PROJECT BRIEF

1. IDENTIFIERS

PROJECT NUMBER:	
PROJECT TITLE:	Development of National Biosafety Frameworks
IMPLEMENTING AGENCY:	United Nations Environment Programme (UNEP)
EXECUTING AGENCIES:	National Governments
COUNTRY:	Global
GEF FOCAL AREA:	Biodiversity
ELIGIBILITY:	All countries eligible that have ratified the Convention on Biological Diversity[1]
GOVERNMENT CONTRIBUTION:	In-kind
GEF OPERATIONAL FOCAL POINT:	Respective national GEF Focal points[2]
ESTIMATED STARTING DATE:	March 2001
PROJECT DURATION:	Three years 6 months

2. SUMMARY:

New legal and regulatory structures may be required in order to implement much of the Cartagena Protocol. Many developing countries and countries with economies in transition will have to make decisions regarding the use of the techniques of modern biotechnology or the import and export of products containing or derived from transgenic organisms. In many cases, their decisions will be based on very limited scientific knowledge and information. This project aims to assist countries in preparing a biosafety framework to meet their obligations. It includes regional and sub-regional workshops that provide the information on which to build national frameworks and to collaborate at the sub-regional level to assure the availability of the necessary scientific infrastructure. Assistance will be provided at the national level to identify biotechnological activity within a country and the extent of coverage of already existing laws and regulations. It will provide the necessary assistance to ensure that stakeholders are consulted in drawing up guidelines, regulations or laws to achieve the stated aims.

[1] Note the restriction in paragraph 34 limiting the countries participating in Component II so that disbursement of funds can only occur to those that have signed the Cartagena Protocol on Biosafety.

[2] A list of countries that have applied to UNEP for funding is shown in Table 1, Annex A. Endorsement letters will be obtained as and when each country is accepted onto the project.

COSTS AND FINANCING (MILLION US$)[3]

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

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[3] Annex A

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. Modern biotechnology as defined in the Cartagena Protocol on Biosafety (the Protocol) has the potential to help solve many urgent needs of the world[4], including provision of food, fuel and fibre when targeted products become available. "*Biotechnology promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. It offers new opportunities for global partnerships.*"[5] However, the use and/or release into the environment of living modified organisms resulting from modern biotechnology could have adverse impacts on the conservation and sustainable use of biological diversity. This will become apparent when traits are introduced that modify the impact of organisms within an environment or to human health. Many are questioning the safety of living modified organisms, and it is recognised that many countries have limited capabilities "*to cope with the nature and scale of known and potential risks associated with living modified organisms*"[6]. Countries may also "*take 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*"[7]. Many developing countries and countries with economies in transition will soon have to make decisions regarding the use of the techniques of modern biotechnology or the import and export of products containing or derived from transgenic organisms. In many cases, their decisions will be based on very limited scientific knowledge and information.

2. Few countries have the necessary legal frameworks to engage in risk assessment let alone the scientific and technical capacity to assess the risk to their environment or to human health. In many countries where the expertise exists, it is confined to isolated agencies—many of which may not be engaged in biotechnology research and development. Many of the countries lack the necessary systems needed to mobilise their scientists and direct their skills to the assessment of risks or to the development and application of biotechnology. Where existing expertise does not reside in the institution that is charged with the responsibility for biotechnology research and development, it is often not drawn upon and utilised. It is necessary to identify methods of bringing those with administrative responsibility into contact with those with the expertise needed to assess risk and where appropriate, devise methods for minimising risk both to the environment and to human health.

3. The safe use of modern biotechnology is an important feature of the Convention on Biological Diversity ("the Convention"). Article 8(g) calls on Parties to "*establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological*

[4] Acknowledged in Chapter 16 of Agenda 21, UNCED, Rio de Janeiro, 1992.
[5] *Ibid* and http://www.un.org/esa/sustdev/biot.htm
[6] Cartagena Protocol on Biosafety, Preamble
[7] i*bid*, Article 26.

diversity, taking into account the risks to human health". This obligates countries to institute a regulatory system for risks that might arise within their borders from the use or release of such modified organisms. The obligation to regulate the transfer of such organisms between countries is addressed in Article 19(3) of the Convention, which provides that Parties shall consider "*the need for and modalities of a protocol on biosafety setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity*".

4. While the Conference of the Parties to the Convention was examining the implementation of Article 19(3), the Governing Council of UNEP, in its decision 18/36, affirmed the desirability of UNEP contributing to international efforts on biosafety, including the development of International Technical Guidelines for Safety in Biotechnology. At its second meeting held in Jakarta on 6-17 November 1995, the Conference of the Parties stressed the importance of the urgent finalisation of the UNEP International Technical Guidelines for Safety in Biotechnology and acknowledged that they could contribute to the development and implementation of a protocol on biosafety without prejudicing the development and conclusion of such a protocol. Decision II/5 further noted that the Guidelines might be used as an interim mechanism during the development of the protocol and to complement it after its conclusion, for facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology. The link between Articles 19(3) and Article 8(g) of the CBD is expressly identified in Decision II/5 of the Conference of the Parties.[8] Decision II/7 requires the GEF to facilitate urgent implementation of Articles 6 and 8 of the Convention on Biological Diversity.[9] COP II further noted that the UNEP International Technical Guidelines for Safety in Biotechnology may be used as an interim mechanism during the development of the protocol and to complement it after its conclusion, for the purpose of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop human resources in biotechnology (Decision II/5).

5. The third Conference of the Parties to the Convention held in Buenos Aires on 4-15 November 1996 welcomed the finalisation and adoption, in December 1995, of the UNEP International Technical Guidelines for Safety in Biotechnology. It requested the GEF to provide financial resources to developing country Parties for capacity building in biosafety, including for the implementation of the UNEP Guidelines (Decision III/5, paragraph 2(a)). The Protocol specifically focuses on transboundary movements of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and stable use of biological diversity, taking also into account the risk to human health (Article 1). These two instruments, therefore, are complementary to one another although they may require similar legal systems to implement them. Decision III/5 reiterates the commitment made in paragraph 6 of Decision II/7.

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[8] Decision II/5: The Conference of the Parties, *Recalling* Article 19, paragraph 3 of the Convention of Biological Diversity, *Recognising* the link between paragraphs 3 and 4 of Article 19, *Recognising* the link between Articles 8(g) and 19, paragraph 3….. Decides…..

[9] Decision II/7 paragraph 6: "*Emphasizes* the importance of capacity-building as well as the availability of adequate financial resources to assist Parties in the implementation of Articles 6 and 8 of the Convention, and in this context requests the interim financial mechanism under the Convention to facilitate urgent implementation of Articles 6 and 8 of the Convention by availing to developing country Parties financial resources for projects in a flexible and expeditious manner;"

6. In response to the COP guidance, 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).

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

Some countries (e.g. the Russian Federation) already had elements of National Biosafety Framework in place. In those instances, the funds were applied in improving and expanding the existing structure and integrating the UNEP International Technical Guidelines.

8. 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 in the context of the UNEP Guidelines and/or any future international agreement on biosafety (such as a Protocol to the Convention on Biological Diversity). 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 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.

9. 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 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 biotechnology. The aim was to promote greater awareness, understanding and appreciation of biosafety and biotechnology issues by scientists and administrators, in particular in developing countries and countries with economies in transition. There was a recognised need to promote an exchange of views and information about biosafety amongst countries, the scientific community, relevant NGOs, the private sector, and other organizations.

10. 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.

11. The executive summary of the evaluation of the project is contained in Annex 2. The review by the Scientific and Technical Advisory Panel of the GEF (STAP) is contained in Annex 3.

12. The main conclusion of the UNEP evaluation of the project is that there was no doubt as to "*the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives believed that this was the type of project that the countries would have had to undertake. However, if left entirely to Governments for funding, it would have been greatly delayed, much slower and less effective. Certainly, a majority of the project activities at national level would not have taken place without the UNEP/GEF support. While limited funds are available in some of the countries for fundamental research, or applied research and development, most developing countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. Establishment of sub-regional/regional centres of expertise and nodes for supply and exchange of information, the training of scientists to use the technology safely, and to think about the consequences of their work, were seen to be of extreme importance and urgency*." The report concludes that the funds provided to countries in order to undertake the project were inadequate. In addition time period during which the work had to be undertaken was far too short. Originally intended to run for 12 months, it was extended to 16 months. The funding could not provide for an individual to devote enough time to the project to make it work as well as might be expected, but the output exceeded expectations in providing a basis for legislation or guidelines in all the participating countries.

