



GEF

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February 12, 2001

Dear Council Member:

I am writing to notify you that UNEP, the Implementing Agency for the project entitled, *Global: Development of National Biosafety Frameworks*, has submitted the proposed project document for CEO endorsement prior to final approval of the project in accordance with UNEP procedures.

Over the next four weeks, the Secretariat will be reviewing the project document to ascertain that it is consistent with the proposal included in the work program approved by the Council in November 2000, and with GEF policies and procedures. The Secretariat will also ascertain whether the proposed level of GEF financing is appropriate in light of the project's objectives.

After a further review of the project scope and activities, I am also proposing that the implementing agency fees be revised to US\$668,000, at the time of CEO endorsement, to enable UNEP to perform its implementing agency services.

If by March 12, 2001, I have not received requests from at least four Council Members to have the proposed project reviewed at a Council meeting because in the Member's view the project is not consistent with the Instrument or GEF policies and procedures, I will complete the Secretariat's assessment with a view to endorsing the proposed project document.

We have today posted the proposed project document on the GEF website at www.gefweb.org. If you do not have access to the Web, you may request the local field office of UNDP or the World Bank 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,

cc: Alternates, Implementing Agencies, STAP



United Nations Environment Programme

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PROGRAMME DES NATIONS UNIES POUR L'ENVIRONNEMENT • PROGRAMA DE LAS NACIONES UNIDAS PARA EL MEDIO AMBIENTE
ПРОГРАММА ОРГАНИЗАЦИИ ОБЪЕДИНЕННЫХ НАЦИЙ ПО ОКРУЖАЮЩЕЙ СРЕДЕ

Our Reference: GEF/Biosafety

16 February 2001

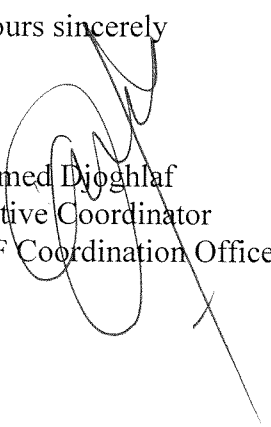
Dear Mr. El-Ashry,

I am pleased to enclose the project entitled “Development of National Biosafety Frameworks,” adopted by the GEF Council at its November 2000 meeting. The response to comments from council members is also attached and these have been addressed in the project document.

As per paragraph 29 and 30 of the GEF project cycle, we are submitting this project for circulation to the Executive Council Members and your final endorsement.

Thank you in advance for expediting the review and approval of this project.

Yours sincerely


Ahmed Djoghla
Executive Coordinator
UNEP/GEF Coordination Office

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DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS

Response to Comments from GEF Council Members

January 2001

<i>Country</i>	<i>Comment</i>	<i>Action taken</i>
France:	“There is a need for such a program, given the wide disparity among countries with respect to their knowledge and experience in these fields. The recommended financing seems reasonable in view of the number of countries involved”	The project is designed to fully take into account such a need.
Switzerland	“The proposal is well prepared and convincingly documented. There is consensus that the Cartagena Protocol has its place and that UNEP is the appropriate international agency to spearhead its implementation.”	The project reflects such an approach.
	“(a) Whether this project deals with a priority issue to be addressed by GEF and (b) whether the funding proposal qualified in principle under GEF statutes. Another question is whether the GEF Council rightfully decided to financially support the Cartagena Protocol in the first place. The Protocol is a brainchild of UNEP. Why then can it not be financed by UNEP if it is of such importance”	The GEF has been designated by the Protocol as its financial mechanism and the project is in line with the policy of the GEF Council as reflected in the Initial Strategy on biosafety.
	“If the project is financed as requested there is still little hope that policies and legislation applying to biosafety standards could actually be enforced. The parties to the Protocol and the GEF need to advance their thinking on	The enforcement issue will need to be addressed by the COP/MOP and subsequent activities related to the implementation will need to address this issue.

	<p>this issue and take further action to ensure that the GEF's investments in biosafety produce lasting results and are indeed sustainable. This project brief does not instil much confidence in this regard. “</p>	
	<p>“The evaluation report of the UNEP Pilot Project by Kinderlerer appears questionable in some of its conclusions and recommendations. For example, he suggests that USD 65 million are needed for a meaningful follow up project to be spent within a time-frame of merely two years while involving no less than 85 countries. Even if such exorbitant funding should become available, it is very doubtful that it could be spent wisely within the requested time frame of two years. Either the time frame should be extended or the number and scope of planned activities reduced in order to make the endeavour appear realistic and doable.”</p>	<p>The financial estimates by the independent evaluator have not been incorporated in the initial proposal. The GEF financing is limited to \$26 million, and the timescale is three rather than two years.</p>
<p>Australia, Korea and New Zealand</p>	<p>“There are a number of references to LMO's and their products”. The Cartagena Protocol on Biosafety deals with LMOs only and does not apply to LMO products. As the project is aimed at assisting countries with the Protocol obligations it is not clear why reference to LMO products is included. References to LMO products should be deleted as they go beyond the scope of the protocol and would increase funding implications substantially. It should also be noted that the Protocol does not refer to LMOs and their product in Article 23.”</p>	<p>All references to LMOS 'and their products' have been deleted</p>
	<p>All specific comments relating to particular paragraphs and changes.</p>	<p>All requested changes have been made to the document. "Biotechnology" is now preceded by "modern" and references to "and their products" have been deleted.</p>

<p>Germany</p>	<p>“Capacity building for the implementation of the Cartagena Protocol on Biosafety (CPB) was designated a priority by the Parties of the CBD. GEF projects that contribute to the implementation of this decision and thus contribute substantially to its entering into force as soon as possible are highly welcomed. Such projects will carry on the activities already begun within the scope of the Pilot Biosafety Enabling Activity Project appropriately designed to serve the CPB Process.”</p>	
	<p>“The only aim and justification for the UNEP project ... must be the implementation of the CPB”</p>	<p>The revised version of the project fully reflects such an objective.</p>
	<p>“The UNEP project should <i>now</i> take into account of</p> <ul style="list-style-type: none"> • The Note by the Executive Secretary of the CBD for the first meeting of the ICCP ... (UNEP/CBD/ICCP/1/4) • Bilateral initiatives, like the German initiative for “Capacity building for the implementation of the CPB” • The work and outcome of ICCP-1 and ICCP-2 <p>Projects and measures supported by the UNEP/GEF project have to ensure that the respective country can develop legal and administrative measures to prepare for the ratification of the Cartagena Protocol on Biosafety</p> <p>The national responsibility for projects supported by the UNEP/GEF project has to be with the appointed National Biosafety or ICCP-1 Focal Point.”</p> <p>(<i>now</i> inserted, as the project brief was submitted to the</p>	<p>The project proposal has been modified to ensure that decisions of the ICCP are incorporated into the project and that the responsibility for the project lies with the designated Focal Point. The project recognises that bilateral initiatives must be taken into account so that duplication of effort should not occur. Such a need for coordination has been stressed by ICCP I and UNEP has been requested to take the lead on this issue.</p>

	GEF Secretariat before UNEP/CBD/ICCP/1/4 was issued.)	
	“In this context the STAP review should not be taken into account because it does not reflect the recent developments in CBD and GEF strategies. Additionally it still tries to promote the obsolete dogma of combining biosafety – biotechnology – expertise”	The STAP review has not been taken into account and is no more contained as an annex. However it can be made available upon request.
	References to Article 8(g)	All references to Article 8(g) have been removed from the text
	Reference to Chapter 16 of Agenda 21.	All references to Chapter 16 of Agenda 21 have been deleted
	Role of UNEP International technical Guidelines	All references to UNEP International technical Guidelines have been deleted
	“The proposed web site on the establishment of biosafety frameworks and their implementation in the partner countries should become part of the BCH”	This comment is reflected in the final version of the project
	“The logical Framework Matrix does not reflect the changes made in the GEF Initial Strategy based on remarks of donors and experts”	The project brief was submitted to the GEF before the strategy document was changed by the November Council meeting. Changes have now been made.

