with the original organism.
10. Possible gene transfer (horizontal or vertical) to other varieties.
11. Characteristics of the expressed proteins.
12. Description of the techniques used for identification. Base sequencing of the inserted material and the vector used in the transformation.
13. Quantitative determination of specificity and levels of significance of techniques used in the process of identification and sequencing of the inserted genetic materials.
14. Health parameters or priorities.
15. The ability of these inserts in combination with other viruses, plasmids and bacteria to become a potential infectious.
16. Considering the origin, toxicity, pathogenicity and other unintended effects, or unexpected effects.
17. Comparing ecosystem of both original and modified organisms.
18. Comparing susceptibility to infectious diseases and parasites of both original and modified organism.
19. Sufficient information of previous use of this organism including results of the research and experimental trials prior to the suggested release.
20. History of previous gene transformation or alteration.
21. Description of gene characteristics involved in prevention of or minimizing dispersion of genetic materials.

E- Supply of information related to human and animal health:

In case of organisms (GMO) which have infectious activities, the required information should cover all data on the modified organism and data of the induced genetic alteration. It should also include characteristics of the donor, recipient and vectors used before being deactivated.

1. Diseases and mechanism of infection (infective), host range, virulence characteristics or activity.
2. Spread by infection.
3. Doses that can cause infection.
4. Host range and degree of adaptation.
5. Ability to survive outside the host (human or animal bodies).
6. Potential for mobility.
7. Biological stability.
8. Allergenicity.
9. Existence of suitable therapy.
10. Potential of the GMO for infection compared to other organisms (recipient, donor, and origin).
11. Antibiotic resistance patterns.
12. Information on regeneration processes in natural habitat and reproductive behaviors of GMO.
13. Information on survival mechanisms, formation of seeds, spones or tissues.
14. Promote virulence.
15. Host range.
16. Information on interaction with other environmental and biological processes.
17. Classification of hazards or impact according to the existing laws for the protection of human health and the environment.

F- Available information on the environment:

The required additional information related to the GMO should include all details about the

donor and recipient organisms as well as information on the vector before having been deactivated or demobilized.

1. Environmental factors (parameters) affecting survival, reproduction, and dissemination of the GMO into the environment.
2. Existing techniques (technology) for identifying, determining and monitoring the GMO.
3. Existing technologies (technology) for determining gene transfer from the GMO into other organisms in the environment.
4. Known and anticipated suitable habitat for the GMO.
5. Description of the expected ecosystem most likely to be affected by the accidental release of GMO.
6. The likelihood interactions of GMO with other organisms and ecosystem in case of accidental release of these organisms.
7. Known and anticipated (expected) effects on plants and animals in the environment e.g. infection, toxicity, virulence activity, pathogenicity, allregencity, and persistence.
8. Expected interference with the cycling processes of elements.
9. Information on the existence of proper procedures to overcome and clear all hazards or impacts in case of accidental release of GMO.
10. Expected impact on traditional cultivation, and other adverse environmental effects.
11. Size and aim of the release.
12. Geographical description of the sites of release.
13. Proximity of the site to human dwellings and activities.
14. Methods and ways of release.
15. Training of the personnel working in this field.
16. Expected climate during the release.
17. Post treatment for the site of the release and plans for waste management.

G- Information related to the use of GMO for biological control purposes:

In addition to the general information required there are other parameters to be considered:

1. Expected interaction of the GMO used for biological control with target organisms, non-target organisms (including the parental organism and its progeny) and other effects on the ecosystem.
2. Identification of the host range to anticipating mechanisms of interaction between GMO used and other non-target organisms.
3. Other possible effects on target organisms (predators, and parasites).
4. Secondary metabolites produced by the GMO and there impact or effects on other organisms and on food chain (nutrient cycle).

H- Information related to the use of GMO for bioremediation:

In addition to the general information required, there are other information to be supplied related to: (e.g.)

1. The effect of the progeny on the involved fermentation processes.
2. The effect of the GMO on the involved fermentation processes.
3. Effect of metabolic byproducts of GMO on other living organisms present in the site of the release.
4. Impact or effect of the GMO on quality of water, air and soil standards.
5. Toxic effects caused by ingestion of GMO by other organisms.
6. Spread of GMO in the site of release and related consequences.
7. Information on the geographical description of the site of the release, and the potential of the receiving environment.
8. Proximity of the site of release to human activity, fauna and flora.

9. Possible impact associated with the release of GMO, on animals, plants and other ecological systems. These information are expected to include data on rare, endangered, endemic, target, and non-target species.
10. Potential for horizontal gene transfer to unrelated species.

I- Information related to Socio-Economic consideration:

1-Expected changes in Socio-economic patterns associated to the introduction of GMO and for its products into the environment.

2-Anticipated threats to biological diversity, traditional crop cultivation, and other products, especially plant variety known by farmers and sustainable cultivation related to the introduction of GMO into the environment.

3-The possible socio-economic problems that may be experienced due to replacement of traditional crops and products with other products of the new biotechnology even outside its normal geographical ranges.

4-The expected social disruption and economic drop due to the loss of genetic diversity, unemployment and marketing, and all life activities that may be affected by the introduction of GMO and its products into the environment.

5-The possible disruption of social life in the effaced communities.

6-The possible effects contradicting social forms, local traditions and religious believe as a consequence of the use of GMO and its products.

Appendix 4

Risk Management

Risk management is employed in a systematic fashion during the development and evaluation of the organism. Risk management started from the experimental phase, through stages of field testing, to commercialization.

A) General Precautions:

1. Appropriate information and training is provided for personnel involved in handling the organisms.
2. Monitoring procedures are applied in such way that appropriate measures can be taken in case of unexpected effects during or after the release.
3. Controlling the dissemination of the released organisms and / or gene flow from the released organisms.
4. Controlling access to the site of release.
5. An official permit from the controlling authority is always required prior to all trials, experimental, and monitoring stages involved in the production of genetically engineered products.
6. An official permit is necessary prior to each experimental release.
7. Implement appropriate monitoring procedures for the released GMO and prepare emergency plans in case of an unexpected release of GMO.
8. Disposal of the GMO, at the end of each trial or release, under safe and controlled conditions.

B) Precautions required in case of plants:

Risk management measures for controlled release include:

1- applying reproductive isolation by :

- Spatial separation.
- Temporal separation: use of plants that will flower either earlier or later than plants of near by reproductively compatible species.

- Biological prevention of flowering (e.g. by omitting vernalization).
- Remove of the male or female reproductive structures.
- Bagging of flowers.
- Making use of sterility.

2- Controlling the persistence or dispersal of reproductive structures such as propagules or seeds.
3- Destroying volunteer plants after harvest; control of volunteers may be necessary during longer periods, depending on the species.

C) Precautions required in case of animals:

1. Confining by appropriate means such as, fence, filters, islands, and ponds.
2. Applying reproductive isolation by using sterile animals.
3. Isolation from feral animals of the same species.
4. Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.
5. The controlling authority should examine thoroughly all related reports about any prior release of the same product conducted in countries other than the center of origin, focussing mainly on procedures adopted in these prior releases to ensure ultimate safety of the products.
6. Risk and safety assessments of GMO experienced in other countries can help in determining the degree of confinement or containment.
7. All controlled releases are only permitted in contained environmental, climatic, nutritional and other conditions suitable for monitoring physiological functions, dissemination of the released organisms and control of gene flow from the released organisms.
8. Risk management measures for controlled release should be commensurate with the risks identified. Preparation of emergency plans that will be implemented in case of any unexpected release of GMO.

D) Precautions required in case of micro-organisms

1. Using organisms with impaired ability to grow or persist in the environment.
2. Minimizing gene transfer by using organisms that do not contain known self-transmissible, mobilizable or transposable genetic element, and ensuring that the introduced traits are stable and well located on the chromosome.

Annex B

The National Environmental Action Plan

Volume 2: Agenda for Action in the 21st Century

Thursday, 24th October, 2000

SUMMARY PRESENTATION

Section Five: Addressing Global Environmental Issues

5.5 BIOSAFETY IN THE EXPLOITATION OF BIOTECHNOLOGY

A. INTRODUCTION

Range of Biosafety Issues:

Biosafety is concerned with *measures aimed at protection of the human environment from potential injury or damage resulting from biological entities.* The classic concept of biosafety related to control of the spread of infectious diseases and pests of humans, animals and plants in the environment and comes under the purview of specialized executive bodies of government. More recently it has become also concerned *with introduced exotic species of plants and animals, which may disturb economic bio-productive systems or the general environment***,** and as such becomes also an environmental concern. *In current terminology, however, "biosafety" refers to a question which evolved only since the early 1970s with the introduction of "genetic engineering" techniques (modern biotechnology) and thence the development, testing of "transgenic" organisms that are foreign to the natural environment*. As such, biosafety started as a concern over unintentional escape of transgenic organisms from laboratories during research and testing, the possible harm that they may cause to the environment, including human health, and over regulating these aspects by appropriate reporting, containment and management procedures**.** *In the mid-1990s the concern became more acute when modern biotechnology products became commercially available for consumer use in large quantities and in international trade.* International concern dictated the need for an International Protocol as part of **the Convention on Biological Diversity (CBD**) to regulate trans-boundary movement of such products A protocol was drafted in January 2000 and has been so far signed by over 80 countries members of the CBD under the

name**: The Cartagena Protocol on Biosafety**. In 1992, Egypt signed the ***CBD*** ratified it on 2 June 1994. Egypt also ratified the Protocol in December 2004

Biotechnology: Classic and Modern:

Biotechnology is defined as techniques that use living organisms or sub-units from these organisms. The aim of this technology is to improve quality and products needed for different aspects of life for the welfare of humanity. Biotechnologies are both multi-sectoral and multi-disciplinary in nature. The successful development and application of biotechnologies thus requires careful co-ordination among many disciplines. *Modern biotechnology* is a technology developed during the past 30 years, which promises to revolutionize the patterns of economic development in the 21st Century. The central material for modern biotechnology are the so called *"Genetically Modified Organisms" (GMOs) also referred to as "Living Modified Organisms "(LMOs).* These are organisms developed in the laboratory, using molecular biology techniques, which break natural barriers between species, genera, families and even biological kingdoms, and hence can not develop in nature. Many non-living processed products of GMOs retain the unique laboratory-developed genetic material and hence may be regarded as equivalent to living GMOs. Potential applications for biotechnologies are broad: in pharmaceuticals and health care, in food and agriculture, in environmental protection and management, and in industry. Modern biotechnology has great potential for human wellbeing if developed and used with adequate safety measures for the environment and for human health. Countries that may fail to exploit the technology will suffer severely in terms of lost income and export potential.