13. The STAP review provides detailed comments on the project. They recommended that, before the ICCP meeting in December 2000, there be a scientific and technical meeting to address, amongst other issues:

(a) The critical mass of the scientists that are needed to implement the framework
(b) The institutional issues to implement the framework, since many countries lack institutional mechanism to mobilize the existing scattered scientists.
(c) The development of scientific and technological competence in biotechnology/ biosafety.
(d) The development of closer collaboration with the existing biotechnology agencies.

These issues were beyond the scope of the project, for they address issues that follow on the development of a Framework. It is, however, necessary to ensure that there is an adequate scientific infrastructure to provide advice on risk assessment and risk management during the development of the Framework. Annexes I, II and III of the Protocol provide the information base for a scientific assessment of risk and are appended as Annexes 7-9 of this paper. It is recognised that there will need to be regional and sub-regional collaboration to provide the necessary infrastructure.

14. The STAP report stressed that, "*[b]ased on the reports submitted at the completion of the project it is obvious that the project has promoted awareness among the participating*

countries on the need of establishing legal framework to assess and manage the risk of the products of biotechnology, in particular LMOs and ONTs. However, from the list of constraints, STAP stresses the importance of the time factor for the project implementation". "*STAP was pleased to observe that countries participating in the project appreciated the efforts of the project to provide them with opportunity to developing and enhancing their capacity in biosafety*".

15. The Protocol was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity, held in Montreal, Canada on 24-28 January 2000. It was open for signature in Nairobi, Kenya from 15-26 May 2000 at the Fifth Conference of the Parties during which a Special Signing Ceremony was held on 24 May 2000. The Protocol provides the foundation on which tensions between environmental concerns associated with the trade in, and development of, LMOs can be reconciled with global aspirations and investments in biotechnology. Sixty-eight countries signed the Protocol in Nairobi, and many more are expected to do so from 5 June 2000-4 June 2001 in New York where it will also be open for signature. The widespread acceptance evident in Nairobi indicates that the Protocol is likely to enter into force in a relatively short period.

16. Article 28(2) of the Protocol provides that the financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for the Protocol. Accordingly, the GEF is the financial mechanism of the Protocol.

17. The Protocol establishes a Biosafety Clearing House (Article 20) to facilitate the transfer of scientific, technical, environmental information between Parties and to "*assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular, the least developed and small island developing countries among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity"* (Article 20 1(b)). Countries are required to make available to the Biosafety Clearing House any information as set out in Article 20(3). The Biosafety Clearing House should be in place before the Protocol comes into effect; therefore, any preparatory work that may need to be done within countries to enable their input into this new mechanism should be in place as soon as possible.

18. 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.

19. 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*".

RATIONALE AND OBJECTIVE

20. Countries that have signed the Protocol have signalled their willingness to assume a number of obligations to provide information to other member states regarding the nature and safe use of living modified organisms resulting from modern biotechnology. 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*".

21. In addition to obligations under the Protocol, Parties to the Convention are required, through Article 8(g) to institute national regulatory systems for management and control of any risks associated with the release of LMOs into their environment. Accordingly, in order to meet these requirements, Parties to the Convention and/or 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, 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.

22. The Convention and the Protocol recognise 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. In particular, these agreements recognise the need to facilitate regional, sub-regional and national capacity building for technology transfer and risk assessment and management. The newness of the Protocol cannot be used to imply that all capacity building should now be built around its terms, without taking into account the needs identified in the Convention. To institute the legal frameworks necessary to implement the Protocol without setting up a framework for identifying and minimising risk when modified organisms that may pose a risk to the environment or to human health are released would be difficult to achieve.

OVERALL OBJECTIVE

23. The overall objective of the project is to prepare countries for the entry into force of the Protocol and, in doing so it will contribute to assisting GEF eligible countries to implement Article 8(g) of the Convention.[10] The project aims at

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

24. This will be achieved through:

(i) Strengthening national capacity in order to implement biosafety procedures and maximize the potential for the safe use of biotechnology;

(ii) Applying biosafety procedures to enhance environmental management;

(iii) Applying biosafety guidelines under the Convention and the Protocol and in response to decisions of the Inter-governmental Committee for the Cartagena Protocol on Biosafety (ICCP) taking into account the UNEP International Technical Guidelines for Safety in Biotechnology;

(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, and their products, to promote informed debate and to ensure that where any use of 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,

(viii) Increasing the overall safety of biotechnology so those citizens may reap the benefits with minimum adverse effects on health and environment where it is decided to allow the use to proceed.

Component I: Promoting regional and sub-regional collaboration and exchange of experience

25. 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

[10] The Protocol, Article 16(1)*: "The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms"*

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 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 biotechnology and biosafety, as is the involvement of international experts from other parts of a region and other regions.

26. 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 biotechnology within the region. Co-operation at sub-regional and regional levels is key to the successful implementation of the objectives of the Protocol. It is recognised that many countries will not have the full complement of expertise needed to allow a comprehensive assessment of risk The full range may however be available with a sub-region or region. 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 biotechnology, research, development and application of LMOs/GMOs:

- human resources and relevant expertise pertinent to issues of biosafety/biotechnology at national, sub-regional and regional levels;
- national and sub-regional capacities to assess and manage risks associated with products of modern technology that may have an adverse impact on the environment;
- guidelines, methodologies and procedures for rapid assessment and management of risks and benefits of products of modern technology and review of applications for field trials and field releases;
- networks for supply and exchange of biosafety information

27. To facilitate such collaboration, 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. These workshops will be followed by 15 sub-regional workshops involving participants from their respective regions. 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.

28. 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.

29. The first regional familiarisation workshops will take place before the start of Activity II. It 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.

30. 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.

- Reports of the meeting(s) of the ICCP of the Protocol and the identification of any action that might be needed to be taken by countries to implement any decision of the ICCP.

- 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;

- Designation of sub-regions and identification of discussion topic in relation to sub-regional workshops including the identification of issues that need to be dealt with at the sub-regional levels (some of the issues that might be referred to sub-regional meetings are indicated in paragraph 32)

31. The expected outcome of the workshops will be a clear understanding by participating countries of the obligations placed upon them by the Convention and 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 and their products. 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*"[11]. The regional meetings will designate sub-regions and refer those issues thought to be of importance at a sub-regional level.

32. 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

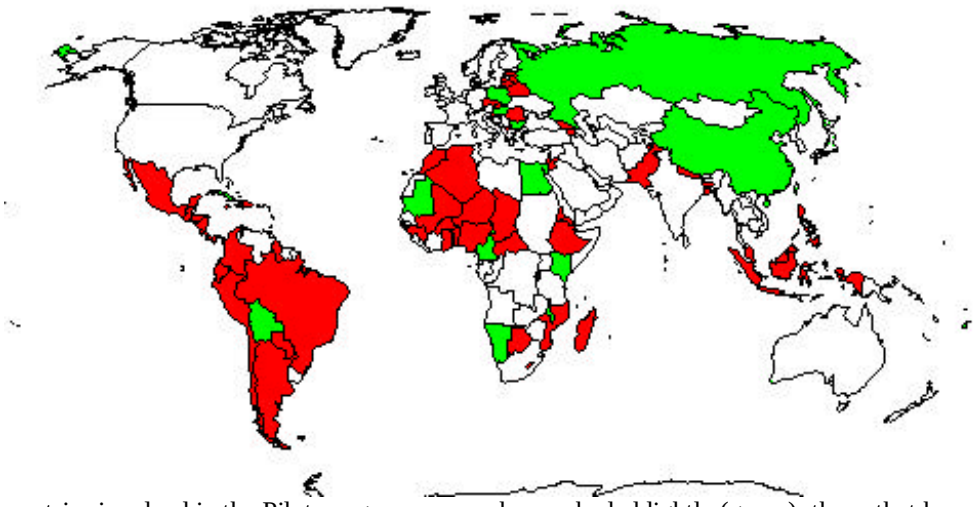
- Identify sub-regional priorities to enhance existing capacities/expertise;
- Discuss ways to collaborate in utilising:
  - human resources and relevant expertise pertinent to issues of biosafety/biotechnology at national and sub-regional levels;
  - national and sub-regional capacities to assess and manage risks associated with products of modern biotechnology 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 products of modern biotechnology 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.