PROJECT BRIEF

PROJECT TITLE:	Development of National Biosafety Frameworks
IMPLEMENTING AGENCY:	United Nations Environment Programme (UNEP)
EXECUTING AGENCIES:	National Governments in collaboration with UNEP
COUNTRY:	Global
GEF FOCAL AREA:	Biodiversity
ELIGIBILITY:	All countries eligible that have signed the Cartagena Protocol on Biosafety
GOVERNMENT CONTRIBUTION:	In-kind
GEF OPERATIONAL FOCAL POINT:	Respective national GEF Focal points
ESTIMATED STARTING DATE:	June 2001
PROJECT DURATION:	Three years 6 months

2. SUMMARY:

Legal and regulatory structures will be required in order to implement the Cartagena Protocol on Biosafety. This project aims to assist GEF eligible countries to prepare for the entry into force of the Cartagena Protocol on Biosafety in accordance with the Initial Biosafety Strategy as endorsed by the 16th GEF council meeting held in Washington, DC on 1-3 November 2000 taking into account other bilateral and multilateral initiatives. More specifically the projects aims at assisting GEF eligible countries that have signed the Cartagena Protocol on Biosafety to prepare national biosafety frameworks and promote regional and sub-regional cooperation through the convening of regional and sub-regional workshops. The implementation of the project will be guided by the "Indicative framework for capacity building under the Cartagena Protocol on Biosafety"(UNEP/CBD/ICCCP/1/4) as well as the guidance of the Intergovernmental Committee of the Cartagena Protocol.

COSTS AND FINANCING (MILLION US\$)

GEF:	Project	26.092
Co-financing	UNEP and countries	12.341
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Total Project Cost		38.433

IA CONTACT:

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LIST OF ACRONYMS

AIA	Advance Informed Agreement
CBD	Convention on Biological Diversity
CHM	Clearing House Mechanism
COP	Conference of Parties
FAO	Food and Agricultural Organisation
GEF	Global Environment Facility
GIS	Geographic Information System
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee on the Cartagena Protocol on Biosafety
ICGEB	International Centre for Genetic Engineering and Biotechnology
IRRO	International Research on the Release of Organisms into the Environment
ISNAR	International Service for National Agricultural Research
IUCN	IUCN The World Conservation Union
LMO	Living Modified Organism
MSDN	Microbial Strain Data Network
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plan
NEA	National Executing Agency
NGO	Non Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
ONT	Organism with Novel Traits
R & D	Research and Development
STAP	Scientific and Technical Advisory Panel
UK	United Kingdom
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
WHO	World Health Organisation

In addition, the Convention on Biological Diversity will be referred to as the Convention and the Cartagena Protocol on Biosafety as the Protocol.

PROJECT DESCRIPTION

BACKGROUND AND CONTEXT

1. The objective of the Cartagena Protocol on Biosafety, opened for signature in Nairobi, on 24 May 2000 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 into account risks to human health, and specifically focussing on transboundary movement.”¹ As the financial mechanism of the Convention on Biological Diversity, the GEF is also called upon to serve as the financial mechanism of the Protocol.²

2. The GEF Council at its November 2000 meeting adopted 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 this initial strategy are to: a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and subregional level, and to promote collaboration with other organizations to assist capacity-building for the Protocol

3. The third Conference of the Parties to the Convention held in Buenos Aires on 4-15 November 1996 requested the GEF to provide financial resources to developing country Parties for capacity building in biosafety. In response to Decision III/5, the 10th meeting of the GEF Council, held in Washington, DC on 4-6 November 1997, approved a Pilot Biosafety Enabling Activity project of US\$ 2.7 million. The National Level Component of the project aimed at assisting eighteen eligible countries to prepare National Biosafety Frameworks (US\$ 1.9 million), with the Global Level Component aiming at facilitating the exchange of experience at regional levels through the convening of 2 workshops in each of four regions (US\$ 0.8 million).

4. As part of the National Level Component, national surveys were carried out to identify existing applications of modern biotechnology; the extent and impact of releases of LMOs, biosafety, risk assessment and risk management systems, and reviews of existing legislation relevant to biosafety. The participating countries were of variable sizes, geographical locations, level of socio-economic development; different stages of modern biotechnology development and application of biotechnology products as well as different stages of preparation of their National Biodiversity Strategies and Action Plans (NBSAPs). The countries were

Bolivia	Hungary	Poland
Bulgaria	Kenya	Russian
Cameroon	Malawi	Federation
China	Mauritania	Tunisia
Cuba	Mauritius	Uganda
Egypt	Namibia	Zambia

¹ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 1.

² *Ibid*, Article 28

5. Some countries (e.g. the Russian Federation) already had elements of a National Biosafety Framework in place. In those instances, the funds were applied in order to improve and expand the existing structure and integrating the UNEP International Technical Guidelines into the national framework.

6. The objective of the National Component was to develop and/or strengthen national instruments for environmental management and methods for implementation of National Biosafety Frameworks. This called for harmonisation of biosafety instruments at sub-regional, regional and global levels as well as development of greater awareness of potential benefits and possible risks resulting from modern biotechnology, among a wide spectrum of stakeholders at sub-regional/regional/global levels. Accordingly, the project incorporated a Global Level Component consisting of two back-to-back UNEP/GEF Regional Workshops on Biosafety in each region.

7. Workshop 1 covered issues related to risk assessment and risk management of living modified organisms (LMOs) The topics addressed included organisms with novel traits resulting from modern biotechnology for enhancement of biosafety. The analysis allowed for a full environmental impact assessment. Workshop 2 focused on issues related to transboundary transfer of LMOs, including appropriate mechanisms and methods for supply and exchange of information regarding biosafety. The UNEP/GEF Regional Workshops on Biosafety brought together many government-nominated biosafety experts from different countries of the region as well as representatives from the scientific community, UN bodies, bio-industry, NGOs and other organizations, to discuss and exchange views on a wide range of issues related to safety in modern biotechnology.

8. These regional workshops were held in Havana, Cuba on 26-30 October 1998, for the Latin American and Caribbean region, in Bled, Slovenia on 11-15 November 1998 for Central and Eastern Europe, in Nairobi, Kenya on 23-27 November 1998 for Africa and in New-Delhi, India on 7-11 December 1998 for the Asia and Pacific region. More than 267 government designated experts benefited from these regional workshops.

9. The executive summary of the evaluation of the project as well as the review by the Scientific and Technical Advisory Panel of the GEF (STAP) are available at the secretariat of the GEF.

10. A Ministerial Round Table on “*Capacity-building in Developing Countries to Facilitate the Implementation of the Protocol*” was held in Nairobi on 23 May 2000 during the Fifth Conference of the Parties to the CBD. The Ministerial Round Table acknowledged the need for capacity-building at the national level, in order to allow “*the safe use of modern biotechnology, in particular the safe transfer of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity between countries which may have very different climatic, social and economic conditions*”. Paragraph 9 of the Statement of the Ministerial Round Table emphasises “*the importance of the financial mechanism and financial resources in the partnership that the Protocol represents and welcome the commitment of GEF to support a second phase of the UNEP/GEF Pilot Biosafety Enabling Activity project*”. The need for capacity-building was also emphasised at the GEF workshop on the UNEP/GEF Pilot Biosafety Enabling Activity held on 24th May 2000 in the margins of CBD COP5 with the participation of more than 150 delegates.

11. The decisions adopted by the Fifth Conference of the Parties to the Convention on “*Further guidance to the financial mechanism*” (Decision V/13) as well as on the Biosafety Protocol (Decision V/1) welcomed “*the decision taken by the Council of the Global Environment Facility at its fifteenth meeting with regard to supporting activities which will assist countries to prepare for the entry into force of the Protocol*”.

12. The GEF Initial Biosafety Strategy as well the UNEP/GEF biosafety projects, including the results of the pilot project, were presented and discussed during the plenary meeting of Working Group II of the First meeting First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpellier on 11-15 December 2000. The UNEP/GEF projects were further discussed during a side event held on 13th December at the margins of the meeting. The Montpellier Declaration adopted by the, “*Reiterated that capacity-building for many Parties, especially developing countries, in particular the least developed and small island developing States among them, is the foremost priority for the moment, acknowledged that action to address these needs must be demand driven, identified the framework of these needs and highlighted various means to meet these needs, including the UNEP/GEF biosafety initiative.*” The meeting urged UNEP “*to expedite the implementation of the project entitled Development of National Biosafety Frameworks in a flexible manner, having regard to the comments made by the Intergovernmental Committee for the Cartagena Protocol at its first meeting, and to support the implementation of national biosafety frameworks.*”

RATIONALE AND OBJECTIVE

13. Articles 1 and 2 of the Protocol require Parties to: “*ensure an adequate level of protection in the field of the safe transfer, handling and use of these LMOs*”, and to ensure that “*the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health*”. Each Party is required to “*take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol*”. In addition “*Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health*”.