Possible Risks of the Release of Biotechnology Products:

Like any new technology, biotechnology is not without its specific risks. Fortunately, however, consideration of risk took place side by side with the development of the technology. Again fortunately, many such risks could be eliminated, or be made acceptable in terms of cost benefit analysis, with proper regulation of the use of biotechnology products and its release into the environment. The possible risks of the use and release of GMOs and their processed products are focused on:

1. Risks to the biological diversity in the environment which are often irreversible. This becomes even more relevant in centers of origin and centers of genetic diversity, such as Egypt.
2. Risks to human health.
3. Risks to the socio-economic integrity of a community, *(exaggeration of discrepancies between small and large producers and between the poor and the rich),* and
4. risks to the political sovereignty of a country ***(****loss of cash or export market to a new GMO product or dependence on imported packages)*.

Safety is achieved through the provision of transparent information on the product and the process and conducting adequate risk assessment and risk management by the regulatory authority in the receiving environment.

Exploitation of Biotechnology in Egypt:

In Egypt's quest for increasing food production and to overcome significant constrains of agricultural productivity, the country embarked on the development and application of relevant biotechnologies. In addition, the country is in the process of acquiring

biotechnologies and biotechnology products developed elsewhere. This has led to plans for the release and commercialization of GMOs into the environment. However, a major issue that will affect and impede national efforts towards the transfer and application of biotechnology is the lack of a comprehensive regulatory climate governing:

(i) The safe development and application thereof;

(ii) The safe transfer (including during importation) and use of its products and, in particular,

(iii) The intentional release of GMOs into the Egyptian environment.

Lack of national regulations could seriously impede international trade in these commodities and the Cartagena Protocol states that "environment and trade should be mutually supportive for achieving sustainable development".

Biosafety in the exploitation of Biotechnology, Through Regulation:

Three cardinal principles govern the regulation system. The first is the application of the *Precautionary Principle* adopted at *the Rio Earth Summit* in 1992 (Principle 15 of the Rio Declaration on Environment and Development) which requires caution in application of actions which could have serious long term impacts on the environment unless there is solid proof of the absence of possible harm. The second is recognition that GMOs are distinct and intrinsically different from natural organisms because they did not develop in harmony with the environment and because their behavior can not be predicted with certainty hence require specific regulation. The third is the right of the community to know the source of the material being made available through appropriate segregation and labeling of GMOs.

Accordingly, the regulation system must be a specific legislation to be introduced by the executive structure entrusted with environmental protection. It applies only to GMOs and products thereof, and requires environmental approval before application of other regulatory requirements, which apply to both GMOs and non-GMOs. The legislation would call for prohibiting intentional release of GMOs, before being approved, by a special committee established by the Ministry of the Environment in which the Ministries of Health, Agriculture, Industry, Trade, Higher Education, Justice and Scientific Research and of Foreign Affairs designate members with appropriate expertise. The committee also establishes an executing body with the responsibility of following up implementation of the permit and ascertaining adherence to its conditions.

B. PROGRAMME AREAS

5.5.1 REGULATION OF THE HANDLING AND UNINTENTIONAL RELEASE OF BIOLOGICAL MATERIAL WITH POTENTIAL ENVIRONMENTAL RISKS

BASIS FOR ACTION

Current regulations on the handling of biological material that may constitute an environmental hazard were designed specifically at personal or public human health protection or at the protection of economic plants and animals. The scope of environmental hazards has expanded to cover broader environmental impact on genetic diversity and ecological balance. The scope of biological material too has expanded beyond disease-causing organisms into bio-entities such as vectors, introduced exotic species, strains and varieties. Moreover, research into such biological material and especially into "transgenic" organisms through molecular biology and

genetic engineering techniques may have surpassed current legislation. Often legislation and regulation has not been up-dated for tens of years becoming far removed from current scientific knowledge and practice, has become obsolete or has become less rigorously enforced with geographical and sectoral practice multiplied many times. With the increased size and means of mobility of people and material within the country, and across international borders, national environmental impacts acquired global dimensions and this trend promises to continue expanding.

OBJECTIVES

1. To protect workers handling potentially hazardous microbial and other biological material and pests (and their vectors) for humans, plants, animals and the surrounding environment from unintentional spread of such material.
2. To protect biological diversity and ecological balance from possible disturbance due to introduced exotic species, strains or varieties of plants, animals and microorganisms.
3. To protect biological diversity and ecological balance from possible disturbance due to unintentional release of genetically engineered elements derived from plants, animals or microorganisms during research, testing and contained field trials.

ACTIVITIES

1. To collect current legislation and regulations governing the handling and unintentional release of the three categories of material listed under the objectives.
2. To analyze the suitability of the legislation and regulations collected in fulfilling the objectives taking current state of scientific knowledge into account and to identify gaps and needs for adjustments.
3. To draft suggested adjustments of and additions to current legislation and regulations, along with enforcement mechanisms, and to sponsor its approval.

The output of the activities is a set of modernized legislation and regulations which respond To current environmental concerns. The outcome is a higher level of protection for biological diversity, the health of the environment, of people and of bio-productive systems.

MEANS OF IMPLEMENTATION

Responsible Parties and Finance:

Ministry of Environment as a coordinator and Ministries of Health, Agriculture, Higher Education, Scientific Research, Finance, Trade and Industry as responsible executing bodies. The program can be financed through donor assistance programs to Egypt in the field of biological diversity, health and agriculture. Beneficiaries can also incur portion of costs to finance this program. The experience of other countries in regulation should be sought.

Human Resources and Capacity Building:

Physicians, plant and animal protection experts, biologists, microbiologists, geneticists, legal, public health, customs, quarantine and trade experts, and technical support staff will receive training to fulfill their respective duties for the successful implementation of the proposed regulation. There is a need for establishing reference laboratories that are capable of testing and certifying material and of certification of facilities in conformity with the regulations

5.5.2 REGULATION OF INTENTIONAL RELEASE OF GMOs INTO THE ENVIRONMENT TO PROTECT BIOLOGICAL DIVERSITY AND HUMAN HEALTH, AGAINST POTENTIAL HAZARDS

BASIS FOR ACTION

While Egypt ratified the CBD and the Cartagena Protocol on Biosafety, current national legislation does not recognize that being a GMO makes an article different, requiring specific declaration, labeling, handling or treatment, while the international market is abound with such products in health care, food, agriculture, raw materials and industry. Environmental Law 4/1994 makes no mention of GMOs altogether. .Accordingly a domestically produced or an imported GMO could be legally released into the environment and consumed by people and animals with neither notification nor labeling. In addition to the risks this may present to the environment and to the health of people, lack of national legislation could negatively impinge on obligations under international law, hinder international trade, and leave Egypt as a dumping ground for risk-loaded biotechnology products. In 2000, the EEAA, with financial support from UNEP, produced a framework for a national biosafety instrument, including a draft legislation, which has been reviewed by the Ministries of Foreign Affairs and Justice but still needs further review and refinement before it could be sponsored by the Ministry of Environment for legislative consideration.

OBJECTIVES

1. To conform to obligations under international law and to avoid conflicts with Egypt's trade partners.
2. To protect biological diversity from possible risks due to intentional release of GMOs and their products into the environment, and hence promote the participation of Egypt in safely harvesting the fruits of modern biotechnology.
3. To protect the health of people without unnecessarily hindering the application of modern biotechnology products safely in the environment, and to promote the safe use of modern biotechnology in environmental management

ACTIVITIES

1. Outlining and implementing a series of actions so that Egypt can make use of funding and facilities made available to Members of the Protocol – especially in the areas of capacity building and interaction with the Biosafety Clearing House mechanism.
2. Review and analysis of legislation and regulations on which the intentional environmental release of GMOs would have an impact, and of the report of the EEAA on the Biosafety Framework and the Cartagena Protocol on Biosafety. Identification of elements of the Framework which need to be further polished in light of current state of the art on the subject, the provisions of the Cartagena Protocol on Biosafety, and the OAU suggested legislation.
3. Outlining and implementing a series of actions which would lead to a consensus on the draft national legislation currently available at the EEAA, especially through circulation to stakeholders for opinions and views, through involvement of the Media, through public hearings and possibly through specialized workshops.