33. 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

34. One hundred eligible countries will be supported to prepare national biosafety frameworks. At the time of the preparation of the project proposal, requests had been received from the countries listed in Annex D. The table indicates the date of ratification of or accession to the Convention. It is anticipated that most of the countries that have applied to UNEP for funding will start preparations under this national component but that disbursement of funds will occur only after the country concerned has signed the Protocol. 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 when the Protocol comes into force countries are able to implement that that is required.

[11] The Protocol, Article 2.



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).

35. 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 E. and are designed to

✓ Assist countries to meet their national obligations in order to implement the terms of the Convention and the Protocol and to prepare for meetings of the Inter-Governmental Committee for the Cartagena Protocol on Biosafety, taking into account the UNEP International Technical Guidelines for Safety in Biotechnology. 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 Mechanism 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: Action will include[12]:

- 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.

[12] Note also appendix I: Elements to be included in the Memorandum of Understanding with National Executing Agencies section vi.

- 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 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 "*[A]ware 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 and their products, to promote informed debate.[13] Action will include[14]:

- 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 and their products 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 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 product 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

[13] 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."

[14] Note also appendix I: Elements to be included in the Memorandum of Understanding with National Executing Agencies Section viii

all stages of the project in order to work towards a common goal of promoting only the safe use of biotechnology.

✓ Strengthen national capacity for decision-making and implementation of biosafety procedures. Action will include[15]:

- 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 (the Protocol Article 14).

- 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.

36. 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. The volume of information on technical, policy and legislative aspects of biotechnology and biosafety is growing exponentially. The topic has changed very dramatically since the initiation of the pilot project. The Protocol will make a substantial difference even to those countries that had already implemented legal and administrative frameworks for modern biotechnology. An enormous amount of information is becoming available about the changes to organisms that we are able to make, the manner in which new traits are expressed and about the impact of new varieties (whether modified or not) in a particular ecosystem. Each participating country will need both to use and to add to this information and there are large economies of effort to be gained from disseminating and exchanging this information.

37. To respond to this need, technical advisory support will be offerered. This will be used to complement any Biosafety Clearing House mechanism put into place that will probably deal with very specific information as detailed in the Annexes to the Protocol

[15] Note also appendix I: Elements to be included in the Memorandum of Understanding with National Executing Agencies section x.

attached to this document and any decisions made by the ICCP. The advice and information provided through the project will be designed to ensure no duplication with that which is put into place in the Biosafety Clearing House. The main responsibility will be to 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.

38. 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;
  (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 biotechnology and biosafety public awareness and education, and for monitoring and contributing to press coverage of biosafety issues.

INSTITUTIONAL FRAMEWORK

39. 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.

40. 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.

41. 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.

42. 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 Africa. Three Programme Officers will assist him. Each Programme Officer will be responsible for overseeing the preparation of the national biosafety frameworks in one geographical region. Under the overall supervision of the Scientific Coordinator, an additional Programme Officer will be responsible for the management of the biosafety technical advisory programme. A Fund Manager will be also appointed. The Scientific Coordinator will act as the secretary of the Steering Committee.

STAKEHOLDER PARTICIPATION AND IMPLEMENTATION ARRANGEMENTS

43. 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 E.

44. Governments 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.

45. 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

46. 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 A.

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
	Fees					**1,226,484**		

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**	**27,318,567**	12,341,463	38,103,546

47. 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 recommendations of the Co-chairs of the Steering Committee.

48. 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 similar to that provided as Annex E. 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 and those articles of the CBD that relate to biosafety, 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. The Pilot Project demonstrated a desperate need for advice on the many issues that arise from the conflicting needs to promote the use of this new technology so as to allow real benefit to flow and the need to assure safety and minimise risk to the environment and to human health. It is almost essential that every country participating in the project is visited at least once as early as possible in order to place the issues in their context and help identify all the stakeholders that need be consulted. This imposes a very large workload on the staff required to provide the necessary infrastructure to set up the country level project and the advice necessary to achieve something that is worth doing.

49. 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.

50. To justify the amount of money spent to ensure that Biosafety Frameworks do exist when the Protocol comes into force, we project 4 members of staff needed (in addition, UNEP will provide secretarial assistance, finance management and office facilities and accomodati0n) for the project.

- A Task Manager at level L6 will manage the project, report to the Steering Committee and be responsible for all African countries that are involved in the project. African countries currently have the least developed biotechnology frameworks, and will form a major part of the project. The Task Manager will be employed for 3 years and 6 months, the extra six months being used to ensure that completion of the project and its evaluation.

- Three Programme Officers will be appointed (L4), with primary responsibility for each of the other regions. Two will be appointed for three years, the fourth for 3 years and 6 months for the same reason as the Task Manager. Technical Support Officer (L3) will be appointed by UNEP, supported by UNEP funds to ensure that the support programme operates efficiently and to act as a liaison officer with UNEP Divisions.

MONITORING EVALUATION AND DISSEMINATION

51. 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.

52. 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.

53. 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

54. 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 A: Incremental Cost: This is an Enabling Activity project and is therefore considered fully incremental in the context of GEF funding. The full budget for the project is included here.

Annex B: Logical Framework Matrix

Annex C: STAP Roster Technical Review: No specific technical review was undertaken for this Enabling Activity. The draft. STAP selective review of the UNEP/GEF Pilot Biosafety Enabling Activity Project is included here (Page C-1), as is the Executive Summary of the evaluation of the UNEP/GEF Pilot Enabling Activity Project (page C-9)

Optional Annexes:

Annex D: Table 1: Table of countries that have expressed an interest in the UNEP/GEF Biosafety Enabling Activity Project

Annex E: Elements of the Memorandum of Understanding with National Executing Agencies.

Annex F: Workplan for this project

Annex G: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Annex I: Information required in notifications under articles 8, 10 and 13

Annex H: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Annex II: Information required concerning Living Modified Organisms intended for direct use as food or feed, or for processing under Article 11

Annex I: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Annex III: Risk Assessment

ANNEX A

BUDGET

This is an Enabling Activity project and is therefore considered fully incremental in the context of GEF funding. The full budget for the project is included below

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 liase 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

Notes:

* 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
3.1	**Project Management**							
3.1.1	Negotiation and conclusion of necessary agreements with participating countries						330,000	
3.1.2	Day-to-day management of the project							
3.1.3	Provision of scientific and technical backstopping							
3.1.4	Preparation of quarterly progress and financial reports							
3.1.5	Peer-review of draft National Biosafety Framework Documents		40,000			40,000		40,000
3.1.6	Self evaluation and external evaluation (2 Overseeing Reviewers + 1 reviewer for each region, travel, meetings and preparation of reports, assumes 2 months work per reviewer)			150,000		150,000		150,000
3.1.7	Organisation of Steering Committee Meetings (1 per year)	50,000	50,000	50,000		150,000	26,400	176,400
3.1.8	Travel to regional workshops (5 professionals)	80,000				80,000		80,000
3.1.9	Travel to sub-regional workshops (2 professionals per subregion)		60,000	60,000		120,000		120,000
3.1.10	Travel to national workshops (1 or 2 international resource persons per country)		200,000	200,000		400,000		400,000
3.1.11	Travel to countries participating in the project (1 trip of 1 professional per country)	180,000	180,000	180,000		540,000		540,000
3.2	**Staffing**							
3.2.1	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
3.2.2	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
3.2.3	Programme Officer, CE&E (L4) (uprated at 5% per annum)	150,000	157,500	165,375	-	472,875		472,875
3.2.4	Programme Officer, Asia/Pac (L4) (uprated at 5% per annum)	150,000	157,500	165,375	-	472,875		472,875
3.2.5	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**

DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS

SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	CRITICAL ASSUMPTION AND RISK
Overall Objective			
To prepare countries for the entry into force of the Cartagena Protocol on Biosafety and, in doing so, to contribute to assisting GEF eligible countries to implement Article 8(g) of the Convention on Biological Diversity. These requires 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.	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	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 and the CBD. 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	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 CBD or for the Protocol when it comes into force. 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 to ensure that when biotechnology is used it is safe and is seen to be so by interested parties as required by the CBD and the Protocol.