14. Accordingly, in order to meet these requirements, Parties to the Protocol need to develop comprehensive frameworks for biosafety, and to put in place appropriate legal and regulatory systems to assess any possible impact on their environment. The capacity building initiatives must take into account procedures for risk assessment and risk management as identified in of the Protocol, including any scientific skills that might be required. This would allow the countries to:

- Regulate, manage and control risks and adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, including risks to human health;
- Ensure adequate protection of the environment;
- Minimise the risks posed to their ability to trade with other countries; and
- Provide mechanisms for technology transfer and benefit sharing.

15. The First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpellier on 11-15 December 2000 stressed the need for capacity building and strengthening of human and institutional resources of developing countries, especially in least developed and Small Island Developing States, and countries with economies in transition. The meeting also stressed the importance of a regional approach.

OVERALL OBJECTIVE

16. The overall objective of the project is to prepare countries for the entry into force of the Protocol. The project aims at:

- Assisting up to 100 eligible countries to prepare their national biosafety frameworks³,
- Promoting regional and sub-regional collaboration and exchange of experience on issues of relevance to the national biosafety frameworks, and

17. This will be achieved through:

- (i) Strengthening national capacity in order to implement biosafety procedures and maximize the potential for the safe use of modern biotechnology;
- (ii) Applying biosafety procedures to enhance environmental management;
- (iii) Applying biosafety guidelines under the Protocol taking into account the work of the Inter-governmental Committee for the Cartagena Protocol on Biosafety (ICCP);
- (iv) Harmonising regional and sub-regional legal instruments to simplify the process of applying and conforming to regulations;
- (v) Raising public awareness of the issues involved in release of living modified organisms to promote informed debate and to ensure that where any use of modern biotechnology is permitted, it is done in an open and transparent way;
- (vi) Providing all stakeholders with an opportunity to be involved in the design and implementation of a national framework for biosafety;
- (vii) Carrying out an assessment of technological capacity, its effect on implementation of national biosafety frameworks and means to improve it; and,

COMPONENT I: PROMOTING REGIONAL AND SUB-REGIONAL COLLABORATION AND EXCHANGE OF EXPERIENCE

18. National biosafety decisions and activities need to take into account legislative measures and biosafety regulatory systems implemented in adjacent countries from an early stage. The Protocol is, primarily, an agreement about (intentional and unintentional) transboundary movement of LMOs. Sub-regional co-operation in information-sharing and harmonising legal and regulatory instruments is crucial for effective management of transfer of LMOs across borders. The information needed for the safe introduction of LMOs into the environment may not necessarily be available within a single country, but expertise may be

³ If the number of eligible countries seeking GEF assistance exceeds 100 additional financial resources will be required

able to be exploited at the sub-regional level. Maximising the use of scarce institutional, financial, technical and human resources within a region is essential for effective and efficient establishment of national frameworks on modern biotechnology and biosafety, as is the involvement of international experts from other parts of a region and other regions.

19. Since no country is isolated from its neighbours, there is a clear need to strengthen regional ties between countries, either by assisting in setting up regional networks or by helping to set up systems with the necessary authority to oversee the development of modern biotechnology within the region. Co-operation at sub-regional and regional levels is key to the successful implementation of the objectives of the Protocol. Support for sub-regional and regional co-operation will facilitate development and the realisation of the following key aspects of capacity building for enhancement of safety in modern biotechnology, research, development and application of LMOs/GMOs:

- Human resources and relevant expertise pertinent to issues of biosafety at national, sub-regional and regional levels;
- National and sub-regional capacities to assess and manage risks associated with living modified organisms that may have an adverse impact on the environment;
- Guidelines, methodologies and procedures for rapid assessment and management of risks and benefits of living modified organisms and review of applications for field trials and field releases;
- Networks for supply and exchange of biosafety information

20. The first meeting of the Intergovernmental Committee for the Cartagena Protocol stressed the importance of regional approach developed by concerned countries in a consultative manner

21. Four regional workshops, one each for Africa, Latin America and the Caribbean, Asia and the Pacific and Eastern Europe will be convened at an early stage of the project. 15 sub-regional workshops will be convened to allow countries to work together to identify common ground for collaboration. The following sub-regions have been identified: North Africa, West Africa, Central Africa, Eastern Africa, Southern Africa, Caribbean region, South America, Central America, West Asia, South East Asia, South Asia, Central Asia, Pacific Islands, Eastern Europe, and the Baltic countries. The sub-regions may change through discussion with participating countries.

22. The task managers of the 18 participating countries of the UNEP/GEF Pilot Biosafety Project will be invited to attend appropriate regional and sub-regional meetings as resource persons to provide others with an insight into their expertise and experience gained from the pilot project. The secretariat of the Convention, a member of the Scientific and Advisory Panel of the GEF and pending the entry into force of the Protocol, the Chairperson of the Intergovernmental Committee of the Cartagena Protocol on Biosafety will be invited to attend regional meetings.

23. The Regional Workshops will provide a basis for planning activities in order to assist in the formulation of national biosafety frameworks, allow regional or sub-regional collaboration to be instigated at a very early stage in the development of national frameworks and provide the necessary incentive to countries to sign the Protocol where appropriate so that they may participate in Component II.

24. The regional workshops will address:

- Presentation of the Pilot Phase and its outputs, including focal points (Task Managers for the appropriate group of the 18 countries that participated in the Pilot Project) that could act as mentors and advisors.
- Introduction of the project, its steering/advisory committee, UNEP task management secretariat, etc.
- Follow-up actions on guidance arising from relevant decisions/recommendations of the Intergovernmental Committee for the Cartagena Protocol on Biosafety of relevance to the implementation of the objectives of the project.
- Issues relating to the transboundary transfer of LMOs, including appropriate mechanisms and modalities for supply and exchange of information;
- Global trends on biosafety issues;
- National obligations in preparation to the ratification and implementation of the Protocol (AIA, CHM, etc.);
- Introduction of the project objectives/activities;
- Identification of key players including legislators, technical resources (national/international), private sectors, regional institutions, NGOs, public, International Governmental Organisations, other UN agencies, etc. and their possible roles;
- Issues relating to risk assessment and risk management of LMOs, including environmental impact assessment, in order to provide expertise to minimize risk at a national level and taking into account Articles 15 and 16 of the Protocol and its relevant Annexes;

25. The expected outcome of the workshops will be a clear understanding by participating countries of the obligations placed upon them by the Protocol. This will require an understanding of the risk analysis and management procedures that are needed for to ensure the safe use of relevant living modified organisms. The workshops will provide information on those organisms that fall within the scope of the Protocol and the Advanced Informed Agreement procedures. They will allow decision on the scope of any National Biosafety Framework, which may be different from that of the Protocol. They will include providing a basis for decision within each country on the need for taking into account, “*consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities*”⁴. The regional meetings will designate sub-regions and refer those issues thought to be of importance at a sub-regional level.

⁴ Article 2 of the Cartagena Protocol on Biosafety.

26. The sub-regional workshops will deal with issues identified during the regional workshops, primarily in relation to collaboration in mechanisms for assessing risk and where applicable, advising on measures to minimise risks to the environment and human health. The first workshops will attempt to

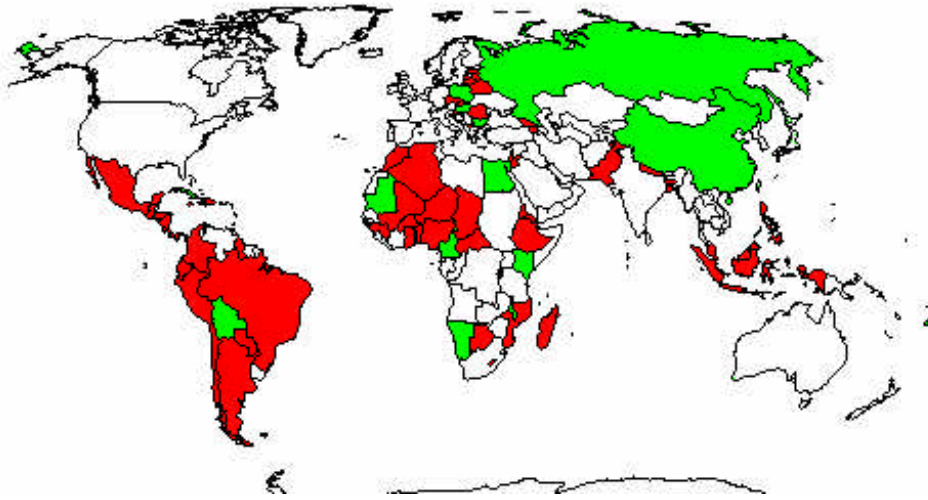
- Identify sub-regional priorities to enhance existing capacities/expertise;
- Discuss ways to collaborate in utilising:
 - Human resources and relevant expertise pertinent to issues of biosafety at national and sub-regional levels;
 - National and sub-regional capacities to assess and manage risks associated with living modified organisms that may have an adverse impact on the environment;
- Provide information leading to the harmonisation of guidelines, methodologies and procedures for the assessment and management of risks and benefits of living modified organisms and review of applications for field trials and field releases;
- Establish networks for supply and exchange of biosafety information; and
- Provide mechanisms for sharing national experience regarding the execution of the project.
- Ensure complementarity and co-ordination with the capacity building efforts of individual governments and other international bilateral and multilateral agencies such as UNDP, the World Bank, FAO, WHO, UNIDO, OECD, ICGEB, IUCN, ISNAR, etc. by involving all who are pursuing biosafety programmes within the sub-region.

27. The second sub-regional workshops will consider lessons learned from the national components including the provision of information about national progress, decide on what collaboration are possible, and assess the network and mechanisms that have been put into place for information sharing. Countries will decide on actions based on the information provided.

COMPONENT II: PREPARATION OF NATIONAL BIOSAFETY FRAMEWORKS

28. One hundred eligible countries will be supported to prepare national biosafety frameworks⁵. There is a critical need for this component to proceed so as to ensure that the necessary Frameworks are in place as quickly as possible so that to ensure that eligible countries will be well prepared for the entry into force of the Protocol. The implementation of this component will take into account the work of the ICCP as well as the note of the Executive Secretary of the Convention on Biological Diversity to the first ICCP meeting on “Capacity-building for the implementation of the Cartagena Protocol on Biosafety” (UNEP/CBD/ICCP/1/4).

⁵ If the number of eligible countries seeking GEF assistance exceeds 100 additional financial resources will be required



The countries involved in the Pilot programme are shown shaded lightly (green); those that have applied to UNEP for funding are shown in darker shading (red).

29. The activities listed below will be executed through a national institution officially designated by the participating countries (the National Executing Agency or NEA) in accordance with the elements of the Memorandum of Understanding contained in Annex IV, and are designed to :

- ✓ Assist countries to meet their national obligations in order to implement the terms of the Protocol and to prepare for meetings of the Inter-Governmental Committee for the Cartagena Protocol on Biosafety. Action will include:
 - The convening of workshops for discussion of requirements for the implementation of the Advance Informed Agreement (AIA) procedures (Articles 7-13 of the Protocol), and of risk assessment and risk management (Articles 15 and 16 of the Protocol);
 - The establishment and implementation of internal procedures that enable participation in the Clearing House as required by the Protocol.

- ✓ Assist countries to identify existing technological and legal capacity, its effect on the implementation of National Biosafety Frameworks and means for improvement. This will require the identification of the talent, expertise and experience they do have and the gaps that need to be covered to ensure that risk is assessed and managed appropriately as required in the Protocol Action will include:
 - A survey to provide detailed knowledge of the status of the use of biotechnology and its applications. The survey will include all organisations that are involved in modern biotechnology and thereby allow the efficient interaction between the public and private sectors to ensure that where appropriate, the new technology is effectively used.

- A survey to identify any existing legal instruments or guidelines that might impact on the use, import or export of living modified organisms.
 - A survey of existing and/or available bilateral/multilateral support on modern biotechnology and biosafety to ensure best use of resources.
 - The setting up a national (or sub-regional) roster of experts and the provision of mechanisms for their interaction.
- ✓ Ensure and enhance stakeholders' involvement in the decision making process. There is a need to fully involve all stakeholders including the public and private sector, consumers, consumer organisations and NGOs. The parties to the Protocol are "*[Aware] of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health*" Article 23 of the Protocol places a duty on Parties to involve the public and media, and requires a raising of public awareness of the issues involved in the release of Living Modified Organisms to promote informed debate.⁶ Action will include⁷:
- Assisting in the provision of information and tools to raise public awareness of the issues involved in the use or release of Living Modified Organisms that might impact on the environment or on human health to promote informed debate. This will include assisting in the provision of information to the public and media about (i) the use of modern and traditional biotechnology in traditional agriculture and industry; (ii) the safe use of modern biotechnology including possible impacts on the environment and on human health; and (iii) mechanisms put into place to ensure that safety with respect to the environment and human health of any LMO that might pose a risk has been carefully considered. The project will provide for countries to produce outreach materials, press releases and the monitoring of national press coverage. Countries will provide the information on media coverage to the project management and will enable a consultation process on the framework for biosafety.
 - Assisting countries to develop methods of involving the public sector (including educational and scientific research organisations), the private sector and NGOs at all stages of the project in order to work towards a common goal of promoting only the safe use of modern biotechnology.

⁶ Article 23:

- "The Parties shall:
- (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
 - (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House."

⁷ See also Section viii of Annex 4: Elements to be included in the Memorandum of Understanding with National Executing Agencies

- ✓ Strengthen national capacity for decision-making and implementation of biosafety procedures. Action will include⁸:
 - Drafting of legal instruments including regulatory frameworks and guidelines, as appropriate;
 - Establishing systems needed for risk assessment, audit of risk assessments and risk management in order to ensure the safe use of the modern biotechnology taking into account national and sub-regional/regional needs.

- ✓ Assist harmonisation of guidelines, regulations or laws at the national level with those in neighbouring countries and where appropriate, sub-regional agreements on biosafety to simplify the process of applying and conforming to regulations. Action will include
 - Provision for sharing of scientific assessments at sub-regional levels whilst allowing for decision at national level if necessary (Article 14 of the Protocol).
 - Provision for sub-regional/regional consultations integrated at the national level, for harmonising guidelines, identifying regional expertise; compatibility of initiatives and collaboration possibilities, and priority areas in capacity-building. Reports to the sub-regional meetings and networking with others in the sub-region, including the invitation of some from the sub-region to attend national workshops will provide the necessary links.

30. The experience of implementing the UNEP/GEF Pilot Biosafety Project revealed that there is limited in-country technical expertise available at national level in developing countries. This limited technical capacity is exacerbated by a lack of easy access to relevant information and to opportunities for training. The Pilot project demonstrated the value of the sharing of information on specific technical issues that were raised during the regional and national workshops. Indeed, access to relevant information is key to the success of the implementation of the objectives of the Cartagena Protocol on Biosafety. The first meeting of the Intergovernmental Committee for the Cartagena Protocol stressed the important interconnection between information sharing and capacity building.

31. To respond to this need, technical advisory support will be offered under this project. It will play a proactive role in ensuring that all project national focal points have ready access to appropriate assistance via a range of different mechanisms and media. Training and public awareness materials will be also prepared. This technical advisory support scheme will take be complementary to, provide assistance to countries to develop the ability to participate in and avoid duplication with Biosafety Clearing House.

32. The technical advisory support will develop the following:

- A project website which will
 - (i) Provide a linkage between the work programmes of individual participating countries in order to spread experience and best practices;

⁸ See section x of Annex 4: Elements to be included in the Memorandum of Understanding with National Executing Agencies.

- (ii) Establish a resource database representing a distillation of the most important and relevant biosafety information emerging at a global level with links to the Biosafety Clearing House where appropriate; and
 - (iii) Provide a portal to other relevant internet-based resources;
- A project list server which will allow rapid exchange of information between participating countries and ensure that essential project information is disseminated quickly and efficiently to all participating countries, to provide regular updates on significant developments in biosafety and to facilitate the timely provision of specific information, on request, to participating countries;
 - A project newsletter, to be published on a quarterly basis which will complement the information provided by the list server but which can be used to increase the public awareness of the project;
 - Biosafety outreach materials including publications, video, brochures, articles in local press, etc. for public awareness raising purposes;
 - Liaison with participating countries to develop and disseminate training materials, including technical manuals and best practice guidelines, on specific areas of biosafety which can be used during the regional and sub-regional workshops, or as stand-alone workshops; and
 - Liaison with participating countries to establish a database of global, regional and national level resources for biosafety public awareness and education, and for monitoring and contributing to press coverage of biosafety issues.

INSTITUTIONAL FRAMEWORK

33. A Steering Committee will be established to monitor on a regular basis the progress towards achieving the objectives of the project, the disbursements made to participating countries and other financial objectives. The Steering Committee will be co-chaired by the GEF Secretariat and UNEP. It will also comprise a representative of UNDP, the World Bank, the Secretariat of the CBD, FAO, ICGEB, and UNIDO. A representative of the Scientific and Technical Advisory Panel of the GEF (STAP) will be also invited to attend meetings of the Steering Committee when consideration of scientific and technical issues arising from the implementation of the project is being discussed. At its first meeting the Steering Committee will identify mechanisms for including representation of developing countries in its deliberations.

34. The Steering Committee will meet on a quarterly basis via teleconferencing. Two weeks prior to each meeting, the scientific coordinator of the project will submit a short progress report. An initial meeting of the Steering Committee will be held prior to the start of the project activities to review the draft project work plan.

35. The Steering Committee will have the responsibility to promote coordination with other bilateral and multilateral donors at a national level with a view to avoiding duplication of effort and in identifying activities that complement the GEF intervention.

36. A Scientific Coordinator will be appointed for the management of this project. In addition to the overall management responsibility for the implementation of the project, the Scientific Coordinator will also oversee the preparation of the national frameworks in the Central and East European Region. Three Programme Officers will assist him. Each Programme Officer will be responsible for overseeing the preparation of the national biosafety frameworks in one of the following geographical regions: Africa, Latin America and the Caribbean, and Asia. A Fund Manager will be also appointed. The Scientific Coordinator will act as the secretary of the Steering Committee. He will also report on a quarterly basis to the UNEP Inter Divisional Biosafety Group specially established by the Executive Director to oversee the implementation of this project.

STAKEHOLDER PARTICIPATION AND IMPLEMENTATION ARRANGEMENTS

37. The primary stakeholders in this project are the designated government departments in each of the participating countries. It is anticipated that wide involvement of many government departments will be required, resulting in high level government acceptance of the outcome of the preparatory activities leading to the drafting of primary or secondary legislation and guidelines which may need the approval of national legislatures. Each NEA will have established an intra-governmental committee to ensure the efficient flow of information within government as specified in Annex 4.

38. Participating countries will need to identify all stakeholders that may have a legitimate interest in the use of living modified organisms that may have an adverse effect on the environment or on human health, provide mechanisms for consultation and taking the broad range of views into account. The active participation of a broad range of individuals and organisations will be needed to obtain maximum support for the Biosafety Framework.

39. Regional and sub-regional coordination of actions will enhance the systems that form the Biosafety Framework in each country, and enable the maximum and effective use of human and scientific resources.

INCREMENTAL COSTS AND PROJECT FINANCING

40. This is an Enabling Activity project and is therefore considered fully incremental in the context of GEF funding. The full project budget summary and component financing is provided in Annex I.

BUDGET SUMMARY

PROMOTION OF REGIONAL AND SUB-REGIONAL COLLABORATION AND EXCHANGE OF EXPERIENCE

1		YEAR 1	YEAR 2	YEAR 3	TOTAL GEF	IN-KIND /COUNTRY	TOTAL
1.1	Regional Workshops	385,000	-	-	385,000	297,000	682,000
1.2	Sub-regional Workshops (participants' travel, subsistence, meeting facility and equipment)	225,000	225,000		450,000	594,000	1,044,000
1.3	Management of regional/sub-regional Activities	120,000	100,000	80,000	300,000	-	300,000
1	Subtotal	730,000	325,000	80,000	1,135,000	891,000	2,026,000

PREPARATION OF NATIONAL BIOSAFETY FRAMEWORKS FOR 100 COUNTRIES

2		PER COUNTRY	YEAR 1	YEAR 2	YEAR 3	TOTAL GEF	IN-KIND / COUNTRY	TOTAL
2.1	Strengthen national capacity for decision-making/implementation of biosafety procedures	175,000	2,600,000	3,100,000	4,100,000	9,800,000	7,700,000	17,500,000
2.2	Meeting national obligations for the CBD, and the Cartagena Protocol on Biosafety	45,000	500,000	2,500,000	500,000	3,500,000	1,000,000	4,500,000
2.3	Identify existing technological and legal capacity, its effects and means for improvement	35,000	3,500,000			3,500,000		3,500,000
2.4	Ensure and enhance stakeholders' involvement in the decision making process	35,000	1,500,000	500,000	500,000	2,500,000	1,000,000	3,500,000
2.5	Assist harmonisation of national and sub-regional legal instruments on biosafety	30,000		1,000,000	1,000,000	2,000,000	1,000,000	3,000,000
2	Subtotal	320,000	8,100,000	7,100,000	6,100,000	21,300,000	10,700,000	32,000,000

PROJECT MANAGEMENT

3		YEAR 1	YEAR 2	YEAR 3	YEAR 4	TOTAL GEF	IN-KIND / UNEP OR COUNTRY	TOTAL
3	Subtotal	940,000	1,191,500	1,334,575	191,008	3,657,083	750,463	4,077,546

TOTAL

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	TOTAL GEF	IN-KIND / UNEP OR COUNTRY	TOTAL
TOTAL	9,770,000	8,616,500	7,514,575	191,008	26,092,083	12,341,463	38,443,546

41. This project provides for an overall funding of GEF resources of \$26.092 million, which will be released to the Implementing Agency in tranches on the basis of the number of signatories to the Cartagena Protocol requesting assistance. The release of the first tranche will be authorised by the CEO at the time of project endorsement. The release of subsequent tranches will be authorised by the CEO on the basis of the joint recommendation of the Co-chairs of the Steering Committee. Because of the very different starting point of each country

that will introduce a Framework for Biosafety, the terms will have to be negotiated directly with each country under a memorandum of understanding based on the elements contained in Annex 4. Different countries have different ways in which they implement environmental, phyto-sanitary, trade and other relevant legislation. These differences will have to be reflected in their decisions as to whether to introduce new primary legislation specifically to implement the Protocol, to introduce secondary legislation or regulations under existing legislation or to provide guidelines. The different social and economic conditions will also influence these decisions, and appropriate mechanisms for consultation with stakeholders form an important part of the development of a biosafety framework.

42. The same four regions used for the Pilot Project will be used - Africa, Central and Eastern Europe, Latin American and the Caribbean and Asia and the Pacific. It is expected that approximately 15 sub-regions will be required if sub-regional structures are to be meaningful or useful.

43. The project will be managed by the following staff members:

- A Scientific Coordinator at level L6 will manage the project, report to the Steering Committee as well as the UNEP Inter Divisional Biosafety Group and be responsible for Central and Eastern European region.
- Three Programme Officers for Africa, Asia and the Pacific, Latin America and the Caribbean will be appointed at L4 level.
- A Fund Manager at P3 will also be appointed.

MONITORING EVALUATION AND DISSEMINATION

44. Monitoring of the progress of all activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. GEF requirements of quarterly and half-yearly reports on substantive and financial matters will be provided by UNEP. Reports by countries to UNEP will be detailed and need to provide information on all activities undertaken and completed. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and reports will be required at specified time points in the programme.

45. The Steering Committee will monitor progress annually and will advise the project manager and the countries on progress and any necessary adjustments to the workplan and timetable.

46. A mid-term independent evaluation will be undertaken under the supervision of the Steering Committee. The evaluation will include an assessment of on-going activities including a diagnosis of possible problems and recommend any corrective measures. A final evaluation of the project will be undertaken in accordance with UNEP approved Monitoring and Evaluation procedures. Two independent evaluators will be appointed to perform the initial mid-term evaluation and the final evaluation. Up to four other individuals will need to be appointed to visit a selection of countries and produce reports for the independent evaluators. These may either be based on region or where appropriate on language use

47. Dissemination of results will take place via the sub-regional meetings, via periodic meetings between the project management team and the government departments in each

country, via the publication of the National Biosafety Framework and other publications and via the public media. The publication of national laws, regulations and /or guidelines will represent the most important tangible output of the project.

LIST OF ANNEXES

ANNEX I: Budget.

ANNEX II: Logical Framework Matrix.

ANNEX III: Work plan.

ANNEX IV: Elements of the Memorandum of Understanding with National Executing Agencies.

ANNEX I: BUDGET

1	Promoting regional and sub-regional collaboration and exchange of experience	Year 1	Year 2	Year 3	Total GEF	In-kind /Country	Total
1.1	Regional Workshops						
1.1.1	Regional Workshop for C&EE, for total of 20 participants*	60,000	-	-	60,000	39,600	99,600
1.1.2	Regional Workshop for Asia/Pacific, for total of 50 participants*	125,000	-	-	125,000	99,000	224,000
1.1.3	Regional Workshop for LAC, for total of 30 participants*	75,000	-	-	75,000	59,400	134,400
1.1.4	Regional Workshop for Africa, for total of 50 participants*	125,000	-	-	125,000	99,000	224,000
1.2	Sub-regional Workshops (participants' travel, subsistence, meeting facility and equipment)						
1.2.1	15 Sub-regional Preparatory Workshop for (10 participants, 4 days)*	225,000	-	-	225,000	297,000	522,000
1.2.2	15 Sub-regional Assessment Workshop for (10 participants, 4 days)*	-	225,000	-	225,000	297,000	522,000
1.3	Management of regional/sub-regional Activities						
1.3.1	Monitoring and coordination actions required for organisation of regional/sub-regional workshops	-	-	-	-		-
1.3.2	Preparation of executive summary and other papers of regional/sub-regional workshops	5,000	-	5,000	10,000	-	10,000
1.3.3	Establishment of a project website	20,000	10,000	10,000	40,000	-	40,000
1.3.4	Establishment of a project list server	10,000	5,000	5,000	20,000	-	20,000
1.3.5	Quarterly Publication of project newsletter	20,000	20,000	20,000	60,000	-	60,000
1.3.6	Biosafety outreach materials for public awareness raising purposes	30,000	30,000	30,000	90,000	-	90,000
1.3.7	Develop and disseminate training materials	25,000	25,000	-	50,000	-	50,000
1.3.8	Establish database of global, regional and national level resources	10,000	10,000	10,000	30,000	-	30,000
1	Subtotal	730,000	325,000	80,000	1,135,000	891,000	2,026,000

Notes:

In-kind country contributions for regional & sub-regional meetings are calculated at the D1 daily rate (US\$330) for the duration of the conference plus 2 days for travel.

2	Preparation of National Biosafety Frameworks for 100 countries	Per country	Year 1	Year 2	Year 3	Total GEF	In-kind /Country	Total
2.1	Strengthen national capacity for decision-making/implementation of biosafety procedures							
2.1.1	Project Coordination	90,000	2,000,000	2,000,000	2,000,000	6,000,000	3,000,000	9,000,000
2.1.2	Establish an intra-governmental committee to liaise within government	30,000					3,000,000	3,000,000
2.1.3	Establish a task force to advise and guide the NEA (meetings, papers etc)	25,000	600,000	600,000	600,000	1,800,000	700,000	2,500,000
2.1.2	Drafting, circulation and revision of the regulatory frameworks and guidelines	15,000		500,000	500,000	1,000,000	500,000	1,500,000
2.1.3	Translation and publication of the draft regulatory framework**	15,000			1,000,000	1,000,000	500,000	1,500,000
2.2	Meeting national obligations for the CBD, and the Cartagena Protocol on Biosafety							
2.2.1	Convening of national workshops to review findings of assessment/survey*	15,000		1,000,000		1,000,000	500,000	1,500,000
2.2.2	Convening of national workshop on AIA, Risk Assessment and Risk Management*	15,000		1,000,000		1,000,000	500,000	1,500,000
2.2.3	Establishment/implementation of Internal procedures for participation in CHM (equipment, travel)	15,000	500,000	500,000	500,000	1,500,000		1,500,000
2.3	Identify existing technological and legal capacity, its effects and means for improvement							
2.3.1	A survey of the status of the use of biotechnology and its applications**	10,000	1,000,000			1,000,000		
2.3.2	A survey to identify existing legal instruments/guidelines**	10,000	1,000,000			1,000,000		
2.3.3	A survey of bilateral/multilateral support on biotechnology/biosafety**	5,000	500,000			500,000		
2.3.4	Setting up roster of experts and provide mechanisms for their interaction	10,000	1,000,000			1,000,000		
2.4	Ensure and enhance stakeholders' involvement in the decision making							
2.4.1	Provision of tools to raise public awareness and information on media coverage	15,000	1,000,000			1,000,000	500,000	1,500,000
2.4.2	Develop methods to involve public/private sector and NGOs at all stages of the project	20,000	500,000	500,000	500,000	1,500,000	500,000	2,000,000
2.5	Assist harmonisation of national and sub-regional legal instruments on biosafety							
2.5.1	Sharing of scientific assessments at sub-regional levels whilst allowing decision at national level	15,000		500,000	500,000	1,000,000	500,000	1,500,000
2.5.2	Sub-regional/regional consultations integrated at the national level	15,000		500,000	500,000	1,000,000	500,000	1,500,000
2	Subtotal	320,000	8,100,000	7,100,000	6,100,000	21,300,000	10,700,000	32,000,000

otes:

Costs include participants' travel and subsistence, meeting facilities and equipment

* Cost per country will vary

3	Project Management	Year 1	Year 2	Year 3	Year 4	Total GEF	In-kind / UNEP or Country	Total
1	Project Management							
1.1	Negotiation and conclusion of necessary agreements w ith participating countries						330,000	
1.2	Day-to-day management of the project							
1.3	Provision of scientific and technical backstopping							
1.4	Preparation of quarterly progress and financial reports							
1.5	Peer-review of draft National Biosafety Framework Documents		40,000			40,000		40,000
1.6	Self evaluation and external evaluation (2 Overseeing Review ers + 1 review er for each region, travel, meetings and preparation of reports, assumes 2 months work per review er)			150,000		150,000		150,000
1.7	Organisation of Steering Committee Meetings (1 per year)	50,000	50,000	50,000		150,000	26,400	176,400
1.8	Travel to regional workshops (5 professionals)	80,000				80,000		80,000
1.9	Travel to sub-regional workshops (2 professionals per subregion)		60,000	60,000		120,000		120,000
1.10	Travel to national workshops (1 or 2 international resource persons per country)		200,000	200,000		400,000		400,000
1.11	Travel to countries participating in the project (1 trip of 1 professional per country)	180,000	180,000	180,000		540,000		540,000
2	Staffing							
2.1	Task Manager (L6) (Africa) (uprated at 5% per annum) The contract is extended by 6 months at the end of the project to allow completion.	180,000	189,000	198,450	104,186	671,636		671,636
2.2	Programme Officer, LAC (L4) (uprated at 5% per annum) The contract is extended by 6 months at the end of the project to allow completion.	150,000	157,500	165,375	86,822	559,697		559,697
2.3	Programme Officer, CE&E (L4) (uprated at 5% per annum)	150,000	157,500	165,375	-	472,875		472,875
2.4	Programme Officer, Asia/Pac (L4) (uprated at 5% per annum)	150,000	157,500	165,375	-	472,875		472,875
2.5	Technical Support Officer (L3) (uprated at 5% per annum)						394,063	394,063
	Subtotal	940,000	1,191,500	1,334,575	191,008	3,657,083	750,463	4,077,546

	Year 1	Year 2	Year 3	Year 4	Total GEF	In-kind / UNEP or Country	Total
Total	9,770,000	8,616,500	7,514,575	191,008	26,092,083	12,341,463	38,433,546

ANNEX II: LOGICAL FRAMEWORK MATRIX

DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS

SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	CRITICAL ASSUMPTION AND RISK
Overall Objective			
<p>To prepare countries for the entry into force of the Cartagena Protocol on Biosafety.</p> <p>These require countries to</p> <ul style="list-style-type: none"> • Regulate, manage and control risks and adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, including risks to human health; ▪ Ensure adequate protection of the environment; ▪ Minimise the risks posed to their ability to trade with other countries; and ▪ Provide mechanisms for technology transfer and benefit sharing. ▪ Provide the basic tools necessary to implement the Biosafety Clearing House Mechanism. 	<ol style="list-style-type: none"> 1 Legislation, regulations and /or guidelines will be in place to allow for the assessment and management of risk associated with the use of modern biotechnology, including contained use, deliberate, accidental or incidental release into the environment, import or export of living modified organisms that might impact on biological diversity, taking also into account risks to human health. 2 Regional and sub-regional meetings to allow for cooperation and rationalisation in introducing biosafety frameworks 3 Stakeholders will have been informed and consulted on the many issues raised by the use of modern biotechnology. 4 Public meetings will have been held to inform and educate about living modified organisms. 	<ol style="list-style-type: none"> 1 Publication of laws, regulations or guidelines on modern biotechnology. These may be new legislation or modification of existing legislation to meet national needs. 2 Publication of reports of regional and sub-regional meetings including the indication of mechanisms for collaboration and rationalisation of laws amongst countries within a region or sub-region to ensure the safe use of modern biotechnology as required in the Cartagena Protocol . 3 Publication of plans for regional or sub-regional collaboration and the use of expertise across a region to enable a wide range of scientific experience and expertise to be exploited 	<p>It is assumed that many of the countries participating in the project will have little or no legislation for modern biotechnology as required for Parties to the Protocol. This project will allow for the investigation of coverage and the modification of laws and regulations to meet these needs. It will require interacting with all stakeholders as required by the Protocol.</p>

OUTCOMES

<p>The promotion of regional collaboration and exchange of experience on issues of relevance to National Biosafety Frameworks.</p>	<p>Regional meetings will be held to</p> <ol style="list-style-type: none"> 1 Identify the tasks required of countries that have signed the Protocol; 2 Decide on those issues that may be addressed at a regional, sub-regional or national level and the methods that are to be used to address each of these issues; 3 Identify key players in each country, and the way in which expertise and experience may be used across the region; 4 Designate sub-regions and decide on those issues to be referred to sub-regional meetings. 	<ol style="list-style-type: none"> 1 Publication of reports of meetings 2 Designation of sub-regions and identification of issues to be considered at regional, sub-regional and national level 3 Publication of information identifying the key players and the manner in which their experience may be used. 	<p>There is a need for a critical mass of scientific expertise and experience that may not be available in any one country. The assessment of risk and its management may therefore need consideration in a sub-region or region. The project provides for mechanisms for interaction at the regional or sub-regional level but assumes a willingness of countries to work together at this level so as to assure effective management of risk.</p>
<p>The promotion of sub-regional collaboration following the regional meetings and the exchange of information on issues of relevance to implementing the Protocol at a sub-regional level.</p>	<p>Sub-regional meetings will be held to:</p> <ol style="list-style-type: none"> (i) Identify sub-regional priorities to enhance existing capacities and expertise; (ii) Discuss ways to collaborate in utilising human resources and relevant expertise and to provide mechanisms for sharing national experience; (iii) Provide information leading to the harmonisation of procedures for the assessment and management of risks and benefits of living modified organisms and review of applications for field trials and field releases; (iv) Ensure complementarity and co-ordination with the capacity building efforts of individual governments and other international bilateral and multilateral agencies. 	<ol style="list-style-type: none"> 1 Publication of reports of meetings and of the solutions (if any) to the questions raised relating to collaboration and harmonisation. 2 Establishment of networks in the sub-region that enable exchange of information and sharing national experience regarding execution of the project. 3 Publish information on all biosafety capacity building projects in the sub-region. 4 Publication of a roster of experts in for each of the countries in the sub-region identifying their area of expertise and the provision of mechanisms for their interaction 	<p>It is assumed that countries within each sub-region are willing to collaborate at some level to ensure the efficient assessment of risk and the design of effective risk management procedures.</p>

Provision of assistance for up to	1. Each country will survey the use of	1. Publication of a survey of the status of	It is necessary to involve all
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<p>100 eligible countries to prepare their national biosafety frameworks</p>	<p>biotechnology, the existing legislative framework, and existing projects for capacity building in biosafety.</p> <ol style="list-style-type: none"> 2. Each country will set up a roster of experts identifying their experience and expertise so that coverage and gaps can be identified. 3. Provide information and guidance to all stakeholders in accordance with the requirements of the Protocol as well as mechanisms for adequate public involvement. 4. Countries should involve the public and private sectors in the debate on biosafety and foster collaboration. 5. Countries will convene national public meetings to involve all stakeholders to identify and content of the Biosafety Framework. 6. Countries will draft legal instruments which may be guidelines, as appropriate 7. Countries will establish the systems needed for risk assessment, audit of risk assessments and risk management, taking into account national and sub-regional/regional needs 8. Provide as appropriate mechanisms for sharing of scientific assessments at sub-regional levels (whilst allowing for decision at national level if necessary) 9. Identify country needs for participation in the Biosafety Clearing House. 	<p>the use of biotechnology and its applications within a country.</p> <ol style="list-style-type: none"> 2. Publication of a survey identifying any existing legal instruments or guidelines that might impact on the use, import or export of living modified organisms. 3. Publication of a survey of existing and/or available bilateral/multilateral support on biotechnology and biosafety to ensure best use of resources survey of existing and/or available bilateral/multilateral support on biotechnology and biosafety to ensure best use of resources 4. Publication of a roster of experts in for each of the countries in the sub-region identifying their area of expertise and the provision of mechanisms for their interaction. 5. Publish the reports of all national meetings as appropriate 6. Publication of draft guidelines, regulations and guidelines. 	<p>stakeholders and attempt to produce a consensus on the mechanisms that are used to ensure that legislation or guidelines are aimed at implementing the objectives of the Protocol .</p>
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COMPONENTS/ACTIVITIES

COMPONENT 1: PROMOTING REGIONAL AND SUB-REGIONAL COLLABORATION AND EXCHANGE OF EXPERIENCE

<p>1) The convening of a global workshop on capacity building , as requested by ICCPI, to identify the needs of developing countries and the issues that need to be addressed in any programme designed to ensure compliance with the Cartagena Protocol.</p> <p>2) The convening of 4 regional workshops for each of four regions: Africa, Latin America and the Caribbean, Central and Eastern Europe and Asia and the Pacific. These workshops will address a variety of issues pertinent to capacity building in Biosafety to ensure that countries have the information on which to build frameworks for Biosafety. The issues to be explored include:</p> <ul style="list-style-type: none"> a) Introduction to the Protocol and to this project, identifying what is needed to set up a system capable of implementing the biosafety points arising from the Convention and the Protocol. b) Identification of the importance of risk assessment and management procedures in the light of the Protocol and trans-boundary movement of living modified organisms that may pose a risk to the environment or to human health. c) Identification of key players d) Identification of the scientific expertise needed for risk assessment and management, and discussion as to how limited resources may best be exploited. e) Designation of sub-regions and those issues that would be best tackled within sub-regional meetings. 	<p>These meetings will identify those areas of biosafety that require regional or sub-regional support and expertise, and explore ways in which the need to use expertise from outside an individual country can be achieved. The need to harness regional expertise whilst retaining national decision-making processes presents a challenge.</p>
<p>3) The convening of an estimated 15 sub-regional workshops. The main issues that are expected to be referred from the regional workshops will be methods of ensuring collaboration for assessing risk and where applicable, advising on measures to minimise risks to the environment and human health. There will be two such workshops for each sub region.</p> <p>4) The first workshops will attempt to</p> <ul style="list-style-type: none"> a) Identify sub-regional priorities to enhance existing capacities/expertise. b) Discuss ways to collaborate in utilising the human resources and to identify the capacity available in the region for assessing and managing risk c) Provide ideas for the harmonisation of legislation, regulations and guidelines d) Establish networks for the exchange of information and allow for participation in the Biosafety Clearing House Mechanism. <p>5) The second sub-regional workshops will consider lessons learned from the national components including the provision of information about national progress. Decisions will be taken on the areas of possible collaboration. An assessment of the network and mechanisms that have been put into place for information sharing will be made. Countries will decide on actions based on the information provided</p>	<p>These meetings will attempt harmonisation of the legislative frameworks or guidance that exists, and identify the manner in which the expertise in the region can be effectively utilised. Countries will have to identify where, to what extent and how they may subordinate national sovereignty to effectively perform risk assessments and management. Recognition that organisms cross borders once introduced into an environment is not necessarily easily accepted.</p>

COMPONENT II: PREPARATION OF NATIONAL BIOSAFETY FRAMEWORKS	
<ol style="list-style-type: none"> 1. Countries are to assess the level of biotechnological activity, identify the scientists working in the field who may have an input into risk assessment and management, and identify the laws that already exist that might apply to aspects of biosafety as defined in the Protocol. This will assist countries to meet their obligations under the Protocol. 2. Countries will have to identify all stakeholders and consult widely on that which is needed for assuring minimal risk from living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health 3. This will result in decisions as to whether new primary legislation is needed, whether regulations under existing regulations could be used, or whether guidance is appropriate. 4. Assessment of the need for harmonisation and use of expertise from outside the borders of an individual country will need to be considered. 5. A draft memorandum of understanding between UNEP and each individual country is included as Annex E. 	<p>Countries will have to appoint intra-departmental committee to allow decisions within Government Departments as to what might be done. They will also have to appoint some form of task force to run national workshops to allow consultation, and effectively to put the options to Government concerning draft legislation. The task force will be responsible for consulting stakeholders, publishing relevant information, and performing the necessary survey that allow the many decisions to be made.</p>

ANNEX III: WORKPLAN

1	Promoting regional and sub-regional collaboration and exchange of experience	Year 1	Year 2	Year 3	4
	Global Workshop on Capacity Building				
1.1	Regional Workshops				
1.1.1	Regional Workshop for C&EE, for total of 20 participants*				
1.1.2	Regional Workshop for Asia/Pacific, for total of 50 participants*				
1.1.3	Regional Workshop for LAC, for total of 30 participants*				
1.1.4	Regional Workshop for Africa, for total of 50 participants*				
1.2	Sub-regional Workshops (participants' travel, subsistence, meeting facility and equipment)				
1.2.1	15 Sub-regional Preparatory Workshop for (10 participants, 4 days)*				
1.2.2	15 Sub-regional Assessment Workshop for (10 participants, 4 days)*				
1.3	Management of regional/sub-regional Activities				
1.3.1	Monitoring and coordination actions required for organisation of regional/sub-regional workshops				
1.3.2	Preparation of executive summary and other papers of regional/sub-regional workshops				
1.3.3	Establishment of a project website				
1.3.4	Establishment of a project list server				
1.3.5	Quarterly Publication of project newsletter				
1.3.6	Development of guidelines for biosafety outreach materials including publications, video, brochures, articles in local press, etc. for public awareness raising purposes				
1.3.7	Develop and disseminate training materials with and for countries				
1.3.8	Establish a database of global, regional and national level resources for biotechnology and biosafety public awareness and education, and for monitoring and contributing to press coverage of biosafety issues in collaboration with participating countries				

2	Preparation of National Biosafety Frameworks for 100 countries	Year 1	Year 2	Year 3
2.1	Strengthen national capacity for decision-making/implementation of biosafety procedures			
2.1.1	Project Coordination	■		
2.1.2	Establish an intra-governmental committee to liaise within government	■		
2.1.3	Establish a task force to advise and guide the NEA (meetings, papers etc)	■		
2.1.2	Drafting, circulation and revision of the regulatory frameworks and guidelines		■	
2.1.3	Translation and publication of the draft regulatory framework**		■	
2.1.4	Report to Project team	■	■	■
2.2	Meeting national obligations for the Cartagena Protocol on Biosafety			
2.2.1	Convening of national workshops to review findings of assessment/survey*		■	
2.2.2	Convening of national workshop on AIA, Risk Assessment and Risk Management*		■	
2.2.3	Establishment/implementation of Internal procedures for participation in CHM (equipment, travel)		■	■
2.3	Identify existing technological and legal capacity, its effects and means for improvement			
2.3.1	A survey of the status of the use of biotechnology and its applications**		■	
2.3.2	A survey to identify existing legal instruments/guidelines**		■	
2.3.3	A survey of bilateral/multilateral support on biotechnology/biosafety**		■	
2.3.4	Setting up roster of experts and provide mechanisms for their interaction		■	
2.4	Ensure and enhance stakeholders' involvement in the decision making process			
2.4.1	Provision of tools to raise public awareness and information on media coverage		■	
2.4.2	Develop methods to involve public/private sector and NGOs at all stages of the project		■	
2.5	Assist harmonisation of national and sub-regional legal instruments on biosafety			
2.5.1	Sharing of scientific assessments at sub-regional levels whilst allowing decision at national level		■	
2.5.2	Sub-regional/regional consultations integrated at the national level		■	

ANNEX IV: ELEMENTS TO BE INCLUDED IN THE MEMORANDUM OF UNDERSTANDING WITH NATIONAL EXECUTING AGENCIES

The National Executing Agency (NEA) of each participating country will undertake the following tasks:

- (i) Designate, in consultation with UNEP, a **full time** Task Manager for the duration of the project in accordance with the job description contained in the attached appendix (to be developed);
- (ii) Establish an intra-governmental committee able to liaise with all government departments with interests in and information about biotechnology;
- (iii) Establish a Task Force to advise and guide the preparation of a National Biosafety Framework. The Task Force will be established within the NEA, and should be multidisciplinary and multisectoral in fields of relevance to the Cartagena Protocol on Biosafety and the UNEP International Technical Guidelines for Safety in Biotechnology. The Task Manager will act as the secretary of the Task Force and of the intra-governmental committee and ensure that information is available to the Task Force about Government activities which impact on any use of modern biotechnology.
- (iv) Provide the necessary scientific, technical, financial and administrative support to the work of the Task Force and ensure the Task Manager submits to UNEP quarterly progress reports on the activities of the Task Force for submission to UNEP as required.

The Task Force will meet at least on a quarterly basis to oversee the preparation of the national biosafety frameworks and more specifically to develop detailed workplan/timetable; mobilize necessary expertise; and develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework.

- (v) Work in close cooperation with relevant ministries, government departments, NGOs, the scientific community and the private sector, to enhance/ensure synergy with other relevant bilateral/multilateral programmes in the area of biotechnology/biosafety.
- (vi) Undertake a stocktaking exercise and assessment of the state of play in the country on matters related to biosafety through a number of surveys on:
 - (a) Existing uses of biotechnology and the arrangements for the safe use of biotechnology. This will include a review and assessment of existing legislation that may impact on the use of modern biotechnology, including phytosanitary, pesticide, herbicide, import and export legislation and guidelines;

- (b) Existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology;
 - (c) Existing national biosafety frameworks in the countries of the sub-region;
 - (d) Existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation;
 - (e) Extent and impact of release of LMOs and commercial products.
- (vii) Create a database listing national experts in fields related to biotechnology and biosafety, as well as in fields relevant to risk assessment and risk management of LMOs.
- (viii) Organise or ensure attendance at national, regional or sub-regional workshops for the identification and analysis of options to implement relevant provisions of the Protocol and to submit to UNEP national workshop reports, including lists of participants and their constituencies. These workshops may include:
 - (a) A national workshop to review the findings of the surveys, identification of gaps, needs and priorities;
 - (b) Training workshops on risk assessment and risk management;
 - (c) Training workshops on monitoring and enforcement mechanisms for national controls;
 - (d) Stakeholder workshops on the national biosafety framework targeted to relevant stakeholders including, in particular, national legislators;
 - (e) A sub-regional workshop on harmonisation efforts in the preparation of the national biosafety frameworks and sharing of experiences; and.
 - (f) Public awareness workshops on the national biosafety framework with the participation of NGOs, consumer organisations, the scientific community and the private sector including farmers, the food and feed industry and the chemical industry.
- (ix) Submit quarterly progress reports, quarterly expenditure accounts, cash advance requests, final expenditure statements, terminal reports and final audited statement of accounts using UNEP standard formats for reporting. Any additional documents produced in the above mentioned activities will also be submitted as appropriate.
- (x) Maintain regular communication with UNEP, and report on dates when the activities were accomplished, any problems encountered, etc. for consultation.

- (x) Prepare a National Biosafety Framework, including procedures for the safe application of biotechnology in accordance with the Protocol. This will entail:
 - (a) The circulation of a draft national biosafety framework among relevant stakeholders and experts at national level for review and comments
 - (b) The draft should be translated if necessary and presented to UNEP well in advance for peer review, which will be undertaken by UNEP at least six months prior to the completion of the project. The comments of the reviewers will be provided to the countries to allow them to be taken into consideration before a final document is produced
 - (c) The finalisation of the National Biosafety Framework, taking into account all comments received; and,
 - (d) Printing and distributing the National Biosafety Framework (number of copies to be agreed with the NEAs) to as wide an audience as possible for information.
- (xi) Submit the final version of the National Biosafety Framework no later than (month, 2003 - exact date to be agreed upon with each NEA).
- (xii) Identify follow-up actions as appropriate.