4. Establishing the necessary instruments for implementation of the proposed legislation, including training of necessary human resources and provision of reference laboratories capable of backing proper implementation of the legislation.

The output of these activities will be a legislative instrument capable of maintaining biosafety of biotechnology products along with mechanisms for its enforcement. The outcome will be enabling of Egyptian participation in safely harvesting the fruits of biotechnology and be a partner in safe international trade in GMO products without jeopardizing its biodiversity, ecological equilibrium and the health of its people.

MEANS OF IMPLEMENTATION

Responsible Parties and Finance:

Ministry of Environment as a coordinator. The EEAA as the executing body. The program can be financed through donor assistance programs to Egypt in the field of biological diversity and biosafety

Human Resources and Capacity Building:

Physicians, pharmacologists, toxicologists, geneticists, biotechnologists, molecular biologists, microbiologists, biochemists, ecologists, botanists, zoologists, computer scientists, entomologists, legal, public health, customs, quarantine and trade experts, and technical support staff will receive training to fulfill their respective duties for the successful implementation of the proposed legislation. There is a need for establishing reference laboratories that are capable of testing and certifying material and of certification of facilities in conformity with the regulations. There is also need to establish an electronic communication node to be linked to the Biosafety Clearing House of the Cartagena Protocol on Biosafety secretariat.

ANNEX C

Summary of the some of the existing Egyptian ministerial decrees impacting on biosafety

1. Ministry of Agriculture and Land Reclamation (MALR).

Egypt's effort to address environmental responsibility for products of biotechnology was set in motion in 1992 by the terms of collaboration between Agricultural Genetic Engineering Research Institute (AGERI) and the Agricultural Biotechnology Support Project (ABSP).

During the period 1993-99, the ABSP-AGERI collaboration supported biosafety awareness and implementation with a series of internships, consultations and workshops. Around 10 AGERI scientists and managers have attended a biosafety internship program at Michigan State University. In 1993, one of them was assigned the full-time responsibility of drafting biosafety guidelines for laboratory, greenhouse, and field experiments with GMOs. To further biotechnology research at AGERI, the ABSP project supported construction of a bio-containment greenhouse facility completed in 1995.

Egypt's biosafety system was formally instituted by MALR in two decrees issued early 1995. Ministerial Decree No. 85 (January 25, 1995) establishes a Biosafety Committee (BC), later re-designated National Biosafety Committee (NBC); Ministerial Decree No. 136 (February 7, 1995) adopted biosafety regulations and guidelines for Egypt – all being under the Central Administration for Seed Testing and Certification (CASC).

The system touches on several ministries, organizations, and/or government agencies involved with the importation, exportation, and local production of natural products. Within the MALR, the CASC controls, tests, and registers new plant varieties. In the Ministry of Health, the Supreme Committee for Food Safety ensures the safety of food production and consumption and controls food import permitting. The National Organization for Drug Control and Research oversees pharmaceutical quality control. The Ministry of Trade and Supply controls the import and export of products. In the Ministry of Industry, the Egyptian Organization for Standardization and Quality Control sets the standards for food and industrial products whether imported or locally produced. The Ministry of Environment, through the Egyptian Environmental Affairs Agency (EEAA) ensures implementation of the Environment Protection Law No 4 0f 1994 in Egypt.

Developers of the biosafety system adopted an approach in which components were added only as they became necessary. For example, testing requirements for GMO seed certification were not clarified until the first applications for release were submitted to the Seed Registration Committee. Similarly, no decisions on the labeling of GMO-based food products have been made, as those products are not yet being sold in supermarkets.

Guidelines

Biosafety regulations and guidelines were published in draft form in January 1994 by the MARL . Research materials from the ABSP-AGERI collaboration were nearing completion of greenhouse tests, providing impetus to move forward with developing biosafety policy and procedures for conducting GMO field tests. The first guidelines were adopted under the CAS by Ministerial decree No. 136 The guidelines were intended to describe the modalities of use, handling, transfer, and testing of GMOs; they address laboratory practices, greenhouse containment, and small-scale field testing.

The guidelines describe the structure, composition, roles, and responsibilities of the NBC. NBC duties include formulating, implementing and updating biosafety guidelines; conducting risk assessments; issuing permits; coordinating with national and international organizations; providing training and technical advice; and, reporting to governmental authorities.

The guidelines call for establishment of an Institutional Biosafety Committee (IBC) at all institutions conducting recombinant DNA (r-DNA) research. The IBC is responsible for establishing a facility inspection program; assembling a set of appropriate institutional guidelines that comply with the NBC guidelines; assessing facilities, practices, and procedures; periodically reviewing r-DNA research being conducted in the institute; adopting emergency plans for accidental spills and personnel contamination; periodically reviewing containment measures; overseeing IPR matters as they apply to the institute; and reporting annually to the NBC. Since the NBC was established by MALR decree under the seed certification act (and not by a national legislation), it is not legally binding to the handling of GMOs not intended for seed certification, even with respect to laboratory research and field testing of seeds if there is no announced intention to apply for seed certification. In addition, it is not sufficiently comprehensive with regard to procedures and does not mention penalties for not abiding by the decree. As a result, the vast majority of r-DNA research and testing in Egypt does not report to the NBC and IBCs exist only in some, not even all, MALR institutions. Universities and research institutions are largely unaware of the existence of a NBC.

Egypt's National Biosafety Committee is the official body responsible for ensuring that biotechnology products are used safely. Members of the NBC are appointed by the Chair, the Minister of Agriculture and Land Reclamation. Terms of service are open-ended, thus the committee now includes some members with five years experience.

The initial committee consisted of 10 members; subsequent appointments have expanded it to 30. Current members include: seven representatives, in personal capacity, from the Ministries of Agriculture, Health, Environment, Industry, and Commerce, the Egyptian Academy of Science and Technology; 12 members from academic institutions; an attorney; eight people from government research institutes; and a seeds expert. Based on area of expertise, members are appointed to one of three subcommittees specializing in agriculture (crops), environment (bio-pesticides, bio-fertilizers, agents for bioremediation), and health (pharmaceuticals, human and veterinary vaccines) but these subcommittees hardly hold any activities or meet. The NBC does not meet regularly and on the average meets about once a year

IBCs are to be composed of people with expertise in r-DNA technology, biological safety and physical containment, policies and applicable law, and a biological safety officer (BSO). The BSO reports to the IBC regarding follow-up on his duties, which include enforcing approved policies and regulations; ensuring that all facility standards are rigorously followed; ensuring safety of all facility work and prevention of the accidental escape of GMOs; maintaining data on all aspects of biosafety related to mandated crops; checking and advising on biosafety issues on a day-to-day basis; and monitoring worldwide biosafety requirements for r-DNA technology. In practice, BSOs rarely communicate with the NBC.

The Review Process

A standardized Permit Application form (see later) is used to request NBC approval of a proposed greenhouse study or field test. Upon submission of the application, all members of the appropriate subcommittee are expected to be given copies and one member is designated the Principal Investigator. The Principal Investigator, who may consult with other subcommittee members, is assigned to thoroughly review the application, visit the field test location, inspect the facilities, and submit a report to the NBC. The proposed release is then discussed at a meeting of the full NBC, where a decision is made to issue or deny the requested permit. Where a Committee member is the applicant or had been involved in the research leading to the GMO to be considered, that member does not vote on the application.

Approval may stipulate certain conditions or practices during field tests that the NBC deems appropriate to the proposed release. For approved tests, the Principal Investigator advises institutional staff regarding standard and specific biosafety practices and techniques. Because of lack of a secretarial arrangement, the applications are in practice submitted directly to the NBC when this may meet.

PERMIT APPLICATION FORM
NATIONAL BIOSAFETY ANNEX-FORM (Submit this Annex with form)
Application No:-..... Form No:- .....

PERMIT APPLICATION FOR GENETICALLY MODIFIED ORGANISMS (GMOs)
Applicant
Names:-
Address:
Telephone #:-.....

"X" one of the following in these corning questions:Permit request for:-

Permit for:

Limited movement
Limited importation
Release to green house
Release for small-scale trial

Genetically Modified Organism
Exotic materials
Transformed biological agent
Others (specify on a separate pier)

Means of movement:-
Mail

Common carrier Baggage or handcarried

New permit
Renewal permit
Supplemental
Date required for importation, movement or release:-.....

Country of origin of regulated article:-... ....

Arrival destination of movement:- ... ...

Number, quantity or volume or regulated article: .....

Any biological material accompanying the regulated article:-.....

Signature of applicant Date

Procedures for field tests: Applications to field-test GMO plant material are submitted to the Chair of the NBC. Genetically modified material to be imported requires an import permit that must be obtained in advance from the Supreme Committee on Food Safety, Ministry of Health but there is no formal coordination with the NBC. Requests should be made a minimum of eight weeks prior to the proposed initiation of the importation or field test.