OUTCOMES			
The promotion of regional collaboration and exchange of experience on issues of relevance to National Biosafety Frameworks.	Regional meetings will be held to 1 Identify the tasks required of countries that are Parties to the CBD and have signed or about to sign 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.	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.	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.
The promotion of sub-regional collaboration following the regional meetings and the exchange of information on issues of relevance to implementing the Protocol and relevant sections of the CBD at a sub-regional level..	Sub-regional meetings will be held to: (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 products of modern biotechnology 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	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	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.

	other international bilateral and multilateral agencies.		
Provision of assistance for up to 100 eligible countries to prepare their national biosafety frameworks	1. Each country will survey the use of biotechnology in each country, the existing legislative framework, and existing projects for capacity building in biosafety. 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 so that all stakeholders can be fully informed about modern biotechnology and biosafety and can participate in the national debate. 4. Countries should involve the public and private sectors in the debate on biosafety and foster collaboration. 5. Countries will convene national 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)	1. Publication of a survey of the status of the use of biotechnology and its applications within a country. 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.	The diverse views about the use of LMOs in each country may inhibit the process of scientific evaluation and decision on the safe use of biotechnology. It is necessary to involve all stakeholders and attempt to produce a consensus on the mechanisms that are used to ensure that legislation or guidelines are aimed at ensuring biosafety.

Components/Activities	
COMPONENT 1: PROMOTING REGIONAL AND SUB-REGIONAL COLLABORATION AND EXCHANGE OF EXPERIENCE	
1) 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: a) Introduction to the CBD and 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.	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.
2) 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. 3) The first workshops will attempt to 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 the sharing of information 4) 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	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.

COMPONENT II: PREPARATION OF NATIONAL BIOSAFETY FRAMEWORKS	
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 UNEP Technical Guidelines, the Convention or the Protocol. This will assist countries to meet their obligations under the Convention and 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.	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 takes force will be responsible for consulting stakeholders, publishing relevant information, and performing the necessary survey that allow the many decisions to be made.

Annex C

1

Report of The STAP Selective Review of "Pilot Biosafety Enabling Activity Project[16]"

PREPARED BY

The Scientific and Technical Advisory Panel (STAP)
of the Global Environment Facility (GEF)

STAP Secretariat
United Nations Environment Programme

BACKGROUND

The UNEP/GEF Pilot Biosafety Enabling Activity Project was approved by the GEF Council at its November 1997 meeting. It is intended to promote a comprehensive understanding and approach by countries, within a regional/sub-regional context, to safeguarding biological diversity under *in-situ* conservation against possible adverse impacts from living modified organisms (LMOs)/organisms with novel traits (ONTs) resulting from biotechnology, by enhancing safety in biotechnology. The project comprises two main elements:

(i) **National Component** which entails the Preparation of National Biosafety Frameworks by eighteen (18) countries[17] of variable sizes, geographical locations, level of socio-economic development, as well as different stages of biotechnology development and application of biotechnology products; and

(ii) **Global Component** which caters for the convening of 8 regional workshops[18] with the main aim of providing a better understanding and appreciation of biosafety issues pertinent to the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology[19].

At the adoption of the project by the GEF Council in November 1997, STAP was requested to undertake a Selective Review, on completion of the project. The purpose of the independent

[16] This is a preliminary report prepared for the Inter-Agency Task Force Meeting. The final report will be considered and adopted at the Seventh Meeting of STAP to be convened in September, 2000.
[17] The countries participating in this component include: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda and Zambia.
[18] i.e. two workshops to be conducted in each of the following 4 regions: Africa; Asia/Pacific; Latin America and Caribbean; and Central and Eastern Europe regions
[19] UNEP International Technical Guidelines for Safety in Biotechnology was adopted by the Global Consultation of Government-designated experts in 1995. The Conference of the Parties (COP) to the Convention of Biological Diversity (CBD) in its decision II/5, 1995 stated that, during the development of a Protocol on Biosafety of the CBD, internationally agreed guidelines such as that of UNEP's may serve as an interim mechanism.

technical review undertaken by the Scientific and Technical Advisory Panel (STAP) to the Global Environment Facility (GEF) is to broadly to (i) review the scientific and technical issues arising from the implementation of the activities of the Pilot Project; (ii) assessment of the scientific and technical issues that need to be addressed in the context of the implementation of National Biosafety Frameworks (iii) advise on ways and means to enhance the scientific and technical capacity of the participating countries in terms of risk assessment and risk management (iv) advise on the scientific and technical issues that need to be addressed by contemplated regional/subregional centres of expertise and (v) highlight pertinent issues in the context of follow-up action to the Pilot Phase.

The selective review undertaken by STAP, consists essentially, of a desk study of the available document produced as part of the project activities. The STAP Selective review team composed of Prof. José Sarukhan (STAP); Dr. Setijati Sastrapradja (STAP) and Dr. Jorge Larsana, Biosafety/Biotechnology specialist.

1. Review of the Scientific and Technical Aspects of the Project

Based upon the outputs of the projects, the following comments and conclusions are made in accordance with the terms of reference of the selective review.

2.1 SCIENTIFIC AND TECHNICAL ISSUES ARISING FROM THE IMPLEMENTATION OF THE ACTIVITIES OF THE PILOT PROJECT

The issue of scope of the biosafety frameworks is both a policy decision and a scientifical and technical issue. A clear definition in this regard will benefit all national Frameworks and their future articulation with multilateral biosafety frameworks. Biosafety in its general sense involves practices relating to many fields of expertise and various sectoral authorities. However, within the Cartagena Protocol on Biosafety a clear emphasis is given to the evaluation and management of the potential risks to biological diversity associated to the release of Living Modified Organisms to the environment. Accordingly, GEF funds designated to biosafety should prioritize the biodiversity-related component of the National Frameworks.

Within the National Frameworks a sound delimitation of scope - either including or excluding health issues and/or products derived from LMOs - will benefit future efforts (regional and national) that specifically address the environmental issues or the release of LMO. Thus, the recommendation is to promote and support clear definitions of scope, regardless of their amplitude or specificity, which is a sovereign decision. Whatever the final national decisions on scope, it is important to have clearly defined attributions to facilitate articulation with regional and global biosafety instruments.

During the time of implementation of the Pilot Project the Cartagena Protocol has been agreed upon. Its aspects of risk evaluation and risk management, including the annexes, are very useful for identifying the scientifical and technical issues that will need to be addressed by countries.

2.2 SCIENTIFIC AND TECHNICAL ISSUES THAT NEED TO BE ADDRESSED IN THE CONTEXT OF THE IMPLEMENTATION OF THE NATIONAL BIOSAFETY FRAMEWORKS.

Clarity in scope definition needs scientific and technical expertise to understand clearly the differences between releasing living modified organisms to the environment, the production and/or commercialization of their living products (e.g. seeds, tuber) and the use and commercialization of non living derived or purified products. Although UNEP has provided guidelines that have proven useful, more on site training and capacity building might be needed to ensure clarity in definitions of scope within National Frameworks.

Intent of use of the LMO or its products should also be carefully considered because this will also be useful in clear definitions of scope.

Finally, the process of building and implementing the NBF's should be viewed as an aid in the political-administrative decisions that will further help in defining the scope of the biosafety framework in each country.

Depending on national capacity and existing institutions, a centralized authority dealing with all aspects related to biotechnology or a specific authority dealing exclusively with modern biotechnology and the release of LMOs to the environment are the two extremes of a full range of possibilities. These national decisions should be taken with sound scientific and technical understanding of their consequences in order to facilitate the articulation between National Frameworks and multilateral agreements.

2.3 WAYS AND MEANS TO ENHANCE THE SCIENTIFIC AND TECHNICAL CAPACITY OF THE ACTIVITIES OF THE PARTICIPATING COUNTRIES IN TERMS OF RISK ASSESSMENT AND RISK MANAGEMENT

Although most NBF suggest creating a specific LMO register (or similar concepts), it is very important to include minimum standards for information management. Many countries have developed GIS and biological inventories capacities, many with GEF support, that should be articulated with biosafety information. This is crucial if monitoring is going to be implemented in the medium term.

Biosafety databases (including information of LMOs and their uses) should not be isolated from biodiversity information management. In fact, resources from biosafety procedures (risk evaluation and management) should positively benefit biodiversity information management through the support of baseline inventories of pollinators). Precise geographical information will also prove very useful in risk evaluation - including modeling - and management, as well as in monitoring.

There are many databases and GIS utilities that have developed specific biodiversity applications. Such software and database should be extended - as needed in each country - to include information specific to risk evaluation (e.g. distribution of wild relatives and landraces or their reproductive systems). These efforts will profit if viewed within the context of projects related to the implementation of the obligations of inventorying and monitoring in the CBD and its Annex 1.

The efforts in capacity building should balance the disciplines related to risk assessment and management such as biological inventories (taxonomy and molecular systematics), ecology (population ecology and genetics, evolutionary ecology, interactions and reproductive systems) and molecular biology with those related to capacity to produce and manage LMOs such as biotechnology, agronomy, etc. This balance will help both the understanding potential risks of LMOs and also the production of biological information needed for risk assessments in local environments. This will foster a scientifically sound application of the precautionary principle, its approaches and practices. The importance of this balance between areas of expertise is fundamental for sound environmental risk assessments.

At national level, it would be very useful to clarify the differences between the direct potential hazards posed by LMOs to human health (e.g. living vaccines or direct consumption of LMOs), consumption of purified derivatives of LMOs and the potential indirect risks to human health through damage to biodiversity and the environment. This has long been a problematic issue of interpretation and it would be important to promote a common understanding of the issue. This problem is also illustrated by the tendency to use risk level classifications that have been developed with human health considerations. These levels of risk do no apply to many of the biotechnological applications foreseen in the short or middle term to be used or imported to developing countries.

Recommendations in part 3 can be applied to part 4 in some instances but viewed at the regional/subregional level.

2.4 SCIENTIFIC AND TECHNICAL ISSUE THAT NEED TO BE ADDRESSED BY THE CONTEMPLATED REGIONAL/SUBREGIONAL CENTERS OF EXPERTISE

Will we need a risk level classification for environmental releases? This is a specific scientific and technical issue to be addressed at the regional/subregional level of coordination.

Similar to the scientific and technical capacity comment (see 2.3), STAP is of the view that not only agricultural biotechnology centre should be envisioned, but also strong networking between global agricultural facilities and biodiversity libraries (e.g. herbaria, collections and germplasm bank) and national research institutions. The repatriation of information needed for risk assessments in tropical and developing areas is deposited in developed countries. Much of this already exists, what is lacking is a formal linkage of this efforts on biodiversity information with the biotechnology and biosafety oriented efforts.

It would be very useful to start developing a conceptual framework that will eventually lead us to some form of classification of environmental risk levels, particularly those related to biodiversity. This will benefit all countries and multilateral agreements in the long run.

The project was undertaken between April 1998 and September 1999, during which the two main components of the project were implemented, namely;

3.1 National component: Of the 18 countries selected to participate in the project one[20] was not able to continue its participation in the pilot phase. Most countries accomplished the tasks as outlined in the Term of Reference of the project, which among others are:

(a) The status of biotechnology capacity in the country
(b) The Task Force on Biosafety established
(c) The National Biosafety Framework formulated
(d) The awareness of the importance of biosafety framework Multidisciplinary team on biotechnology/biosafety formed

Thorough survey and national workshop in each country data on activities, infrastructures, and human resources engaged in biotechnology research and development was gathered. Moreover, awareness on the need to develop biosafety measures was enhanced among different disciplines of scientific community and the different sectors in the government. In most countries, before the project, there was no legal framework to assess and manage the risk. Through the project, these countries were able to formulate the National Biosafety Framework. In conclusion, STAP was pleased to observe that countries participating in the project appreciated the efforts of the project to provide them with opportunity to developing and enhancing their capacity in biosafety.

3.2 Regional/International Component: A total of 8 regional workshops were organized in Latin America and the Caribbean, Central and Eastern Europe, Africa, and Asia-Pacific. The main issues discussed in the workshops were:

(a) Issues related to risk assessment and risk management of living modified organisms (LMOs) or organisms with novel traits (ONTs).
(b) Issues related to transboundary transfer of LMOs and ONTs.

The workshops brought together biosafety experts from different countries and sectors and provided them with a forum to exchange views and information on the above issues. In this way, awareness on the issues related to biosafety and biotechnology of the participants who represented governments, the scientific community, United Nation Bodies, non-government organizations, and private sectors was arisen. Moreover, the workshops facilitated the development of national regulatory frameworks, particularly for those countries participating in the project.

The workshops also provided participants with the opportunity to learn from each other on the state of the art of biotechnology in various countries. This in turn reflected the state of the art of biotechnology in particular regions. The workshops were also able to identify the trends in commercialization and international trade of biotechnology products. A major conclusion arising from those discussions is that regulatory and efficient systems are needed to provide safety to the users of biotechnology products. As for the transboundary movement of LMOs and ONTs; legal issues, including advance informed agreement (AIA); and compensation and labeling were also addressed. It becomes obvious that such legal issues are related to the national capacity for establishing a strong regulatory system.

[20] Pakistan

The need to develop and increase capacities including human resources, infrastructure and mechanisms for information supply and exchange was identified as prerequisites to implement the UNEP Guidelines for Safety in Biotechnology and Protocol of Biosafety after its completion. International cooperation was considered as not only essential for the development of capacities in biotechnology and biosafety but also for the harmonization of efforts between national and regional level.

The need to enhance national capacity for biosafety biotechnology was stressed.

3.3 Issues highlighted in the context of follow-up actions to the Pilot Phase Project

Based upon the content of the various reports, the following issues are being highlighted in the context of any follow-up action to Pilot Phase Project.

(i) **Time Factor:** Based on the reports submitted at the completion of the project it is obvious that the project has promoted awareness among the participating countries on the need of establishing legal framework to assess and manage the risk of the products of biotechnology, in particular LMOs and ONTs. However, from the list of constraints, STAP stresses the importance of the time factor for the project implementation.

(ii) **The continuation of the project:** All participating countries expressed the desire to continue with the project implementation considering the elements of biosafety framework is now in place. They stressed the need to enhance the capacity building to conduct the risk assessment and risk management. STAP is of the opinion that legal frameworks/regulation/law should be accompanied by the competence of human resources. Therefore, for those participating countries, if and when the project will be continued, the following aspects need further consideration:

(a) The scope of the project needs to be broadened and deepened.
(b) Biotechnology policy: to cover not only in environment sector but cross sectoral issues as well.
(c) Clarity of institutional set up to implement the framework.
(d) Training to enhance human resources capability on this subject is most appropriate so that assessment on scientific and technical issues can be conducted properly.
(e) National and regional dialogues to strengthen national capacity.
(f) Biodiversity aspect is included in the biosafety framework not only health and environment.
(g) Awareness on this subject of community outside the scientific community
(h) The active involvement of the Steering committee on the project Implementation.

(iii) **The Project Expansion:** The regional workshops recommended that the project should be expanded to countries which need assistance form UNEP-GEF. Considering this recommendation, STAP is in the opinion that before the first meeting of the ICCP of the CBD is convened, a scientific and technical meeting should be convened by UNEP/GEF to address issues such as, but not limited to;

(a) The critical mass of the scientists that are need to implement the framework

(b) The institutional issues to implement the framework, since many countries lack institutional mechanism to mobilize the existing scattered scientists.

(c) The development of scientific and technological competence in biotechnological/ biosafety.

(d) To develop closer collaboration with the existing biotechnology agencies.

STAP Selective Review of the Pilot Biosafety Enabling Activity Project

Annex 1

Terms of Reference

1. Review the scientific and technical issues arising from the implementation of the activities of the Pilot Project

2. Assess the scientific and technical issues that need to be addressed in the context of the implementation of the National Biosafety Frameworks

3. Advise on the ways and means to enhance the scientific and technical capacity of the participating countries in terms of risk assessment and risk management

4. Advise on the scientific and technical issues that need to be addressed by the contemplated regional/subregional centres of expertise.