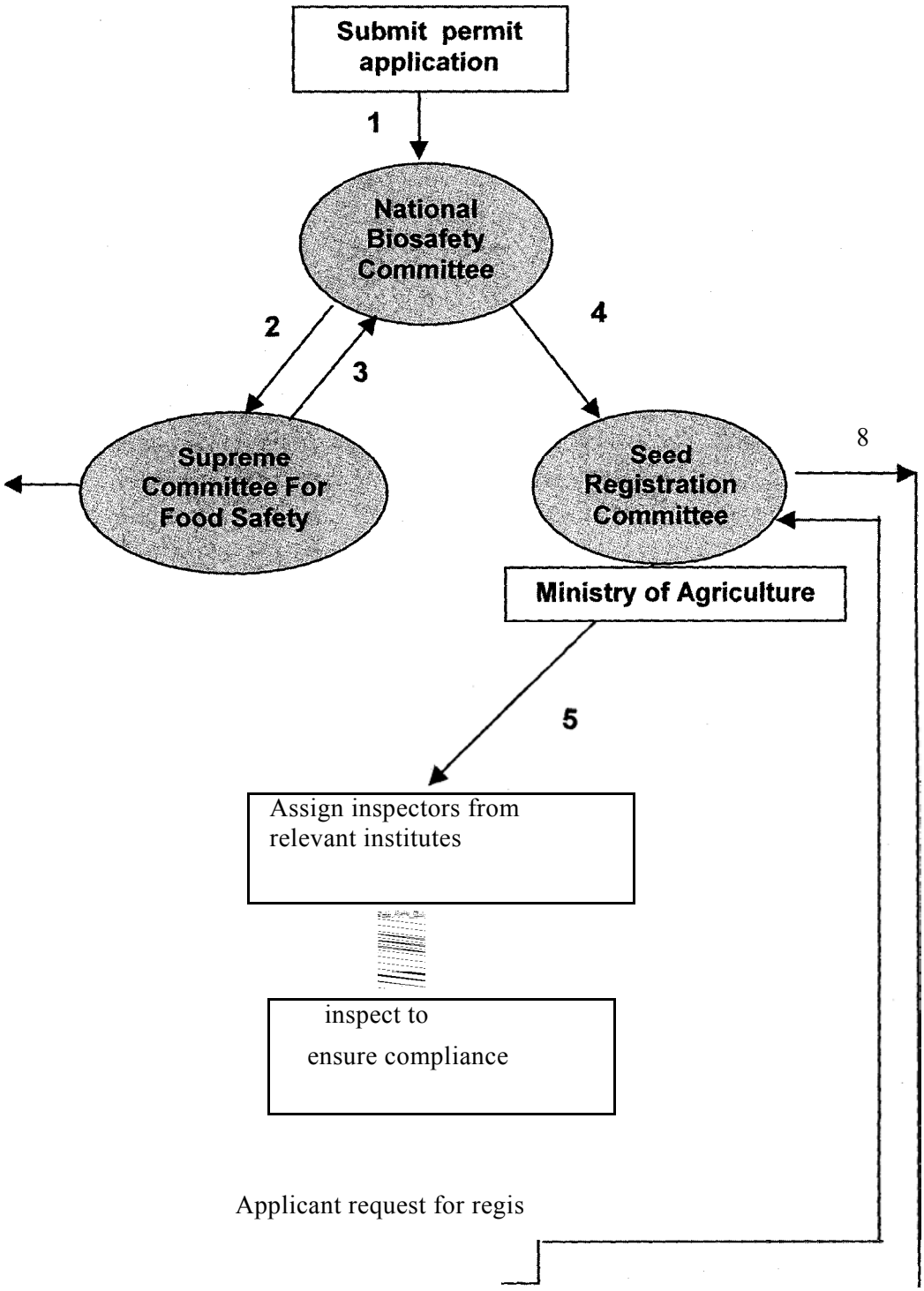
It is stipulated that the NBC, serving as the lead agency, sends duplicate copies to secondary agencies for their assessment (i.e. Supreme Committee on Food Safety), as applicable. Reviews from the secondary agencies are returned to the lead agency, and a final assessment performed. From this a decision is made whether to authorize the field test. Any mitigation procedures required will be determined before authorization. Applicants are required to indicate which information the application is confidential, such as exact trial sites, plasmid maps, exact genetic change, or others to be specified. Other information may initially be designated confidential; however its confidentiality is subject to provisions in the Access to Information and Privacy Act.

Field-test permit applications must describe the plant species modified to exhibit a specific trait, to be tested at a specific location in a specific year. For instance:

- Canola (B. *napus)* lines, one modified to show tolerance to a specific herbicide resulting from the insertion of one specific gene, and another modified to show tolerance to certain insects by the insertion of the delta endotoxin gene from *Bacillus thuringiensis,* both of which will be tested in a small-scale field trial at one location in one year, are considered as two field tests. A separate assessment is made on each of the two different genetic constructs.
- Canola modified to be resistant to a specific herbicide as a result of one specific gene, to be tested for agronomic performance in small-scale field trials at six locations in the same year, will be considered as six field tests. The same modified canola to be tested at the same six sites over two growing seasons will constitute twelve field trials.

Procedures for commercial releases: Procedures for ”commercializing” GMO crops were established in 1998 by Ministerial Decree No. 1648. The sequence of steps and interactions among government agencies are diagrammed in the flow chart on the following figure.

Steps for “Commercial” release of GMO plants.



For varieties produced within Egypt, the process is as follows:

I. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, and other relevant information. The applicant also provides data from food and feed safety studies and evidence supporting a determination of "low or negligible environmental risk". Where applicable, the applicant provides documents indicating approval of similar GMOs for release in "their country of origin".
2. The application form is submitted to the NBC, which, after examination and approval, forwards it to the Seed Registration Committee for their preliminary approval to proceed with standard field trials conducted at several locations. The SRC assigns a team of qualified inspectors drawn from relevant Agricultural Research Center units (even if the applicant is an ARC unit) and/or private certified laboratories (which the decree did not designate yet) to supervise cultivation, ensure adherence to any biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.
3. The NBC has the right to confirm the nature of the genetic modification by taking samples from the field for molecular analysis, but refernece laboratories have not yet been designated.
4. After successful completion of the field trials and submission of a report to the NBC, the NBC authorizes the applicant to submit an application to the Seed Registration Committee for final approval to "commercially release" the new variety presumably for cultivation. Pending this, three years or seasons of agronomic performance trials are conducted under the supervision of the SRC in order to confirm that the new variety is at least 15% agronomically superior to existing ones (this requirement in fact applied to all new varieties whether GMO or not).

The process for securing "commercial" release approval for crops genetically engineered outside of Egypt has an added step. The applicant must first obtain a permit for importing the initial seed material from the Supreme Committee for Food Safety, Ministry of Health. Their are no set procedures or regulations at that Committee specifically focused on GMOs. The EEAA is not involved in the process. The permit is then presented to the NBC and the Seed Registration Committee, after which the seed is imported into the country. From this point forward, the remaining steps in the approval process are exactly the same as for GMOs developed within Egypt.

Data from local and external field tests, findings reported in the scientific literature, reports from risk assessment studies, and proceedings from conferences and workshops are among the potential sources of feedback into the biosafety system. Currently, acquisition of this information is an individual activity on the part of some applicants and biosafety committee members.

In Egypt, approval by the NBC to conduct a field test does not require the applicant to submit a report at its conclusion. During seed registration trials, monitoring is carried out by an appointed team of inspectors. As the purpose of the trials is to evaluate variety performance, monitoring is conducted primarily to ensure compliance with biosafety requirements, not to collect biosafety data.

Most NBC members and scientists at AGERI and other ARC institutes have at least some form of Internet access. Whether or not people retrieve and use the available information, however, is a personal decision based on the individual's ease of connection, amount of access time, familiarity in navigating the Internet, and degree of interest.

Decree No. 1648/1998 of the MALR confirms the authority and responsibility of CAS for releasing GM as well as conventional seeds. It describes procedures for obtaining a small-scale release permit for a new genetically engineered crop variety, registering it, and releasing it for "commercial" use. It outlines important steps to be followed by government or private sector applicants, as well as other local or foreign organizations seeking to commercialize their products. The decree specifies the roles and responsibilities of the NBC, the Seed Registration Committee, and the Committee for Food Safety. A draft paper outlining the protocol for "commercial" release of GMO crop varieties was developed by a panel of experts from MALR and the USAID. The final document was approved by the Minister of Agriculture in July 1999.

Decree No. 702/1999 of the MALR adds DNA fingerprinting to the required protocol for registration of all new agriculture crop varieties in order to confirm identity during the registration process and for subsequent use as a reference, if required. The decree stipulates that:

- DNA fingerprints of the new hybrid variety and its parents are a prerequisite for registration. One copy of the fingerprint is to be kept in the secretariat of the Seed Registration Committee and another copy is to be kept in the management office of the applicant's institution.
- The relevant crop technical committee should verify the fingerprint and its specifics through a laboratory "certified to have the required scientific and technical capabilities".
- The applicant is to pay all costs required for the finger printing process, as determined by the registration committee for agricultural varieties. Sample material is to be submitted to the SRC secretariat, which will pass it to the relevant "certified lab".

IPR in Egyptian Agricultural Research Institutes

Egypt's Law 132 of 1949 on Patents, Designs, and Industrial Models includes an explanatory memorandum that states that the word "industrial" includes the use of patents in agriculture. However, the memorandum excludes inventions of foodstuffs and pharmaceutical compounds, which encompass many genetic engineering applications, since the law allows only 10 years' protection for these. A recently proposed change to the IPR law expressly states that it applies to agriculture, foodstuffs, plant species, and microbiological processes and their products. Thus agricultural products and processes would be subject to protection as they are patentable subject matter.

According to patent records held at the Academy of Scientific Research and Technology, only one patent has been granted to Egyptian scientists in the field of agriculture. It was issued to scientists from AGERI for a microbiological insecticide gene isolated from a strain of the soil bacterium Bacillus *thuringiensis i*solated in Egypt. The patent is the first to be obtained in Egypt for a biotechnology or molecular biology related product.

AGERI has recently drafted a proposed policy for handling IPR within the institute. The draft includes a statement of general policy clarifying assignment of IPR to AGERI; circumstances in which AGERI would release IPR to the inventor; and principles for handling royalties resulting from the licensing of protected IP.

In the proposed policy, the institute will hold all rights and title including, but not limited to, any disclosed invention, discovery, trade secret, technology, scientific or technical.

2. Ministry of Health decree

Decree No. 242 for 1997 was issued by the Ministry of Health and prohibited the import of any foodstuff produced through the use of GMOs "unless safety is confirmed". It also required that any imported "seeds" be accompanied by a certificate from the country of origin confirming that these "seeds" were not produced from "untested GMO crops". Again it did not specify procedures, responsibilities, enforcement or penalties and did not mention how to deal with locally produced foodstuf or "seeds". Since it is not a national legislation it is not explicitly and directly binding to other govertnemental bodies other than the Ministry of Health.

3. National Environmental Protection Law

This is covered by Law No. 4 of 1994, promulgamated well before the issues of GMOs were considered, and has not been ammended since. Article 2 stipulates that "The Prime Minister, upon proposal of the Minister concerned with environmental affairs and after consultting the EEAA shall issue the Executive Regulations of the Law within 6 months from the date the Law comes into force" and the "Ministers, each in so far as he is concerned, shall issue the rates and percentages necessary for implemeting the provisions of Part I of the Law within the same period". The law consisted of: a preliminary part of 4 chapters (articles 1-18), Part 1 on protection of land environment (articles 19-33), Part 2 on protecting air environment from pollution (articles 34-47), Part 3 on protecting water environment from pollution (articles 48-83), Part 4 on penalties (articles 84-101) and Conclusive Provisions (articles 102-104). It states that "Establishments as existing at the time of the present law is promulgamated shall harmonize their situations in accordance with its provisions within 3 years effective the date of publishing its Executive Regulations". These regulations were issued by Prime Minister`s Decree no. 338 of 1995.

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
Development Goal: **Egypt has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations**	A workable and transparent NBF is in place and in line with its international obligations and national development priorities by 2009	Report on NBF, relevant national documents	Implementation of NBF is carried out in isolation from national context and international obligations Lack of workable systems for the implementation of the NBF	Project helps identifying needs Project helps to set up systems (regulatory, handling request, monitoring, etc) which can fit the national context and international obligations
Immediate Objective 1: **To assist Egypt to have a fully functional and responsive regulatory regime in line with CP and national needs**	A finalised regulatory regime reflecting existing policies and defining all the elements of the NBF and related implementing procedures in line with CP and international obligations by 2009	Implementing regulations approved as per GMO Act Technical guidelines available Internal manuals available	Regulatory regime cannot be easily finalised because of lack of government support Regulatory regime cannot be enforced because of lack of implementing regulations, guidelines and manuals (so responsible staff does not know who is who and who does what**)** Regulatory regime cannot be enforced because of inefficiency of existing administrative structures Regulatory regime cannot be enforced because of lack of capacity of personnel in charge	Develop implementing regulations as per GMO Act, Develop tools and training for translation of legislation into practice Provide training for legal experts Promote cooperation and exchange of information throughout government structure
Outcome 1.1 **Draft Biosafety Law on use handling release and placing on the market of locally produced or imported genetically engineered organisms and products into the environment adopted and in place; Executive Directive Regulations drafted, finalised, adopted and in place; ministerial decrees related to biosafety revised and reviewed; analysis on how best to regulate the contained use and confined release of genetically modified organisms is carried out and regulations for legal actions described**	By 2009, Egypt is in compliance with ICCP list Compliance with other related international obligations with the CP	ICCP list filled in and available	Regulatory regime not adequately translated into practice	Promote training on regulatory instruments related to biosafety in the country and the requested minimum compliance with CP
ACTIVITIES				
Carry out a survey of the current status of relevant existing laws and regulations, trials and release of LMOs	A survey of the current status of relevant existing laws and regulations, trials and release of LMOs and	Final report of the survey	Survey is not well structured, does not target the right audience	➢ Careful planning of the survey ➢ Careful identification of sample to analyse

and products thereof in Egypt	products thereof in Egypt			
Legal translation of the final Biosafety Law for ARE into English	Biosafety Law for ARE available in English by mid 2006	Translation of the Biosafety law	Translation is not precise	Careful identification of the translator and accurate monitoring of key words to translate
A four day workshop for 24 technical and legal experts on guidance towards the drafting of the Executive Directive Regulations based on an outline of available options for the contents of the EDR (first draft of the EDR as output	A four day workshop for 24 technical and legal experts on guidance towards the drafting of the Executive Directive Regulations organised by early 2006 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the workshop material is not satisfactory; Participants are not accurately selected; Resource persons are not appropriate; Duration of the workshop is not adequate;	Careful planning of the workshop; Careful identification of the resource persons and participants;
One four-day consultative workshop for 25 government stakeholders (representatives of the nine ministries involved in biosafety, legal experts) to discuss the first draft of the Executive Directive Regulations of the Biosafety Law and revision of the existing ministerial decrees	One four-day consultative workshop for 25 government stakeholders (representatives of the nine ministries involved in biosafety, legal experts) to discuss the first draft of the Executive Directive Regulations of the Biosafety Law and revision of the existing ministerial decrees organised by mid 2006 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the workshop material is not satisfactory; Participants are not accurately selected; Resource persons are not appropriate; Duration of the workshop is not adequate	Careful planning of the workshop; Careful identification of the resource persons and participants
Four-day consultative workshop for 25 stakeholders (legal, technical and trade specialists, legislators, managers and administrators) to review and comment on the second draft of the Executive Directive Regulations for the Biosafety Legislation of the ARE (including statutory forms for applications) and amendments to the existing ministerial decrees before finalisation	Four-day consultative workshop for 25 stakeholders (legal, technical and trade specialists, legislators, managers and administrators) to review and comment on the second draft of the Executive Directive Regulations for the Biosafety Legislation of the ARE (including statutory forms for applications) and amendments to the existing ministerial decrees before finalisation organised by end 2006 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the workshop material is not satisfactory; Participants are not accurately selected; Resource persons are not appropriate; Duration of the workshop is not adequate	Careful planning of the workshop; Careful identification of the resource persons and participants
Final drafting of the EDRs, along with the required amendments to current decrees of relevance, in proper legal language to be presented to the Prime Ministers Office for approval and translation in English	Final draft of the ERDs and amendments to current decrees available by mid 2007	Agreed decrees ; internal documents	Laws, decrees and orders cannot be finalised because of lack of public and institutional support; Internal operational manuals not available	Promote consultation with stakeholders during preparation of the regulations Prepare operational manuals, train legal officers

Analysis on the legal steps to be taken to examine the interaction with the Biosafety Law, and to regulate the contained use and confined release of potentially hazardous genetically modified organisms is carried out and indication of steps for legal actions	Analysis on the legal steps to be taken to examine the interaction with the Biosafety Law, and to regulate the contained use and confined release of potentially hazardous genetically modified organisms is carried out by mid 2007	Final report of the analysis available; steps for legal action, if any, indicated	Lack of adequate knowledge of the national biosafety legislation	Careful identification of the consultant; accurate planning of the activity
Outcome 1.2. **Increased national competence on regulatory issues is available and equipped with tools for related additional capacity building**	Planned training workshops and tools are developed and in use by 2009	Meeting documents, agenda, list of participants, evaluations of participants, records of decisions, media coverage of the meeting	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Four day training workshop for 24 officers from implementing bodies on the application and implementation of the biosafety law and the Executive Directive Regulations.	Two training courses for legal and administrative staff on the interpretation and application of the biosafety laws orders and decrees are held by mid 2007 Minimum of 80% of the invited participants attending each training	Workshop documents and post training evaluations List of participants	Quality of the workshop material is not satisfactory; Participants are not accurately selected; Resource persons are not appropriate; Duration of the workshop is not adequate	Careful planning of the workshop; Careful identification of the resource persons and participants
Preparation of a training guide on regulatory issues	Training guides on the National Regulatory Regime for biosafety produced by mid 2007 and in use by 2008	➢ Training guides on the National Regulatory Regime for biosafety available	➢ Training guides are not clear and do not cover all the issues	➢ Experts are consulted for a revision of the Training guides
Immediate Objective 2: **To have a functional national system for handling requests, performing risk assessment, decision-making, performing administrative tasks, handling, storing and exchanging information in line with the BCH requirements**	NCA(s) nominated and in place with clear distinction of responsibilities (including cases of accidental release, emergency response, illegal movement) Set of procedures for handling requests developed Number of decisions made as result of request within CP timeframe	Set of procedures for handling requests available Decisions are recorded on the BCH	System for handling requests cannot be enforced because of lack of implementing guidelines and manuals System for handling requests cannot be enforced because of lack of capacity on how to handle the request and how to perform risk assessment Lack of implementing regulations and guides	Develop tools and training on handling request (including risk assessment), transport, packaging, and labelling Specify roles and responsibilities so as to minimise inefficiencies
Outcome 2.1 **Administrative processing, risk assessment and decision-making of LMOs are set and operational**	Clearly defined entity for decision-making with clearly defined roles and responsibilities Responsibilities assigned for emergency responses, accidental release and illegal movement Clear definition of procedures for handling notification (AIA) Percentage of requests handled Review of decisions on risk assessment	➢ Decisions are available ➢ Authorities nominated and approved ➢ Staff nominated and tasks described in their job description ➢ Number of emergency cases solved Functional access to the BCH	➢ Lack of capacity on how to handle requests and perform risk assessment ➢ Inefficiency of administrative structure	Develop tools and training to build capacity on handling of requests Define clear roles and responsibilities in the institutional system to minimize inefficiencies