5. Assess the usefulness of the project outputs, and how they contribute to the overall objectives of the project.

6. Based upon (1-4) and taking into consideration the recommendations of the Regional workshops advise on the desirability of expanding the Pilot Biosafety Enabling Activity Project bearing in mind:

   (a) The level of additional support needed, for the future implementation of the National Biosafety Frameworks already prepared, and

   (b) The future actions and types of assistance required to facilitate the preparation of NBFs for other developing countries and countries with economies in transition.

Annex C

2

UNEP/GEF PILOT BIOSAFETY ENABLING ACTIVITY PROJECT

EVALUATION REPORT

EXECUTIVE SUMMARY

BACKGROUND

1. This evaluation was undertaken by Dr. Julian Kinderlerer of the University of Sheffield, U.K. during the period November/December 1999. It covers the two components of the project:

   (i) Support to the preparation of National Biosafety frameworks by 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russia, Tunisia, Uganda and Zambia).

   (ii) Organisation of a series of awareness-raising regional workshops on issues related to biosafety/biotechnology. These were held in Havana, Cuba; Bled, Slovenia; Nairobi, Kenya; and New Delhi, India.

2. The evaluation of the project involved:

   (i) An examination of all country reports submitted to UNEP in relation to the development of National Biosafety Frameworks;

   (ii) Visits to Bulgaria, China, Kenya and Mauritius and discussion with officials responsible for the projects in Poland, Russian Federation while at a meeting of the Central and Eastern European Countries in Bulgaria, December 1999.

   (iii) An examination of the reports emanating from all the workshops held in the four regions, plus reports of the Consultative Meeting of the Countries participating in the Pilot Project and the 2nd Steering Committee meeting held in Cairo, Egypt, 24-26 May 1999.

(iv) The evaluator also gives a brief explanation of the appropriateness of the project in relation to relevant provisions of the Convention on Biological Diversity (such as Article 8g) and relevant aspects of Chapter 16 of Agenda 21 (Environmentally sound management of biotechnology).

PROJECT IMPLEMENTATION

3. The project was implemented by UNEP in association with National Executing Agencies (NEAs) of the respective countries (for the national level component).
The three primary stages in the implementation of the project in each individual country were as follows:

(i) The current use of modern biotechnology within the borders of the country, collecting information on what was being done in national institutions, whether Government, university or private industry, and the level of awareness of biosafety within the institutions;

(ii) The structures required for a risk assessment and audit of these assessments in order to ensure the safe use of modern biotechnology;

(iii) The means by which the safe use of modern biotechnology could be promoted. This was often interpreted as the promotion of use of biotechnology, tempered by a need to involve the public in the development of strategies to ensure biosafety.

UNEP also collaborated with IRRO/MSDN and four institutions designated by respective host governments for the organization of regional workshops.

EVALUATION

4. This was an ambitious project that was successfully executed over a period of 16 months (originally planned for 12 months). Seventeen (17) out of eighteen (18) countries in the pilot project prepared National Biosafety Frameworks. The evaluator is satisfied that the countries have identified the national systems needed to ensure the safe adoption and application of products of modern biotechnology. However, many had not separated their role in promoting the technology from that of audit and safety assessment. The report suggests that it is important, in order to maintain public acceptance of a Government's objectivity, that a clear separation of duties/activities is maintained and the consequential necessary national capacities developed for the execution of the respective roles. These countries now require further support for capacity building initiatives that would enable them to implement the biosafety frameworks in the light of the provisions of the Protocol on biosafety. The UNEP International Technical Guidelines for Safety in Biotechnology (which were used by the participating countries as a guide) may also need updating/reviewing to take into account the Biosafety Protocol Provisions.

5. The evaluator observes that all the regional workshops were held and that a wide spectrum of stakeholders was involved. The regional workshops were successfully conducted, productive and worthwhile. The workshops provided a good understanding and appreciation of the type of assistance that the countries might need to ensure the transparent and safe consideration of the use of products of modern biotechnology. All the workshops concluded that strong regulatory authorities and efficient systems are needed to give users confidence in the safety of products on the market. It was recognised that there is a need for development and/or strengthening of national as well as sub-regional capacities, including the development of human resource infrastructure to attempt risk assessment, management and monitoring of LMOs at national, sub-regional/regional levels.

6. A recurrent theme of the participants at the regional workshops and of the officials and experts in the 17 countries participating in the national level component, was their genuine and honest commendation of UNEP for conceptualising and executing the project and the Global Environment Facility (GEF) for funding it. Both the regional workshops and the Consultative Meeting of the Participating countries as well as the Steering Committee members of the Pilot Project underlined the importance of extending further UNEP/GEF financial and technical support beyond the pilot project and to include additional eligible countries.

7. It is observed that the time scale for the project was severely limiting, and most countries were not able to complete the full legislative process of getting their national biosafety frameworks legally adopted by their Parliaments. However, the preliminary work done towards producing legal systems for safe biotechnology applications demonstrated a commitment to the project and towards ensuring that modern biotechnology is (so far as is possible) conducted in a safe manner.

8. The impetus of the project provided countries with the possibility of establishing a regulatory framework and of kick-starting the use of biotechnological techniques and options in those countries since research and development (R&D) in the area of biotechnology was “lagging”, relative to industrialised countries.

9. Accordingly and most commendably, a majority of the countries involved in the project have passed or drafted new legislation to control the use of LMOs/GMOs within their borders. This type of exercise may extend to other areas of biodiversity and protection of the environment – a very important and welcome development.

10. The level of public participation and involvement in the project in respect of the national level component, differed substantially among the countries, largely reflecting differing traditions, difficulties caused by the size and geographical conditions of the countries, the number of languages and educational deficiencies.

11. Having been an ambitious project, attempting much within a very short timeframe, the achievements attained indicate a well-managed project. The sub-Project documents and the UNEP biosafety guidelines provided a framework for the work involved in this project and the individual participating countries were provided timetables and detailed guidance for

delivery of various aspects of the project. The evaluator was impressed that the structures instituted by UNEP ensured that where countries failed to meet their obligations, the system was flexible enough to ensure that money was withheld. In some circumstances small amounts of extra finance were required, and again, countries were impressed with the flexibility of the system. Task managers at UNEP were clearly willing to talk with country representatives and provide the flexibility in interpreting the needs of countries within the framework set by the project.

12. In an extended/expanded future programme/project, timescales that are more realistic need to be identified. If need be, the terms of reference could be scaled down or drafted to ensure that countries are fully aware of what is readily achievable within the set time-frames, and within the funds that may be provided.

FRAMEWORK FOR COST NORMS

13. The identification of cost norms was one of the goals of the project. This has turned out to be very complex (perhaps virtually impossible). Variety in climate, physical and social geography, the number of local languages needed to bring on awareness of the benefits and risks of biotechnology to all stakeholders should be taken into account in the design of the biosafety systems to be implemented in the respective countries and in deciding on a level of funding support to be provided to the countries.

14. The rate of adoption of modern biotechnology applications may differ considerably and significantly from country to country. Whereas the adoption of technology itself may be cheap, and could be readily implemented at the laboratory stage by many countries, it is not the case with respect to risk assessment and risk management. Consideration of the potential hazards of any new LMO to human health or environment may be very expensive, and the investments required for the commercial exploitation of these novel LMOs may be substantial.

15. Fortunately, in the wake of the project activities at national level, and consequent awareness raised during both the regional workshops and the biosafety protocol negotiations, a majority of countries would not be starting from scratch i.e. from a complete absence of environmental legislation or total lack of some capacity for assessment of the impact of LMOs. However, there is strong need for strengthening national capacities and urgent need for establishing and/or strengthening sub-regional centers of expertise with the relevant capacities, facilities and human resources to support national level risk assessment and risk management initiatives.

16. From the experience gained and lessons learned in the pilot project, five types of broad assistance may be identified namely:

    (i) Support to the development of National Biosafety Frameworks by approximately 60 countries through a consultative and participatory process involving a wide spectrum of stakeholders nation-wide (US$ 18 million).

    (ii) Support to the implementation of National Biosafety Frameworks by 25 countries,

including those that participated in the UNEP/GEF Pilot Biosafety Enabling Activity Project, and other countries that are at various stages of finalisation of their National Biosafety Frameworks prepared on their own initiatives (US$ 14,840,000).

(iii) Support to sub-regional/regional awareness raising workshops on issues related to biosafety and biotechnology (US$ 5.2 million).

(iv) Support to establishment/strengthening of sub-regional/regional centres of excellence for biosafety and biotechnology (US$ 7,780,000).

(v) Support to Integrated, Multi-pronged Global/Regional/Sub-regional Medium-sized Projects on Biosafety (US$ 20 million).

17. **Accordingly, a crude estimate of funding needs required for accelerated capacity building initiatives in the immediate short-term (2 years) in respect of the critical mass of target countries may be given as US$ 65,820,000 starting from the July 2000. This would facilitate enhancement of biosafety at the national, sub-regional and regional levels in the identified critical mass of 85 countries, as further outlined below.**

CONCLUSIONS AND RECOMMENDATIONS

18. There can be no doubt of the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives believed that this was the type of project that the countries would have had to undertake. However, if left entirely to Governments for funding, it would have been greatly delayed, much slower and less effective. Certainly, a majority of the project activities at national level would not have taken place without the UNEP/GEF support. While limited funds are available in some of the countries for fundamental research, or applied research and development, most developing countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. Establishment of sub-regional/regional centres of expertise and nodes for supply and exchange of information, the training of scientists to use the technology safely, and to think about the consequences of their work, were seen to be of extreme importance and urgency.

19. The need expressed by those participating in this project for the funds allocated to them, and the impetus that they have experienced from its implementation, has been clearly demonstrated in this project. The countries involved in the project are fearful of being unable to complete the process started. They believe that much has been accomplished, but that there is much to accomplish in the area of biosafety and biotechnology in relation to biodiversity. If they are to set up strict regulatory systems, there needs to be enforcement and laboratory and field facilities that are capable of testing and validating the presence or absence of modified organisms. It is acknowledged that the project has stimulated a new approach to biotechnology by national and international organisations and that it has

stimulated regional cooperation. It would be a great pity if these 17 countries were unable to continue the good work started in the course of a single year.

20. In the evaluator's view, it is crucial for the future of biotechnology that a project similar to this one is funded in those countries that have yet to develop a consistent framework for the safe use of this science. If at all possible, as many as possible of those countries involved in this project should continue to be involved, acting in some ways as mentors to newly involved countries so as to allow the rapid build-up of expertise in this area. The experience gained and expertise developed as well as lessons learned should not be lost. Many more countries should benefit from similar input of funds and expertise as that available through this project. Many of these countries have applied for funding for their own National Biosafety Frameworks.

21. The follow-up project for new countries would then be similar to that already achieved, requiring a survey of the expertise and use of both biotechnology and of biosafety. An assessment of the need for an overall biosafety framework would then follow.

22. In order to effectively fulfil its functions as a complement to the Protocol on Biosafety, and to further guide the countries in the preparation of the National Biosafety Framework in the light of the provisions of the Protocol on Biosafety Frameworks in the light of the provisions of the Protocol on Biosafety, it is strongly recommended that consideration be given to the review of the UNEP International Technical Guidelines for Safety in Biotechnology.

ANNEX D

ELIGIBLE COUNTRIES THAT HAVE REQUESTED GEF ASSISTANCE FOR DEVELOPING NATIONAL BIOSAFETY PROJECTS

AFRICA REGION	
Country	Ratification of the CBD
*Algeria	14 Aug 95
*Benin	30 Jun 94
Botswana	12 Oct 95
*Burkina Faso	2 Sep 93
*Chad	7 Jun 94
*Central African Republic	15 Mar 95
Republic of Congo	1 Aug 96
*Gambia	10 Jun 94
*Ethiopia	5 Apr 94
Eritrea	21 Mar 96
Ghana	29 Aug 94
Lesotho	10 Jan 95
*Madagascar	4 Mar 96
Mali	29 Mar 95
*Morocco	21 Aug 95
*Mozambique	25 Aug 95
*Niger	25 Jul 95
*Nigeria	29 Aug 94
*Rwanda	29 May 96
Seychelles	22 Sep 92
Republic of South Africa	2 Nov 95
Tanzania	8 Mar 96
*Togo	4 Oct 95
*Uganda	8 Sep 93
Zimbabwe	11 Nov 94
ASIA/PACIFIC REGION	
Country	Ratification of the CBD
Bahrain	30 Aug 1996
*Bangladesh	3 May 1994
*Indonesia	23 Aug 94
Islamic Republic of Iran	6 Aug 1996
Jordan	12 Nov 1993
Lao People's Democratic Republic	20 Sep 1996
Lebanon	15 Dec 1994
*Malaysia	24 Jun 1994
Nepal	23 Nov 1993
Pakistan	26 Jul 1994
*Philippines	8 Oct 1993
*Samoa	9 Feb 94
Solomon Islands	3 Oct 1995
*Sri Lanka	23 Mar 1994
*Turkey	14 Feb 1997
Vietnam	16 Nov 1994
Yemen	21 Feb 1996

CENTRAL AND EASTERN EUROPE REGION	
Country	Ratification of the CBD
Armenia	14 May 1993
Belarus	8 Sep 1993
*Croatia	7 Oct 1996
*Czech Republic	3 Dec 1993
*Estonia	27 Jul 1994
Georgia	2 Jun 1994
*FYR Macedonia	1 Jul 94
Latvia	14 Dec 1995
*Lithuania	1 Feb 1996
Romania	17 Aug 1994
*Slovak Republic	25 Aug 1994
*Slovenia	9 Jul 1996
Ukraine	7 Feb 1995
LATIN AMERICA AND THE CARIBBEAN REGION	
Country	Ratification of the CBD
*Antigua and Barbuda	9 Mar 1993
*Argentina	22 Nov 1994
Barbados	10 Dec 1993
Brazil	28 Feb 1994
*Chile	9 Sept 1994
*Costa Rica	26 Aug 94
*Colombia	28 Nov 1994
Dominica	6 Apr 1994
Dominican Republic	25 Nov 1996
*Ecuador	23 Feb 1993
*El Salvador	8 Sep 1994
*Grenada	11 Aug 94
*Guinea	7 May 93
Guatemala	10 Jul 1995
Guyana	29 Aug 1994
*Haiti	25 Sep 1996
*Honduras	31 Jul 95
Jamaica	6 Jan 1995
*Nicaragua	20 Nov 95
*Mexico	11 Mar 1993
Panama	17 Jan 1995
Paraguay	24 Feb 1994
*Peru	7 Jun 1993
*Venezuela	13 Sep 94

* Countries that had signed the Cartagena Protocol on Biosafety before 22 September 2000.

ANNEX E

WORKPLAN

1	Promoting regional and sub-regional collaboration and exchange of experience	Year 1	Year 2	Year 3	4
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/s 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 liase 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 CBD, and 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 national level			
2.5.2	Sub-regional/regional consultations integrated at the national level			

3		Year 1												Year 2												Year 3												
3.1	**Project Management (3.5 years)**																																					
3.1.1	Negotiation and conclusion of necessary agreements with participating countries																																					
3.1.2	Day-to-day management of the project																																					
3.1.3	Completion of reports and terminal evaluation																																					
3.1.3	Provision of scientific and technical backstopping																																					
3.1.4	Preparation of quarterly progress and financial reports																																					
3.1.5	Peer-review of draft National Biosafety Framework Documents																																					
3.1.6	Self evaluation and external evaluation																																					
3.1.8	Travel to regional workshops (5 professionals)																																					

ANNEX F

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 liase 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, includingphytosanitary, 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.

(i) Submit the final version of the National Biosafety Framework no later than (month, 2003 - exact date to be agreed upon with each NEA).

(ii) Identify follow-up actions as appropriate.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

ANNEX 1

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

ANNEX II

Information required concerning Living Modified Organisms intended for direct use as food or feed, or for processing under Article 11

a. The name and contact details of the applicant for a decision for domestic use.

b. The name and contact details of the authority responsible for the decision.

c. Name and identity of the living modified organism.

d. Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

e. Any unique identification of the living modified organism.

f. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

g. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

h. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

i. Approved uses of the living modified organism.

j. A risk assessment report consistent with Annex III.

k. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

ANNEX III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

   (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

   (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

PROJECT REVIEW SHEET

Project Title: " Development of National Biosafety Frameworks "
Date: 10/03/00

	Work Program Inclusion per criteria established in Draft # 8 of the project review criteria	**Reference Paragraphs and Explanatory Notes:**
1. Country Ownership		
• Country Eligibility		• Eligible countries that have ratified the Convention on Biological Diversity. Disbursement of funds for countries participating in the national component of the project will only occur if they have signed the Cartagena Protocol on Biosafety.
• Country Drivenness	Clear description of Project's fit within: • National reports/communications to Conventions • National or sector development plans. • Recommendations of appropriate regional intergovernmental meetings or agreements.	• National Priorities have been identified in the Convention on Biological and the Cartagena Protocol on Biosafety. They were identified during the Ministerial Round Table during the COP V meeting (see paragraphs 3-5 and 15-19.
• Endorsement	• Endorsement by national operational focal points	• See cover page & Annex D for list of countries that have applied and for which the endorsement of national operational focal points will be required during the negotiation phase.
2. Program & Policy Conformity		
• Program Designation & Conformity	Describe how project objectives are consistent with Operational Program objectives or operational criteria	• See paragraph 3-5 and 15-19
• Project Design	Describe: • Sector issues, root causes, threats, barriers etc affecting global environment • Project logical framework, including a consistent strategy,	• See paragraph 20. The issues raised by the use of living modified organisms are extensively addressed in the Cartagena

	Work Program Inclusion per criteria established in Draft # 8 of the project review criteria	Reference Paragraphs and Explanatory Notes:

	goals, objectives, outputs inputs/activities, measurable performance indicators, risks and assumptions
	• Detailed description of goals, objectives, outputs and related assumptions, risks and performance indicators
	• Brief description of project activities, including an explanation how the activities would result in project outputs (in no more than 2 pages)
	• Global environmental benefits of the project.
	• Incremental cost estimation based on the project logical framework
	  • Describe project outputs (and related activities & costs) that result in global environmental benefits
	  • Describe project outputs (and related activities & costs) that result in global and national environmental benefits
	  • Describe project outputs (and related activities & costs) that result in national environmental benefits
	  • Describe the process used to jointly estimate incremental cost with in-country project partner
	  • Present the incremental cost estimate. If presented as a range, then a brief explanation of the challenges and constraints and how these would be addressed by the time of CEO endorsement.
		Protocol on Biosafety, the UNEP Technical Guidelines on Biosafety and the Convention on Biological Diversity. The project provides countries, regions and sub-regions with a capacity to implement the requirements of these instruments and provides the basis for primary or secondary legislation and guidelines for risk assessment and risk management.
		
		• See Workplan (Annex F), paragraph 23-35 and Annex E: Elements to be included in the Memorandum of understanding with National Executing Agencies.
		
		• Under component 1 of the project countries will be able to meet regionally and sub-regionally to identify issues and problems of common concern and to attempt to address the possible lack of scientific expertise in all the necessary disciplines through sub-regional cooperation.
		
		• Component 2 of the project provides each individual country with the opportunity to identify the expertise and experience in relation to the use of biotechnology and to the legal system that currently exists to ensure the safe use of modern biotechnology. It provides the tools to consult stakeholders and to decide on the format of a Biosafety Framework.

	Work Program Inclusion per criteria established in Draft # 8 of the project review criteria	Reference Paragraphs and Explanatory Notes:
		• This is an Enabling Activity project and is therefore considered fully incremental in the context of GEF funding. A full budget summary is included at paragraph 46 and Annex A.
• Sustainability (including financial sustainability)	Describe proposed approach to address factors influencing sustainability, within and/or outside the project to deal with these factors	• A Framework for Biosafety provides for a capacity to ensure that any use of modern biotechnology, or import or export of products derived using modern biotechnology is at the very least environmentally neutral and may assist planning for sustainability.
• Replicability	Describe the proposed approach to replication (for e.g. dissemination of lessons, training workshops, information exchange, national and regional forum etc.) (could be within project description)	• In addition to the preparation of the Biosafety Framework, the project provides facilities for consultation with all stakeholders and the dissemination and publication of education material to permit the public to understand issues related to biosafety. Many regional, sub-regional and national meeting are planned to ensure an understanding of these issues.
• Stakeholder Involvement	• Describe how stakeholders have been involved in project development • Describe the approach for stakeholder involvement in further project development and implementation	• This project follows on from the Pilot Biosafety Enabling Activity project approved at the 10th meeting of the GEF Council, held in Washington, DC on 4-6 November 1997, and uses the experience gained. Stakeholders on Pilot-countries were consulted and the project is designed to follow similar paths to those used in the pilot.
• Monitoring & Evaluation	• Describe how project design has incorporated lessons from similar projects in the past	This project follows on from the Pilot Biosafety Enabling Activity project approved at the 10th

	Work Program Inclusion per criteria established in Draft # 8 of the project review criteria	Reference Paragraphs and Explanatory Notes:

	• Describe approach for project M&E system, based on the project logical framework, including the following elements:
	  • Specifications of indicators for objectives and outputs, including alternate benchmarks, and means of measurement.
	  • Outline organisational arrangement for implementing M&E
	  • Indicative total cost of M&E (may be reflected in total project cost).
		meeting of the GEF Council, held in Washington, DC on 4-6 November 1997, and uses the experience gained. The information gained from both the UNEP internal evaluation of the Pilot Project (paragraph 11-12 and Annex C: UNEP/GEF Pilot Biosafety Enabling Activity Project, Evaluation Report, Executive Summary) and the STAP review (paragraph 11, 13-14 and Annex C: Report of The STAP Selective Review of "Pilot Biosafety Enabling Activity Project") have been taken into account in the planning of the project.

3. Financing		
• Financing Plan	• Estimate total project cost. • Estimate contribution by financing partners. • Propose type of financing instrument	• See Annex A: Budget for full details
Implementing Agency Fees	Propose IA fee	• The fee estimated in the Budget in Annex A is calculated using the draft formula provided by the Secretariat.
• Cost-effectiveness	• Estimate cost effectiveness, if feasible • Describe alternate project approaches considered and discarded	• It is presumed that this project will allow 100 countries to develop frameworks for biosafety. This framework will assist these countries to implement the Cartagena Protocol. The overall GEF component of the Budget is approximately 27 million that provides an average cost of less than $250,000 per country (including the regional and sub-regional component). The opportunities this presents to participating countries is very significant. • This project follows on from a Pilot project, which identified the effective goals and that which is possible to assist countries in providing for a Biosafety project.

	Work Program Inclusion per criteria established in Draft # 8 of the project review criteria	Reference Paragraphs and Explanatory Notes:
4. Institutional Coordination & Support		
IA Coordination and Support • Core commitments & Linkages	Describe how the proposed project is located within the IA's • Country regional/global/sector programs • GEF activities with potential influence on the proposed project (design & implementation)	This project builds on the experience gained from a Pilot project in 18 countries. There have been no equivalent projects aimed at identifying experience in biotechnology, legislation to achieve the safe use of biotechnology, risk assessment and risk management in response to the sections of the CBD referring to biosafety, the Cartagena Protocol on biosafety and the UNEP technical Guidelines on Biosafety.
• Consultation, Coordination and Collaboration between IAs, and IAs and EAs, if appropriate.	• Describe how the proposed project relates to activities of other IAs and 4 RDBs in the country/region. • Describe planned/agreed coordination, collaboration between IAs in project implementation.	
5. Response to Reviews		
Council	Respond to Council comments at pipeline entry	
Convention Secretariat	Respond to comments from Convention Secretariat.	All comments by the CBD secretariat have been taken into account, and the project document is an agreed position
GEF Secretariat	Respond to comments from GEFSEC on draft project brief.	All comments by the GEF secretariat have been taken into account, and the project document is an agreed position
Other IAs and 4 RDBs	Respond to comments from other IAs, 4RDBss on draft project brief.	Comments from other IAs have been taken into account
STAP	Respond to comments by STAP at work program inclusion.	The Pilot project was reviewed internally within UNEP and the executive summary is included. The Pilot project was also reviewed by a STAP member and two STAP roster members, and that draft report is included with the Project document. This project builds on the experience of the Pilot.
Review by expert from STAP Roster	Respond to review by expert from STAP roster	The Pilot project was reviewed internally within UNEP and the executive summary is included. The Pilot project was also reviewed by a STAP member and two STAP roster members, and that draft report is included with the Project document. This project builds on the experience of the Pilot.