	Compliance with BCH obligations Simulation carried out by 2009 to test if the system works			
Activities One 5-day workshop for 8 specialists to discuss and draft protocols for risk assessment and risk management for LMOs	One 5-day workshop for 8 specialists to discuss and draft protocols for risk assessment and risk management of LMOs organised by end 2006 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the workshop material is not satisfactory; Participants are not accurately selected; Resource persons are not appropriate; Duration of the workshop is not adequate	Careful planning of the workshop; Careful identification of the resource persons and participants
Draft technical guidelines on Risk Assessment and Risk Management protocols	Technical guidelines on Risk Assessment and Risk Management protocols agreed by mid 2007	Technical guidelines for RA/RM of LMOs available	Technical guidelines are not clear and/or appropriate	Experts are consulted for a inputs and revision of the methodologies for RA/RM of LMOs
Preparation of an internal "Manual on procedures for handling requests of LMOs in Egypt"	An internal "Manual on procedures for handling requests of LMOs in Egypt" produced and finalised by end 2007	Manual on procedures for handling requests of LMOs in Egypt handling request available	The manual is not clear , not well structured and does not cover all the issues	Experts are consulted for a revision of the manual
Outcome 2.2. **Increased national competence on handling of request is available and equipped with tools for related additional capacity building**	Planned training workshops and tools are developed and in use by 2009	Meeting documents, agenda, list of participants, records of decisions, media coverage of the meeting	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Organisation of two five-day training courses for 30 participants/course (members of the implementing bodies, including representatives of civil society and private sector) on handling requests for permits, including RA/RM	Two five-day training courses for 30 participants/course (members of the implementing bodies, including representatives of civil society and private sector) on handling requests for permits, including RA/RM organised by mid of 2008 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Organisation of two five-day training courses for 30 administrative officers/course from the biosafety office and relevant Ministries, on the administrative processing related to the handling of requests (including administrative aspects related to monitoring and inspections	Two five-day training courses for 30 administrative officers/course from the biosafety office and relevant Ministries, on the administrative processing related to the handling of requests (including administrative aspects related to monitoring and inspections by mid 2008 Minimum 80% of the invited	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training

	participants attending each workshop			
Immediate Objective 3: **To have a functional national system for "follow-up", namely monitoring of environmental effects and enforcement**	➢ **Roles and responsibilities for monitoring and enforcement in place** ➢ **Set of methodologies and procedures for monitoring of environmental effects established** ➢ **Procedures for enforcement established**	➢ **Written and approved division of roles and responsibilities available** ➢ **Methodologies and procedures for monitoring available** ➢ **Procedures for enforcement available**	➢ **Monitoring and enforcement activities cannot be carried out because of lack of capacity of personnel in charge** ➢ **Monitoring and enforcement activities cannot be carried out adequately because of lack of equipment** ➢ **Methodologies for monitoring activities are not clear and/or appropriate** ➢ **Procedures for enforcement measures are not clear and consistent**	➢ **Reinforcement of the certified labs in terms of equipment needed for monitoring purposes** ➢ **Develop tools and training on monitoring and enforcement activities on biosafety** ➢ **Experts are consulted for a revision of the methodologies** ➢ **Experts are consulted for a revision of the procedures**
Outcome 3.1 **Procedures for monitoring of environmental effects and enforcement actions are defined and in place**	Procedures for monitoring of environmental effects and enforcement actions are finalised by 2007	Manual available; Internal documents	Procedures for monitoring and enforcement are not well defined	Simulation by 2008 to test if the system works
Activities Preparation of a manual on procedures/methodologies for monitoring of environmental effects and inspections	A manual on monitoring for environmental releases is finalised by 2007	Methods and procedures available	Methods and procedures are not clear and do not cover all the steps	Experts are consulted for a revision of the technical guidelines
Outcome 3.2 **Technical means for monitoring and inspections are in place**	Technical means for monitoring in use by end 2009	Invoice and reports on use of technical means	Technical means for monitoring activities do not match needs	Identification of needs Consultation with Task Manager
Activities Survey of existing facilities at universities and research centers	A survey of the current status of facilities and research centres will be ready by end 2006	Final report of the survey	Survey is not well structured, does not target the right audience	Careful planning of the survey Careful identification of sample to analyse
Define the criteria/procedure for the selection and certification of two reference laboratories; designation of operational reference laboratories	Criteria for the selection and certification of two reference laboratories are defined by end 2006	Criteria available	Criteria are not well identified; designated laboratories are not appropriate	Accurate identification of the criteria by a resource group
Providing additional equipment to the selected reference laboratories for LMOs detection, including post-release monitoring and enforcement	Number of monitoring activities carried out by the end of the project using equipment purchased	Reports of monitoring activities	Equipment does not match needs	Identification of lab needs before purchase of the equipment Approval of the list of equipment by the Task manager
Outcome 3.3 **Increased national competence on**	Planned training workshops and tools	Meeting documents, agenda, list of	Quality of the training tools and	Careful identification and planning of

monitoring and inspection is available and equipped with tools for additional capacity building	are developed and in use by 2009	participants, records of decisions, media coverage of the meeting	activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	the training tools and activities, including identification of trainers and feedback mechanism to adapt training
Training guide for LMOs detection in laboratories, including sampling and analysis	Training guides on LMO detection in laboratories finalised and approved by mid 2007 and in place by end 2007	Training guides on follow-up actions available	Training guides are not clear, not well structured and do not cover all the issues	Experts are consulted for a revision of the Training guides
A training for 2 senior scientists from the reference laboratories to improve their capacity/expertise in investigating on GMOs	A training for 2 senior scientists from the reference laboratories to improve their capacity/expertise in investigating on LMOs organised by the end of 2007 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Two national training courses programs (2 weeks each) for 10 selected staff of the two reference laboratories in LMO detection	Two national training courses programs (2 weeks each) for 10 selected staff of the two reference laboratories in LMO detection organised by the end of 2009 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Organisation of a five-day training course for 40 custom officials and inspectors on LMOs investigation and inspection techniques	A five-day training course for 40 custom officials and inspectors on LMOs investigation and inspection techniques organised by the end of 2008 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Two 2-day training workshop for 8 judges on enforcement, dispute settlement and handling of court cases	Two 2-day training workshop for 8 judges on enforcement, dispute settlement and handling of court cases by the end of 2008 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Preparation of a guide on enforcement, dispute settlement and handling of court cases	Guide on enforcement, dispute settlement and handling of court cases by mid 2007 and in place by end 2009	Guide available	Guide are not clear, not well structured and do not cover all the issues	Experts are consulted for a revision of the guides
Immediate Objective 4: **Egypt has a functional national**	**Public debate and discussion in media**	**Reports, plans** **Monitoring media**	**Lack of political support** **Control of media**	**Developing and implementing plans for public education and awareness,**

system for public awareness, education, participation, access to information	**National BCH operational and continuously updated** **Public service advertising and targeting key audience**			**ensuring that the decision-making process includes specific entry points for public participation**.
Outcome 4.1 **Increased public education and participation**	Plan to target public is available by 2006; Number of nationals accessing the BCH; Number of records on the BCH.	Documents, reports and outreach material available (including TV and radio programme)	Tools and methods proposed to increase public education, awareness, participation and access to information are not well targeted and quality is not satisfactory	Careful planning of the tools and methods Careful identification of the audience
Activities				
Preparation of public education and involvement plan	Plan agreed by 2006 Media coverage	Plan available; Internal documents, Comments received ;	Plan is worked out in isolation, Plan does not respond to needs	Plan is circulated to all the involved parties for comments and revision till final agreement Involvement of main categories of stakeholders to identify and address needs in public awareness, education and participation in decision making; Plan fed with results of two workshops
Preparation and dissemination of outreach materials on biosafety	Number of different outreach materials distributed to target groups Lessons learnt and best practices are identified	Published outreach material	Different categories of audience and related needs are not correctly identified Lessons learnt are not identified	Identification of the audience and messages before preparation of the outreach material Consultative process for the identification of lessons learnt and best practices
Setting up the committee web site and preparation of a data entry protocol	Website set up by end 2007; number of hits on the website	Website accessible	Website is a duplication of the national biosafety website	Clear distinction (though linked) and functions of the two websites
Outcome 4. 2 **Increased national awareness on public information and participation**	Planned training workshops and tools are developed and in use by 2009	Meeting documents, agenda, list of participants, records of decisions, media coverage of the meeting	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training

Activities				
Organisation of two two-day information workshop for 40 local administrators each on public awareness education and involvement in biosafety	Two-day information workshop for 40 local administrators each on public awareness education and involvement in biosafety organised by end 2008 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training
Organization of a two-day workshop for 35 participants, including parliamentarians, media and NGOs representatives on the Law and its Executive Regulations with specific focus on public involvement	Two-day workshop for 35 participants, including parliamentarians, media and NGOs representatives on the Law and its Executive Regulations with specific focus on public involvement organised by end 2007 Minimum 80% of the invited participants attending each workshop	Workshop documents; post workshop evaluations List of participants	Quality of the training tools and activities is not satisfactory Developed tools do not cover adequately the issues Resource persons are not appropriate	Careful identification and planning of the training, including identification of trainers and feedback mechanism to adapt training

Annex E: Log-frame on Project against Key Performance Indicators ,and Baseline and Methods of Data Collection

Project Intervention Strategy	Key performance indicator	Baseline (if not known, please identify how and when will be established	Method of data collection/data collection strategy (including frequency)
Development Goal: **Egypt has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations**	A workable and transparent NBF is in place and in line with its international obligations and national development priorities by 2009	Baseline information is provided by the country and includes the draft laws .It complements the final report of the GEF enabling activity completed in 1999. Formalized at project start to constitute baseline	Information on the status of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project
Immediate Objective 1: **To assist Egypt to have a fully functional and responsive regulatory regime in line with CP and national needs**	**A finalized regulatory regime reflecting existing policies and defining all the elements of the NBF and related implementing procedures in line with CP and international obligations by 2009**	**National Strategy for Biotechnology and Genetic Engineering**	**Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project**
Outcome 1.1 Draft Biosafety Law on use handling release and placing on the market of locally produced or imported genetically engineered organisms and products into the environment adopted and in place; Executive Directive Regulations drafted, finalized, adopted and in place; ministerial decrees related to biosafety revised and reviewed; analysis on how best to regulate the contained use and confined release of genetically modified organisms is carried out and regulations for legal actions described	By 2009, Egypt is in compliance with ICCP list Compliance with other related international obligations with the CP	Final draft of the Biosafety Law on use, handling, release and placing on the market of all genetically engineered organisms and products into the environment, ready for final presentation at People's Assembly	Law as published in the official gazette (first year) , draft executive regulations as per internal documents and background material provided at planned consultative workshops with main stakeholders during the first and second year of the project Internal reports associated to the approval of the laws and EDRs as well as final reports coming out of the stakeholders consultations. Actions on how to address and regulate the contained use and confined release of genetically modified organisms will be part of the consultant(s) report and will be used as platform for further discussions.

Outcome 1.2. Increased national competence on regulatory issues is available and equipped with tools for related additional capacity building	Planned training workshops and tools are developed and in use by 2009	Collection of material used to date for training purposes; no training guide exists	Reports from training workshops, post-training evaluations, feedback from resource persons at the end of each workshop (and review of training material) Reports and feedbacks on the manual from the consultants involved
Immediate Objective 2 **To have a functional national system for handling requests, performing risk assessment, decision-making, performing administrative tasks, handling, storing and exchanging information in line with the BCH requirements**	**NCA(s) nominated and in place with clear distinction of responsibilities (including cases of accidental release, emergency response, illegal movement)** **Set of procedures for handling requests developed** **Number of decisions made as result of request within CP timeframe**	**Provisions of the draft Biosafety Law on use, handling, release and placing on the market of all genetically engineered organisms and products into the environment on handling requests** **No Executive Directive regulations**	**Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project**
Outcome 2.1 **Administrative processing, risk assessment and decision-making of LMOs are set and operational**	Clearly defined entity for decision-making with clearly defined roles and responsibilities Responsibilities assigned for emergency responses, accidental release and illegal movement Clear definition of procedures for handling notification (AIA) Percentage of requests handled Review of decisions on risk assessment Compliance with BCH obligations	Final draft of the Biosafety Law on use, handling, release and placing on the market of all genetically engineered organisms and products into the environment ICCP list, BCH No methodology for RA/RM is approved Statutory forms for application available only under the current system limited to seed certification	Law as published in the official gazette (first year) Details in the Executive regulations (first and second year) Internal documents and reports Reports from consultants
Outcome 2.2. **Increased national competence on handling of request is available and**	Planned training workshops and tools are developed and in use by 2009	Collection of material used to date for training purposes; manual exist	Regular review of the content of the exiting training material based on needs and post training evaluations , feedback on the manual on

equipped with tools for related additional capacity building			procedures for handling requests of LMOs in Egypt by the end of second year guides from consultants and/or experts
Immediate Objective 3 **To have a functional national system for "follow-up", namely monitoring of environmental effects and enforcement**	**Roles and responsibilities for monitoring and enforcement in place by 2009** **Set of methodologies and procedures for monitoring of environmental effects established by 2009**	**Provisions of the draft Biosafety Law on use, handling, release and placing on the market of all genetically engineered organisms and products into the environment on monitoring and enforcement measures** **No Executive Directive regulations**	**Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It will be collected in the final project**
Outcome 3.1 Procedures for monitoring of environmental effects and enforcement actions are defined and in place	Procedures for monitoring of environmental effects and enforcement actions are defined by 2007	No Executive Directive regulations is currently in place Procedures/methodologies for monitoring of environmental effects and inspections to be defined	Details in the Executive regulations (first and second year) Internal documents and reports Reports from consultants
Outcome 3.2 Technical means for monitoring and inspections are in place	Technical means for monitoring in place and in use by 2009	Existing laboratory equipment to support monitoring and inspections of LMOs	Documents of purchase of the equipment
Outcome 3.3 Increased national competence on monitoring and inspection is available and equipped with tools for additional capacity building	Planned training workshops and tools are developed and in use by 2009	Collection of material used to date for training purposes;	Reports from training workshops, post-training evaluations, feedback from resource persons at the end of each workshop (and review of training material) Feedbacks and reports on the guides on monitoring and enforcement from consultants and/or experts
Immediate Objective 4: **Egypt has a functional national system for public awareness, education, participation, access to information**	**Public debate and discussion in media** **National BCH operational and**	**Provisions of the draft Biosafety Law on use, handling, release and placing on the market of all genetically**	**Information on the status of this component of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to the country. It**

	continuously updated **Public service advertising and targeting key audience**	**engineered organisms and products into the environment which address public information and involvemnet** **No public education and involvement strategy**	**will be collected in the final project**
Outcome 4.1 Increased public education and participation	Plan to target public is available by 2007; Number of nationals accessing the BCH; Number of records on the BCH	Limited educational and information material on biosafety Limited involvement of public and NGOs No official biosafety website	Progress reports with indications of type and number of outreach material disseminated to different target groups Hits and records on the national committee website and BCH at the end of the project
Outcome 4. 2 Increased national awareness on methods for public information and participation	Planned training workshops carried out by 2009	Limited awareness on biosafety	Reports from training workshops, post-training evaluations, feedback from resource persons at the end of each workshop (and review of training material)

ANNEX F
Incremental cost assessment

Project Components	Baseline	Alternative	Increment
Biosafety regulatory regime	Current Egyptian system only applies to seed certification and is instituted by ministerial decrees. A national biosafety Law is in the last stage of approval at People's Assembly; Executive Directive Regulations (EDRs) to be formulated	The implementation of the Cartagena Protocol is supported by a regulatory regime reflecting existing policies and defining all the elements of the NBF , in line with CP and international obligations.	A legal regime , which includes a Biosafety Law and related EDRs, is in place. Decision-makers and personnel involved in the application of the regulatory regime are trained.
System for handling requests for permits	Egypt needs to set up procedures for handling requests as per Biosafety Law and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively.	The implementation of the Cartagena Protocol is supported by an operational system for handling requests, which includes administrative processing, risk assessment and decision-making in line with national legislation and CP procedures	A system for handling requests for LMOs, including administrative processing, risk assessment and decision-making is in place. National capacities are strengthened in terms of training courses, training tools and equipment.
System for follow-up, namely monitoring for environmental effects and enforcement	Egypt needs to finalise methodologies/procedures for monitoring of environmental effects and procedures for enforcement. Technical means and training are needed so as to enable inspectors, custom officers and technicians to carry out their tasks	The implementation of the Cartagena Protocol is supported by an operational system for monitoring for environmental effects and enforcement	Systems for monitoring of environmental effects and enforcement are in place. Reference Laboratories are selected and upgraded with facilities for LMO monitoring and inspection
Public information, participation, awareness and education	Awareness and education on biosafety need to be further raised, involvement of the public need to be part of the system so as to reflect Article 23 of the Cartagena Protocol	The implementation of the Cartagena Protocol is supported by a strengthened system for public information, education, awareness and involvement	A plan for public education, awareness, participation and access to information is formulated and implemented. Outreach material is produced and disseminated for different target groups, the national website for biosafety committee is operational and updated regularly, training courses on public information and participation are carried out.

Broad development goals

This project is part of GEF's wider effort in assisting countries to implement a biosafety regulatory regime in accordance with Agenda 21 and the CBD. More specifically, GEF resources will be used to assist Egypt to meet the objective of the Cartagena Protocol (*i.e.* to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements) through the full implementation of its NBF.

The project is consistent with, and based on, stated national priorities, plans and programmes in both the development and conservation sectors, including the National Agenda 21 and the National Strategy of Biological Diversity

Baseline

Within the context of the project, the baseline includes the activities carried out at domestic level with respect to each specific project component; the increment includes the activities proposed under this project proposal for the purpose of meeting the requirements of the Cartagena Protocol, to be financed through GEF contribution and national co-financing.

The cost of baseline activities at the national level is detailed in Table 6.

It is worth mentioning that project builds on experience gained up to date through the demonstration projects, which can add to the baseline and is complemented by the BCH project approved in January 2004.

The commitment of the Egyptian Government is demonstrated by the national co-financing to the project, in-kind (US $1,093,000). Details of the budget are enclosed in Annex G.

Finally, though baseline refers only to activities other than the GEF sponsored ones , it is worth mentioning that Egypt benefited from previous funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project, to develop a National Framework for Biological Safety. The project is therefore a logical follow-up to the first support already provided to the country to meet the obligations of the Protocol.

GEF alternative (complement demonstration and BCH)

Though the maintenance of global benefits with respect to biodiversity conservation has been absorbed as priority goal at national level, limited human capacity, financial resources and infrastructures would not allow Egypt to meet its obligations as Party to the Cartagena Protocol, when this comes into force in the country.

Under the GEF alternative, support activities needed to fill the gaps related to four components of the NBF will be carried.

In summary, the incremental cost of the project components is estimated as follows:

Costs in total

The total baseline expenditure amounts to US$ 2,105,000. The alternative has been estimated at US $. 3,402,100 .

The incremental cost analysis shows that a total amount of 2,297,100US$ is required to achieve the project's global environmental objectives. A portion of US $908,100 is required to GEF support, while the remaining is provided in kind by the country.

	First Year		Second Year		Third Year		Forth Year		Total GEF	Total Govt. Contribn.	TOTAL
	12		24		36		48				
PROJECT ACTIVITIES	**GEF**	**Govt. cofinance**	**GEF**	**Govt. cofinance**	**GEF**	**Govt. cofinance**	**GEF**	**Govt. cofinance**	**GEF**	**Govt. cofinance**	
Regulatory regime											
Survey · Relevant existing laws and regulations which need to be adjusted to conform with the currently proposed draft legislation · Current status of trials and releases of LMO material in closed and open environments in Egypt · Current practices of the	18,000	12,000							**18,000**	**12,000**	**30,000**
Legal translation of the Egyptian Biosafety Law into English	2,500	2,000							**2,500**	**2,000**	**4,500**
One four days consultative workshop for 24 techncial and legal experts on EDR (preparation first draft)	21,000	4,000							**21,000**	**4,000**	**25,000**
Consultative workshop for 25 government stakeholders to discuss first draft of EDR and revision of exisiting ministerial decrees	4,000	4,000							**4,000**	**4,000**	**8,000**
Four-day consultative workshop for 25 government stakeholders (representatives of the nine ministries involved in biosafety, legal experts) to review and comment on the second draft of the Executive Directive Regulations for the Biosafety Legislation of t	7,100	4,000							**7,100**	**4,000**	**11,100**
Final drafting of EDRs in legal terms and translation into english	12,000	8,000							**12,000**	**8,000**	**20,000**
4--day training workshop for 24 officers on the application and implementation of the biosafety law and the executive directive regulations.Preparation and publication of a training guide			25,000	8,000					**25,000**	**8,000**	**33,000**
Analysis on the legal steps to be taken to examine the interaction with the Biosafety Law, and to regulate the contained use and confined release of genetically modified organisms and indication of steps for legal actions			9,000	6,000					**9,000**	**6,000**	**15,000**
									98,600	**48,000**	**146,600**
Handling of requests											
One 5-day workshop led by national/international consultants for 8 specialists to discuss and draft protocols for risk assessment and risk management for LMOs	18,900	8,000							**18,900**	**8,000**	**26,900**
Draft technical guidelines on Risk Assessment and Risk Management protocols			4,000	6,000					**4,000**	**6,000**	**10,000**
Preparation of an internal "Manual on procedures for handling requests of LMOs in Egypt			9,000	6,000					**9,000**	**6,000**	**15,000**
Organisation of two 5-day training courses for 30 participants each (members of the implementing bodies,including representatives of civil society and private sector) on handling requests for permits, including RA/RM			21,800	12,000	21,800	12,000			**43,600**	**24,000**	**67,600**
Organisation of two 5-day training courses for 30 administrative officers from the biosafety office and relevant Ministries, on the administrative processing related to the handling of requests (including administrative aspects related to monitoring and			20,800	12,000	20,800	12,000			**41,600**	**24,000**	**65,600**
									117,100	**68,000**	**185,100**

Systems for follow-up actions, namely monitoring for environmental effects and enforcement											
Preparation of a manual on procedures/methodologies for monitoring of environmental effects and inspections	4,000	4,000							**4,000**	**4,000**	**8,000**
Survey of existing facilities at universities and research centres	2,500	4,000							**2,500**	**4,000**	**6,500**
Define the criteria/procedure for the selection and certification of two reference laboratories; designation of operational reference laboratories the reference laboratories	4,000	6,000							**4,000**	**6,000**	**10,000**
Providing additional equipment for existing laboratories to be certified for LMOs detection, including post-release monitoring and enforcement			220,000	700,000	67,000	300,000			**287,000**	**1,000,000**	**1,287,000**
Training guide for LMOs detection in laboratories, including sampling and analysis			6,000	2,000					**6,000**	**2,000**	**8,000**
Training for 2 senior scientists from the reference laboratories to improve their capacity/expertise in investigating on GMOs			2,000	4,000					**2,000**	**4,000**	**6,000**
Two national training courses programs (2 weeks each) for 10 selected staff of the two reference laboratories in LMO detection					32,500	30,000	32,500	30,000	**65,000**	**60,000**	**125,000**
Organisation of a five-day training course for 40 custom officials and inspectors on LMOs investigation and inspection techniques					11,000	10,000			**11,000**	**10,000**	**21,000**
Two 2-day training workshop for 8 judges on enforcement, dispute settlement and handling of court cases .Training guide prepared and published					4,800	1,500	4,800	1,500	**9,600**	**3,000**	**12,600**
									391,100	**1,093,000**	**1,484,100**
Public information and participation											
Prepare a public education and involvement plan	3,000	2,000							**3,000**	**2,000**	**5,000**
Prepare and disseminate outreach materials on biosafety			10,000	12,000					**10,000**	**12,000**	**22,000**
Set up the web site and data entry protocol prepared			5,000	8,000					**5,000**	**8,000**	**13,000**
Organisation of two two-day information workshop for 40 local administrators each on public awareness education and involvement in biosafety					32,000	37,000			**32,000**	**37,000**	**69,000**
Organization of a two-day workshop for 35 participants, including parliamentarians, media and NGOs representatives on the Law and its Executive Regulations with specific focus on public involvement			19,300	10,000					**19,300**	**10,000**	**29,300**
									69,300	**69,000**	**138,300**
Project management											
National Project Coordinator (part time)	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000	**48,000**	**48,000**	**96,000**
Project Assistant (full time)	12,000	3,000	12,000	3,000	12,000	3,000	12,000	3,000	**48,000**	**12,000**	**60,000**
Project Administrative Assistant (full time)	2,500	1,000	2,500	1,000	2,500	1,000	2,500	1,000	**10,000**	**4,000**	**14,000**
National Coordination Committee Meetings	6,000	3,000	6,000	3,000	6,000	3,000	6,000	3,000	**24,000**	**12,000**	**36,000**
Equipment and premises component (expendable and non-expendable equipment)	6,000	9,000	6,000	9,000	6,000	9,000	6,000	8,000	**24,000**	**35,000**	**59,000**
Travels (staff and NCC member travel and per diem-including National project Committe regular meetings) -included in B44											**0**
Audit	2,000		2,000		2,000		2,000		**8,000**		**8,000**
									162,000	**111,000**	**273,000**
Techncial support											
Technical support	17,500		17,500		17,500		17,500		**70,000**		**70,000**
									70,000	**0**	**70,000**

									908,100	**1,389,000**	**2,297,100**

ANNEX H

Draft Terms of Reference for:

- **National Executing Agency (NEA**
- **National Project Coordinator (NPC)**
- **National Coordinating Committee (NCC)**

a) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:

- Establish the National Co-ordinating Committee (NCC);
- Appoint a National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final version of the National Biosafety Framework no later than eighteen months from signature of this Memorandum of Understanding.

b) The **National Coordinating Committee (NCC)** will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

- Develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework;
- Oversee the preparation of the National Biosafety Framework
- Approve the detailed workplan and budget produced by the NPC;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project;
- Ensure that information on the implementation of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
- Assist in mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;
- Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;

c) The **National Project Coordinator (NPC)** will carry out the following tasks

- The National Project Coordinator (NPC) will act as the chair of the NCC

- Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Prepare detailed workplan and budget under the guidance of the NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP Global National Project Team;
- Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NCC, regular progress and financial reports

The **Project Assistants (PA)** will carry out the following tasks

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation detailed work plan and budget under the guidance of the NCC;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outp uts of the NBF;
- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports
- Assist with the preparation of a project monitoring and evaluation plan

- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact
- Assist with capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines