GLOBAL ENVIRONMENT FACILITY
ENABLING ACTIVITY PROPOSAL FOR REVIEW

PROJECT TITLE:	**Pilot Biosafety Enabling Activity**
COUNTRY:	Global Component 1: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Kenya, Hungary, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda, Zambia Component 2: All eligible countries in Africa, Latin America and the Caribbean, Asia/Pacific and Eastern Europe
GEF FOCAL AREA:	Biodiversity
COUNTRY ELIGIBILITY:	All participating countries have ratified the Convention on Biological Diversity
GEF FINANCING:	US$2,744,000
GOVERNMENT CONTRIBUTION:	In-kind and personnel
GEF IMPLEMENTING AGENCY:	UNEP
EXECUTING AGENCY:	Component 1: National Governments Component 2: Information Resource on the Release of Organisms into the Environment (IRRO) in Collaboration with the Scientific and Industrial Research and Development Centre (SIRDC), Zimbabwe; Instituto Interamericano de Cooperacion para la Agricultura (IICA); and the University of Malaysia, Department of Genetics and Plant Breeding (Universiti Kebangsaan)
GEF OPERATIONAL FOCAL POINT:	Respective National GEF Focal Points
CBD FOCAL POINT:	Respective National CBD Focal Points
ESTIMATED STARTING DATE:	April 1998
PROJECT DURATION:	12 months

INTRODUCTION

1. Recognizing that biotechnology can contribute substantively to the improvement of agriculture, fisheries, forestry, industry, health care and environmental management, governments represented at the Earth Summit in Rio de Janeiro in June 1992 undertook to consider international cooperation on biotechnology and relevant safety aspects in order to maximize the benefits associated with biotechnology while minimizing its potential risks (Chapter 16 of Agenda 21). That commitment includes: sharing experience, capacity-building and international agreement on principles for safety.

2. Biotechnology and related biosafety aspects are also important features of the Convention on Biological Diversity (CBD). One issue of particular concern in this context is the use and release of living modified organisms resulting from modern biotechnology which may have adverse impact on the conservation and sustainable use of biological diversity. Indeed, Article 8(g) provides that each contracting Party shall, as far as possible and as appropriate, 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 diversity, taking also into account the risks to human health. In addition, Article 19(3) provides that the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

3. While the Conference of the Parties (COP) was examining how to implement the above Article 19 (3) of the CBD, 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 while avoiding duplication with the work of other organizations in particular the negotiation of a Protocol on Biosafety by the COP.

4. At its second meeting in Jakarta in November 1995, the COP stressed the importance of the urgent finalization of the UNEP International Technical Guidelines for Safety in Biotechnology (hereafter referred to as the Guidelines) 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. COP II further noted that the Guidelines may be used as an interim mechanism during the development of the protocol and to complement it after its conclusion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology (Decision II/4).

5. The Guidelines were then developed through a series of seven regional and sub-regional workshops on the basis of common elements and principles derived from relevant national, regional and international instruments, regulations and guidelines. These workshops, entitled "Consultation of Government - designated Experts to Review Draft International Technical Guidelines for Safety in Biotechnology and Related Capacity-building Requirements", were conducted in San Jose (Costa Rica - for Central America); Bangkok

(Thailand - for Asia/Pacific), Amman (Jordan - for Western Asia); Buenos Aires (Argentina - for South America and Caribbean); Geneva (Switzerland - for Western Europe and North America); Cairo (Egypt - for Africa); and Keszthely (Hungary - for Central and Eastern Europe). The Guidelines were adopted at a global Workshop held in Cairo in December 1995. They are based on the premise that adequate mechanisms for risk assessment and risk management and capacity-building through - among others - the exchange of information and the use of these Guidelines at national, regional and international levels can contribute significantly to safety in biotechnology.

6. The Guidelines address the human health and environmental safety of all types of application of biotechnology, from research and development (R&D) to commercialization of biotechnological products containing or consisting of organisms with novel trait(s). They propose mechanisms for evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as biotechnology. They also acknowledge the importance of assessing the socio-economic and other impacts of new biotechnologies, and acknowledge the importance of up-to-date knowledge for any safety mechanisms to be credible.

7. The third meeting of the COP held in Buenos Aires in November 1996 welcomed the finalization and adoption of the UNEP Guidelines and, reiterating the view that they constitute a useful complement in the development and implementation of a protocol on biosafety, requested the GEF to provide financial resources to developing country Parties for capacity-building in biosafety including for the implementation of the UNEP International Technical Guidelines (Decision III/5, paragraph 2 (a)).

8. A survey conducted by UNEP in 1996 on the implementation of the Guidelines and made available to the Conference of the Parties at its third meeting showed that aspects of the Guidelines of most interest to Governments were those related to risk assessment and risk management principles, national regulatory mechanisms and capacity building, regional and international regulatory mechanisms. The survey also indicated that governments were willing to share information and experiences gained to date and that countries were gearing themselves towards putting in place regulations and other mechanisms for biosafety oversight. Finally, the survey revealed that countries might be hampered by three constraints, namely, the lack of human resources, institutional capacities and the infrastructural facilities needed for the effective supply and exchange of information related to biosafety. High priority should therefore be given to initiatives aimed at supporting countries to overcome these constraints.

9. A number of countries approached UNEP seeking financial assistance from the GEF to start implementing those aspects of the Guidelines of most interest to them as well as to develop national capacities for undertaking activities that enhance biosafety in line with COP3 decisions and the provisions of Article 8(g) of the CBD. As of 30th August 1997, the following country requests had been received by UNEP: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritius, Mauritania, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda and Zambia. These countries comprise a representative set of countries of variable sizes, geographical locations, level of socio-economic development, as well as different stages of biotechnology development and application of biotechnology products. These requests were submitted to the GEF but the

GEF felt that, since a number of issues pertaining to biosafety are yet to be agreed upon in the protocol on biosafety currently under negotiation, it is not yet possible to have a full understanding of the kinds of assistance that countries might need towards addressing biosafety issues and future implementation of biosafety agreements. It was agreed that the use of an enabling activity framework to assist countries to first of all make a quick assessment of the state of play in the country on matters of biosafety, accompanied by a global awareness-enhancing initiative on biotechnology and related biosafety aspects given the central importance of these issues for the CBD and the potential longer term operational implications for the GEF, was the best way to proceed on this issue at this time.

10. It is against the above background that the present pilot proposal on biosafety has been formulated. This proposal is the result of discussions between UNEP, the GEF Secretariat, UNDP, the World Bank, the Secretariat of the CBD and STAP and aims at providing the GEF with a much clearer understanding of the kinds of assistance eligible countries might need towards addressing biosafety issues and future implementation of biosafety agreement(s) under the CBD, while recognizing that there is an urgent need to undertake awareness programmes about the importance of biotechnology and related biosafety aspects. The agreement reached at this inter-agency discussion was that the issue might be addressed in the following manner:

(i) based on country requests received so far, UNEP would prepare a representative set of country level sub-projects whose aim is to make a quick initial assessment of the state of play in the country on matters related to biosafety, identify its needs on this basis and the priority areas it wishes to address which will be formulated in a country National Biosafety Framework;

(ii) in parallel and as a complementary effort, UNEP will also implement a global project consisting of regional workshops focusing on the role of biosafety frameworks in awareness building and exchange of information, i.e. those aspects of the Guidelines that proved to be of most interest to Governments through the survey conducted by UNEP, namely: risk assessment and risk management of living modified organisms (LMOs) resulting from biotechnology; issues related to the transboundary transfer of LMOs; appropriate mechanisms and modalities for supply and exchange of information for safety in biotechnology.

(iii) STAP would review this pilot project consisting of the above two components in order to make recommendations that would be taken up by the GEF in extending assistance to other eligible countries for biosafety related activities.

11. The two components of the proposal are annexed hereto and consist of:

Component 1: Eighteen country level proposals (total US$ 1 979 000) for the Preparation of National Biosafety Frameworks. This component comprises a representative set of countries of variable sizes, geographical locations, level of socio-economic development, as well as different stages of biotechnology development and application of biotechnology products. The following countries are included in this pilot phase: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda and

Zambia. All of these countries are at different stages of preparing their National Biodiversity Strategies and Action Plans (NBSAP) and care will be taken to ensure that the preparation of the National Biosafety Framework is closely coordinated with the National Biodiversity Strategies and Action Plans process in order to enhance synergy and avoid duplication. The time frame for implementation of this component is 12 months. As the operational criteria applied for these proposals are the standard ones for enabling activities approved by the Council, only the annexes summarizing the budget for activities to be undertaken by each country included in this component together with the letters of endorsement by the national GEF Operational Focal Points are submitted herewith for Council's consideration. The full project briefs for all the eighteen countries are available at the GEF Secretariat and can be perused by any Council member who so wishes.

Component 2: Support to Regional Workshops on Biosafety

This component (US$765,000) is to be implemented over a 12-month period in Africa, Asia/Pacific, Latin America and Caribbean region, and Eastern Europe. Two workshops will be conducted in each of these regions attended by eligible countries of the respective region with each country represented by 2-3 government nominated experts. The first series of workshops will cover issues related to risk assessment and risk management of LMOs, including their environmental impact assessment, for enhancement of biosafety, while the second series of workshops will deal with issues related to transboundary transfer of LMOs, including appropriate mechan ms and modalities for supply and exchange of information. It is anticipated that these w shops will give the participants a better understanding and appreciation of biosafety iss ertinent to the implementation of the UNEP International Technical Guidelines for Saf Biotechnology as well as the work of the Open-ended Ad-Hoc Working Group on Bio currently negotiating a protocol under the CBD. The full project brief for this compc ereto annexed.

12. The 18 individual n projects under this Pilot Biosafety Enabling Activity are fully country driven. Due caution has been exercised by participating countries themselves to formulate ar e activities (in each item in the implementation plan) relevant and pertinent to th es. The activities adopted for inclusion in the national subproject documents reflec untries current R & D capacities, the presence or status of biotechnology enterprise countries, as well as the respective different stages of biotechnology development plications at country level.

13. It should be further n hat participating countries under this project are also taking part in the proceedings of the Hoc Working Group on Biosafety, established to negotiate a protocol on biosafety. They e thus expected to be fully aware and keeping abreast of the issues and options evolving fr n the on-going negotiations of the biosafety protocol which will be concluded in 1998. W en the national subprojects under this project come to an end in March 1999, the participa ng countries will have formulated their National Biosafety Frameworks, as an integral part of their National Biodiversity Strategy and Action Plans. At that juncture, having incorporated the outcomes of the Regional Workshops on Biosafety in the National Biosafety Framework, and with the provisions of the Biosafety Protocol on hand, the participating countries will be in a vantage position to formulate national biosafety programmes and take other initiatives within a regional and global context. They will by then be in a position to have a fuller and much clearer understanding of the kinds of further assistance they might need towards addressing biosafety issues and subsequent needs for the

implementation of the provisions of the Biosafety Protocol and other consequent/relevant biosafety agreements in future in a more effective and comprehensive manner.

14. Since the project aims also at providing GEF with a much clearer understanding of the kinds of assistance eligible countries might need in the area of biosafety, UNEP, as the Implementing Agency for this project, will ensure that the Council is kept regularly informed of the progress of the project through appropriate monitoring and evaluation reports. Any adjustments to the project implementation as a result of the on-going negotiations on a Biosafety Protocol will be brought to the attention of the Council.

PILOT BIOSAFETY ENABLING ACTIVITY PROJECT PROPOSAL

	Countries	Amount
1.	Bolivia	98 000
2.	Bulgaria	92 000
3.	Cameroon	102 000
4.	China	264 000
5.	Cuba	86 000
6.	Egypt	103 000
7.	Kenya	104 000
8.	Hungary	107 000
9.	Malawi	76 000
10.	Mauritania	77 000
11.	Mauritius	83 000
12.	Namibia	89 000
13.	Pakistan	104 000
14.	Poland	89 000
15.	Russian Federation	248 000
16.	Tunisia	108 000
17.	Uganda	78 000
18.	Zambia	71 000
	Total	**1,979,000**

Pilot Biosafety Enabling Activity: Bolivia

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	3 500	5 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	3 500	5 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	3 500	5 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	3 500	5 000
Sub-total	**6 000**	**14 000**	**20 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**7 000**	**28 000**	**35 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	4 000	7 000
9. Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	4 000	6 000
11. Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total	**14 000**	**22 000**	**36 000**
12. Project Coordination and Monitoring	3 000	4 000	7 000
Sub-total	**3 000**	**4 000**	**7 000**
TOTAL:	**30 000**	**68 000**	**98 000**

Pilot Enabling Activity: Bulgaria

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	2 500	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	2 500	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	2 500	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	2 500	4 000
Sub-total	**6 000**	**10 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**7 000**	**28 000**	**35 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	2 000	3 000	5 000
9. Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	4 000	6 000
11. Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total	**13 000**	**21 000**	**34 000**
12. Project Coordination and Monitoring	3 000	4 000	7 000
Sub-total	**3 000**	**4 000**	**7 000**
TOTAL:	**29 000**	**63 000**	**92 000**

Pilot Biosafety Enabling Activity: Cameroon

Activity	Cost (US$)		
	Product	Process	Total
Stock-taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4. Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total	**8 000**	**16 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	7 000	9 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	7 000	9 000
Sub-total	**7 000**	**26 000**	**33 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	5 000	8 000
9. Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	5 000	7 000
11. Printing, publication and dissemination of the National Biosafety Framework	5 000	2 000	7 000
Sub-total	**13 000**	**24 000**	**37 000**
12. **Project Coordination and Monitoring**	3 000	5 000	8 000
Sub-total	**3 000**	**5 000**	**8 000**
TOTAL:	**31 000**	**71 000**	**102 000**

Pilot Biosafety Enabling Activity: China

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	8 000	10 000	18 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	7 000	8 000	15 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	7 000	8 000	15 000
4. Survey of extent and impact of release of LMOs and commercial products	8 000	10 000	18 000
Sub-total	**30 000**	**36 000**	**66 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	9 000	20 000	29 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	9 000	20 000	29 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	9 000	20 000	29 000
Sub-total	**27 000**	**60 000**	**87 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	10 000	12 000	22 000
9. Public Awareness Workshop on the national biosafety framework	9 000	20 000	29 000
10. Finalization of National Biosafety Framework in the light of feedback received	7 000	9 000	16 000
11. Printing, publication and dissemination of the National Biosafety Framework	16 000	8 000	24 000
Sub-total	**42 000**	**49 000**	**91 000**
12. **Project Coordination and Monitoring**	9 000	11 000	20 000
Sub-total	**9 000**	**11 000**	**20 000**
TOTAL:	**108 000**	**156 000**	**264 000**

Pilot Biosafety Enabling Activity: Cuba

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	2 000	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	2 000	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	2 000	4 000
4. Survey of extent and impact of release of LMOs and commercial products	2 000	2 000	4 000
Sub-total	**8 000**	**8 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	10 000	13 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	7 000	9 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	7 000	9 000
Sub-total	**7 000**	**24 000**	**31 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	4 000	7 000
9. Public Awareness Workshop on the national biosafety framework	3 000	10 000	13 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	3 000	5 000
11. Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total	**14 000**	**19 000**	**33 000**
12. **Project Coordination and Monitoring**	2 000	4 000	6 000
Sub-total	**2 000**	**4 000**	**6 000**
TOTAL:	**31 000**	**55 000**	**86 000**

PILOT

Pilot Biosafety Enabling Activity: Egypt

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4. Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total	**8 000**	**16 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**7 000**	**28 000**	**35 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	4 000	7 000
9. Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	4 000	6 000
11. Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total	**14 000**	**22 000**	**36 000**
12. Project Coordination and Monitoring	3 000	5 000	8 000
Sub-total	**3 000**	**5 000**	**8 000**
TOTAL:	**32 000**	**71 000**	**103 000**

Pilot Biosafety Enabling Activity: Hungary

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4. Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total	**8 000**	**16 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**7 000**	**28 000**	**35 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	6 000	9 000
9. Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	5 000	7 000
11. Printing, publication and dissemination of the National Biosafety Framework	7 000	2 000	9 000
Sub-total	**15 000**	**25 000**	**40 000**
12. Project Coordination and Monitoring	3 000	5 000	8 000
Sub-total	**3 000**	**5 000**	**8 000**
TOTAL:	**33 000**	**74 000**	**107 000**

Pilot Biosafety Enabling Activity: Kenya

	Activity	Cost (US$)		
		Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety				
1.	Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2.	Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3.	Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4.	Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total		8 000	16 000	24 000
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology				
5.	National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6.	Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7.	Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total		7 000	28 000	35 000
Planning and Preparation of National Biosafety Framework				
8.	Preparation and circulation of a draft national biosafety framework	3 000	5 000	8 000
9.	Public Awareness Workshop on the national biosafety framework	3 000	12 000	15 000
10.	Finalization of National Biosafety Framework in the light of feedback received	2 000	4 000	6 000
11.	Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total		14 000	23 000	37 000
12.	**Project Coordination and Monitoring**	3 000	5 000	8 000
Sub-total		3 000	5 000	8 000
TOTAL:		32 000	72 000	104 000

Pilot Biosafety Enabling Activity: Malawi

Activity	Cost (US$)		
	Product	Process	Total
Stock-taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 000	3 000	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 000	3 000	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 000	3 000	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 000	3 000	4 000
Sub-total	**4 000**	**12 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	1 000	7 000	8 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	7 000	8 000
Sub-total	**4 000**	**24 000**	**28 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	2 000	3 000	5 000
9. Public Awareness Workshop on the national biosafety framework	2 000	10 000	12 000
10. Finalization of National Biosafety Framework in the light of feedback received	1 000	3 000	4 000
11. Printing, publication and dissemination of the National Biosafety Framework	4 000	1 000	5 000
Sub-total	**9 000**	**17 000**	**26 000**
12. Project Coordination and Monitoring	2 000	4 000	6 000
Sub-total	**2 000**	**4 000**	**6 000**
TOTAL:	**19 000**	**57 000**	**76 000**

Pilot Biosafety Enabling Activity: Mauritania

Activity	Cost (US$)		
	Product	Process	Process
Stock-taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	2 500	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	2 500	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	2 500	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	2 500	4 000
Sub-total	**6 000**	**10 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	1 000	7 000	8 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	7 000	8 000
Sub-total	**4 000**	**24 000**	**28 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	2 000	3 000	5 000
9. Public Awareness Workshop on the national biosafety framework	2 000	10 000	12 000
10. Finalization of National Biosafety Framework in the light of feedback received	1 000	3 000	4 000
11. Printing, publication and dissemination of the National Biosafety Framework	4 000	2 000	6 000
Sub-total	**9 000**	**18 000**	**27 000**
12. **Project Coordination and Monitoring**	3 000	3 000	6 000
Sub-total	**3 000**	**3 000**	**6 000**
TOTAL:	**22 000**	**55 000**	**77 000**

PILOT

Pilot Biosafety Enabling Activity: Mauritius

Activity		Cost (US$)		
		Product	Process	Process
Stock-taking and assessment of the state of play in the country on matters related to biosafety				
1.	Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2.	Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3.	Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4.	Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total		**8 000**	**16 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology				
5.	National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6.	Awareness Workshop on Risk Assessment and Risk Management principles	1 000	6 000	7 000
7.	Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	6 000	7 000
Sub-total		**4 000**	**22 000**	**26 000**
Planning and Preparation of National Biosafety Framework				
8.	Preparation and circulation of a draft national biosafety framework	2 000	3 000	5 000
9.	Public Awareness Workshop on the national biosafety framework	3 000	10 000	13 000
10.	Finalization of National Biosafety Framework in the light of feedback received	1 000	3 000	4 000
11.	Printing, publication and dissemination of the National Biosafety Framework	4 000	1 000	5 000
Sub-total		**10 000**	**17 000**	**27 000**
12.	**Project Coordination and Monitoring**	2 000	4 000	6 000
Sub-total		**2 000**	**4 000**	**6 000**
TOTAL:		**24 000**	**59 000**	**83 000**

Pilot Biosafety Enabling Activity: Namibia

Activity		Cost (US$)		
		Product	Process	Total
Stock-taking and assessment of the state of play in the country on matters related to biosafety				
1.	Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 000	4 000	6 000
2.	Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 000	4 000	6 000
3.	Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 000	4 000	6 000
4.	Survey of extent and impact of release of LMOs and commercial products	2 000	4 000	6 000
Sub-total		**8 000**	**16 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology				
5.	National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6.	Awareness Workshop on Risk Assessment and Risk Management principles	1 000	7 000	8 000
7.	Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	7 000	8 000
Sub-total		**4 000**	**24 000**	**28 000**
Planning and Preparation of National Biosafety Framework				
8.	Preparation and circulation of a draft national biosafety framework	2 000	5 000	7 000
9.	Public Awareness Workshop on the national biosafety framework	2 000	10 000	12 000
10.	Finalization of National Biosafety Framework in the light of feedback received	1 000	4 000	5 000
11.	Printing, publication and dissemination of the National Biosafety Framework	4 000	2 000	6 000
Sub-total		**9 000**	**21 000**	**30 000**
12.	**Project Coordination and Monitoring**	3 000	4 000	7 000
Sub-total		**3 000**	**4 000**	**7 000**
TOTAL:		**24 000**	**65 000**	**89 000**

Pilot Biosafety Enabling Activity: Pakistan

Activity	Cost (US$)		
	Product	Process	Total
Stock-taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	2 500	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	2 500	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	2 500	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	2 500	4 000
Sub-total	**6 000**	**10 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	4 000	15 000	19 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**8 000**	**31 000**	**39 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	4 000	3 000	7 000
9. Public Awareness Workshop on the national biosafety framework	4 000	15 000	19 000
10. Finalization of National Biosafety Framework in the light of feedback received	3 000	3 000	6 000
11. Printing, publication and dissemination of the National Biosafety Framework	7 000	2 000	9 000
Sub-total	**18 000**	**23 000**	**41 000**
12. **Project Coordination and Monitoring**	3 000	5 000	8 000
Sub-total	**3 000**	**5 000**	**8 000**
TOTAL:	**35 000**	**69 000**	**104 000**

Pilot Biosafety Enabling Activity: Poland

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	2 500	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	2 500	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	2 500	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	2 500	4 000
Sub-total	**6 000**	**10 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	12 000	15 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	7 000	9 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	7 000	9 000
Sub-total	**7 000**	**26 000**	**33 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	4 000	7 000
9. Public Awareness Workshop on the national biosafety framework	2 000	12 000	14 000
10. Finalization of National Biosafety Framework in the light of feedback received	1 000	3 000	4 000
11. Printing, publication and dissemination of the National Biosafety Framework	6 000	2 000	8 000
Sub-total	**12 000**	**21 000**	**33 000**
12. Project Coordination and Monitoring	**3 000**	**4 000**	**7 000**
Sub-total	**3 000**	**4 000**	**7 000**
TOTAL:	**28 000**	**61 000**	**89 000**

Pilot Biosafety Enabling Activity: Russian Federation

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	7 000	11 000	18 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	6 000	9 000	15 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	6 000	9 000	15 000
4. Survey of extent and impact of release of LMOs and commercial products	7 000	11 000	18 000
Sub-total	**26 000**	**40 000**	**66 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	8 000	20 000	28 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	8 000	20 000	28 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	8 000	20 000	28 000
Sub-total	**24 000**	**60 000**	**84 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	8 000	10 000	18 000
9. Public Awareness Workshop on the national biosafety framework	8 000	20 000	28 000
10. Finalization of National Biosafety Framework in the light of feedback received	6 000	8 000	14 000
11. Printing, publication and dissemination of the National Biosafety Framework	14 000	6 000	20 000
Sub-total	**36 000**	**44 000**	**80 000**
12. **Project Coordination and Monitoring**	8 000	10 000	18 000
Sub-total	**8 000**	**10 000**	**18 000**
TOTAL:	**94 000**	**154 000**	**248 000**

Pilot Biosafety Enabling Activity: Tunisia

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	2 500	3 500	6 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	2 500	3 500	6 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	2 500	3 500	6 000
4. Survey of extent and impact of release of LMOs and commercial products	2 500	3 500	6 000
Sub-total	**10 000**	**14 000**	**24 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	3 000	14 000	17 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	2 000	8 000	10 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	2 000	8 000	10 000
Sub-total	**7 000**	**30 000**	**37 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	3 000	5 000	8 000
9. Public Awareness Workshop on the national biosafety framework	3 000	14 000	17 000
10. Finalization of National Biosafety Framework in the light of feedback received	2 000	5 000	7 000
11. Printing, publication and dissemination of the National Biosafety Framework	5 000	2 000	7 000
Sub-total	**13 000**	**26 000**	**39 000**
12. **Project Coordination and Monitoring**	3 000	5 000	8 000
Sub-total	**3 000**	**5 000**	**8 000**
TOTAL:	**33 000**	**75 000**	**108 000**

Pilot Biosafety Enabling Activity: Uganda

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 500	2 500	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 500	2 500	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 500	2 500	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 500	2 500	4 000
Sub-total	**6 000**	**10 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	1 000	7 000	8 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	7 000	8 000
Sub-total	**4 000**	**24 000**	**28 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	2 000	4 000	6 000
9. Public Awareness Workshop on the national biosafety framework	2 000	10 000	12 000
10. Finalization of National Biosafety Framework in the light of feedback received	1 000	3 000	4 000
11. Printing, publication and dissemination of the National Biosafety Framework	4 000	2 000	6 000
Sub-total	**9 000**	**19 000**	**28 000**
12. Project Coordination and Monitoring	2 000	4 000	6 000
Sub-total	**2 000**	**4 000**	**6 000**
TOTAL:	**21 000**	**57 000**	**78 000**

Pilot Biosafety Enabling Activity: Zambia

Activity	Cost (US$)		
	Product	Process	Total
Stock taking and assessment of the state of play in the country on matters related to biosafety			
1. Survey of existing biotechnologies and status of safety in biotechnology application including review and assessment of existing biosafety legislation and guidelines, sectoral manuals, institutional mechanisms and administrative measures	1 000	3 000	4 000
2. Survey of existing national, bilateral and multilateral cooperative programmes in R & D and application of biotechnology	1 000	3 000	4 000
3. Survey of existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	1 000	3 000	4 000
4. Survey of extent and impact of release of LMOs and commercial products	1 000	3 000	4 000
Sub-total	**4 000**	**12 000**	**16 000**
Identification and Analysis of Options to implement UNEP's International Technical Guidelines for Safety in Biotechnology			
5. National workshop to review the findings of the assessment exercise, identify gaps, needs and priorities	2 000	10 000	12 000
6. Awareness Workshop on Risk Assessment and Risk Management principles	1 000	6 000	7 000
7. Awareness Workshop on monitoring and Enforcement mechanisms for National Controls	1 000	6 000	7 000
Sub-total	**4 000**	**22 000**	**26 000**
Planning and Preparation of National Biosafety Framework			
8. Preparation and circulation of a draft national biosafety framework	2 000	2 000	4 000
9. Public Awareness Workshop on the national biosafety framework	2 000	10 000	12 000
10. Finalization of National Biosafety Framework in the light of feedback received	1 000	2 000	3 000
11. Printing, publication and dissemination of the National Biosafety Framework	4 000	1 000	5 000
Sub-total	**9 000**	**15 000**	**24 000**
12. **Project Coordination and Monitoring**	2 000	3 000	5 000
Sub-total	**2 000**	**3 000**	**5 000**
TOTAL:	**19 000**	**52 000**	**71 000**

GLOBAL ENVIRONMENT FACILITY
ENABLING ACTIVITY PROPOSAL

PROJECT TITLE:	Support to Regional Meetings on Biosafety
COUNTRY:	Global: GEF - eligible countries in Africa, Latin America and Caribbean, Asia/Pacific and Eastern Europe
GEF FOCAL AREA:	Biodiversity
COUNTRY ELIGIBILITY:	All participating countries have ratified the CBD
GEF Financing:	US$ 765 000
GOVERNMENT CONTRIBUTION:	In kind and personnel
GEF IMPLEMENTING AGENCY:	UNEP
EXECUTING AGENCY:	Information Resource on the Release of Organisms into the Environment (IRRO) in collaboration with the Scientific & Industrial Research and Development Centre (SIRDC), Zimbabwe, Instituto Interamericano de Cooperacion para la Agricultura (IICA) and the University of Malaysia, Department of Genetics & Plant Breeding (Universiti Kebangsaan)
GEF OPERATIONAL FOCAL POINT:	Respective National GEF Focal Points
CBD FOCAL POINT:	Respective National CBD Focal Points
ESTIMATED STARTING DATE:	April 1998
PROJECT DURATION:	12 months

BACKGROUND/CONTEXT:

In Agenda 21, as well as the Convention on Biological Diversity, Governments undertook to consider international cooperation on biotechnology and relevant safety aspects. That commitment includes: sharing experience, capacity building and international agreement on principles for biosafety. It is acknowledged that biotechnology will contribute substantively to the improvement of agriculture, fisheries, forestry, industry, health care and environmental management. Recent developments in modern biotechnology techniques present strong potential links between conservation and optimum use of biological resources. Biotechnology also offers developing countries a means of tapping their enormous genetic resources for economic development.

A major issue that will, however, affecting the transfer and application of biotechnology is the regulatory climate governing the safe development and application thereof, and, the safe transfer and use of its products, and in particular, the release of living modified organisms (LMOs) into the environment. Questions arise regarding the capacity of existing regulatory approaches and institutions to address issues related to safety in biotechnology. From a review of existing guidelines and legislation at both national and international levels, the Secretariat of the Convention on Biological Diversity, noted: (i) a large number of countries have no national safety framework regulating living modified organisms (LMOs) resulting from biotechnology; (ii) existing national biosafety regulations address only activities relating to domestic handling and use of LMOs; (iii) efforts at promoting international agreements on biosafety often address issues from a perspective different to that of the Convention on Biological Diversity, and Agenda 21; and (iv) relevant international agreements/guidelines currently under consideration are limited in scope.
For biotechnology, as with any new technology, the rate of development and the level of success are dependent not only upon the scientific and technical capabilities of the country, but also on a supporting infrastructure and an accepting environment in which to introduce and use it. As concerns about safety in biotechnology have been raised, a key component in the formulation of a "biotechnology-accepting" environment is the establishment of a biosafety regulatory oversight infrastructure. A cornerstone of such an infrastructure is biosafety regulations or guidelines.

Equally important, however, is acquiring the capacity to implement regulations via scientifically sound environmental impact assessment and risk management. Neither an international biosafety protocol nor guidelines will in and of themselves ensure the safe development and/or application of biotechnology. There must be a capacity to implement the regulations and/or guidelines, based on sound scientific principles with consistency, competence and expedience.

The UNEP International Technical Guidelines for Safety in Biotechnology have been developed under the clear recognition that their implementation depends on the availability of human resources (in terms of quantity and quality), financial resources, information, and/or institutional and infrastructural capacities at the national, regional and international levels; and that such resources and capacities are currently either not available or are not adequate in a number of countries at various levels.

Information collected during the development of the UNEP Guidelines revealed that the following needs and constraints face developing countries and to a large extent countries with economies-in-transition, and impede the achievement of safety in biotechnology development and application:

- lack of formulated biotechnology and biosafety policies;
- insufficient capacity for enforcement of guidelines and/or regulations;
- need for training at all levels to address shortage of human resources;
- formulation and implementation of guidelines and/or regulations;
- need for information collection and exchange (e.g. access to databases and knowledge of global developments;
- need for risk assessment research focusing on specific regional/sub-regional contexts;
- need for more facilities and equipment to carry out proper monitoring and risk assessment research;
- the need for the establishment of biosafety advisory services/committees at the institutional, national regional levels;
- planning and adaptation of methods to monitor effects of field tests and ensure compliance with regulations;
- need for funding of safety issues as integral part of research and development projects; and
- need for national and regional collaboration.

In light of the foregoing, this project's goal is to ensure that, ultimately:

(i) countries develop and strengthen their endogenous capacities to facilitate the development and implementation of sound biosafety frameworks/mechanisms/ legal instruments;

(ii) nations and countries involved in the development, use, release or production of organisms with novel traits are aware of any risks associated with their work and have the means to assess and manage risks;

(iii) governments are able to achieve safety when certain organisms with novel traits are to be transferred into and/or to be used in their countries;

(iv) safe development, transfer and application of biotechnology is enhanced by the development and/or strengthening of appropriate policies, facilities (including adequate information systems) and training in sciences related to biosafety and biotechnology, including training in risk-assessment and risk-management techniques and procedures for biosafety.

The general thrust of the proposed project is to promote a comprehensive understanding and approach in order to safeguard 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 widest possible participation of the public sector, the scientific and the general community at large, as well as the private sector (in particular the biotechnology industry) is envisaged.

PROJECT OBJECTIVES AND SHORT DESCRIPTION:

Article 8(g) of the Convention on Biological diversity provides that each contracting Party shall, as far as possible and as appropriate " 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 diversity, taking into account the risks to human health."

Article 19(3) of the Convention on Biological Diversity states that "the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance 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."

The third meeting of the Conference of the Parties to the Convention on Biological Diversity, held in Buenos-Aires in November 1996 welcomed the adoption of the UNEP International Technical Guidelines for Safety in Biotechnology and endorsed

recommendation II/5 of the Subsidiary Body on Scientific,Technical and Technological Advice and, in particular :

a. The realization of activities to promote the application of the UNEP International Technical Guidelines for Safety in Biotechnology, in accordance with paragraph 2 of recommendation II/5;

b. The importance of funding for capacity-building in biosafety.

The Conference of the Parties requested " the interim institutional structure operating the financial mechanism to provide financial resources to developing country Parties for capacity-building in biosafety, in accordance with paragraph 3 of recommendation II/5, as set out in paragraph 2(a) of decision III/5."

Decision GC 19/16 adopted on 7th February 1997 by the 19th session of UNEP Governing Council affirmed " the role of UNEP, as an Implementing Agency of the Global Environment Facility, in the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology in accordance with decisions III/5 and III/20 of the Conference of the Parties of the Convention on Biological Diversity, which refer to capacity-building in biosafety."

The project has the following objectives:

(i) To promote a better understanding and appreciation of biosafety issues among a wide spectrum of stakeholders in developing countries and countries with economies-in-transition;

(ii) To help harmonize national biosafety instruments and facilitate the implementation of any future international agreements on biosafety as the project will allow valuable experience to be gained at the national, regional and international levels;

(iii) To strengthen developing countries' capacities to introduce and implement national mechanisms for safety in biotechnology consistent with the UNEP International Technical Guidelines for Safety in Biotechnology and relevant provisions of the Biodiversity Convention and appropriate for their particular circumstances whilst providing a harmonized approach to risk assessment and risk management in biotechnology within a global biosafety framework;

(iv) To assist governments in the development and implementation of effective biosafety frameworks for the realization of activities to promote sound application of UNEP Guidelines and any future international agreements on biosafety;

(v) To promote cooperation between governments with regard to supply and exchange of information for safety in biotechnology through appropriate mechanisms and modalities.

Therefore, the emphasis of this proposal is on awareness raising and information exchange through a series of regional seminars for Africa, Asia/Pacific, Latin America and the Caribbean region and Eastern Europe. Every region will hold two (2) workshops/seminars that will address specific themes covering a range of issues aimed at giving participants a better understanding and appreciation of biosafety issues pertinent to the implementation of the UNEP Guidelines as well as the work of the "Open-ended *Ad-Hoc* Working Group on Biosafety. The issues envisaged would be captured in five broad themes namely:

(i) risk assessment and risk management of living modified organisms (LMOs)/organisms with novel traits (ONTs)

(ii) issues related to the transboundary transfer of LMOs/ONTs

(iii) Supply and exchange of information for safety in biotechnology: appropriate mechanisms and modalities

(iv) likely environmental and socio-economic impacts of modern biotechnology

(v) capacity building requirements for safety in biotechnology in the context of national/ regional biosafety frameworks, any future biosafety legal instruments including the biosafety protocol under preparation.

OPERATIONAL CRITERIA:

(i) Coverage without duplication:

Existing planning capacity, plans, programmes and information accumulated to date at national and international level will be fully utilized in this project, whenever possible. These include documents prepared by UNIDO/CABI/UNEP - (Genetically Modified

Organisms - A Guide to Biosafety 1995); World Bank - (Creating an Enabling Environment for the Safe Use of Biotechnology, 1995); UNEP (the UNEP International Technical Guidelines for Safety in Biotechnology, 1995), OECD - (Expert Group on Harmonization of Regulatory Oversight in Biotechnology; and Safety Considerations in Biotechnology); FAO - (Code of Conduct for Plant Biotechnology); UNIDO (Voluntary Code of Conduct for the Release of Organisms into the Environment); and CBD - (Reports of SBSTTA I, 1995 and SBSTTA II, 1996; Decisions of COP II and III on Biosafety). In particular, the capacity, information and mechanisms generated in the National Biodiversity Strategy and Action Plan process will be fully utilized. In so doing, duplication will be avoided and synergy enhanced.

Participants will have the opportunity to discuss issues encompassing topics/areas that would facilitate not only the implementation of the UNEP Guidelines but also the current negotiation of the protocol on biosafety under the CBD as well as the implementation of relevant provisions thereof after its conclusion. These are listed below:

a. Specific transfer of LMOs +
Advanced Informed Agreements (AIAs)
Scope of AIAs
Use of AIAs
Notification procedures
Merits of:
- Explicit consent
- Implicit consent
- Both options

b. Competent authorities/focal points

c. Information sharing

(i) public awareness
(ii) public participation

d. Risk Assessment/Risk Management
e. Unintentional transboundary movement of LMOs
f. Handling, transportation, packaging, transit requirements for transboundary movements
g. Monitoring and compliance
h. Capacity building requirements, including human, institutional, infrastructural and financial resources for the implementation of biosafety agreement
i. Preparation of national biosafety frameworks

(ii) Appropriate overall sequencing of activities:

The project will be conducted over a period of 12 months entailing activities in every region (Africa, Asia/Pacific, Latin America and the Caribbean, East Europe). Under the project it is proposed to stage:

(a) Regional Workshops/Seminars on Risk Assessment and Risk Management of Living Modified Organisms (LMOs)/Organisms with novel traits (ONTs), including their environmental impact assessment, for enhancement of biosafety.

This workshop/seminar will cover the techniques, procedures and measures to be considered, as appropriate, in respect of risk assessment and risk management of living modified organisms (LMOs)/organisms with novel traits (ONTs) at national, sub-regional and regional levels.

The type of risk assessment/risk management techniques/procedures/measures to be applied for contained uses on the one hand and controlled releases and commercial applications on the other will be examined with the national, sub-regional and regional levels in mind.

While there is no consensus between the views of molecular biologists and ecologists on the possible adverse environmental effects of introducing living modified organisms (LMOs)/organisms with novel traits (ONTs) into the environment, there is however consensus that risk analysis should be based on the end-product(s) designed for environmental release rather than the process or method that generated the product(s). The regional workshop/seminar will build on the latter area of consensus and address issues pertinent thereto.

The subject of socio-economic impacts of modern biotechnology, is a focus of considerable concern and controversy in developing countries, particularly in respect of likely socio-economic consequences on vulnerable sections of the populations. The workshop/seminar will, likewise provide a forum to raise the likely issues to be addressed and the type of measures that could be considered to mitigate any profound and/or irreversible impacts.

(b) Regional Workshops/Seminars on issues related to the transboundary transfer of living modified organisms (LMOs)/organisms with novel traits (ONTs), including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of biosafety.

As living modified organisms (LMOs)/organisms with novel traits (ONTs) have been and will be transferred from one country to another for research and development purposes and for placing on the market, this seminar is intended to cover issues pertaining to the supply of information (a) related to transboundary transfer of such organisms; and or (b) needed when the use of such organisms could affect human health in, or the environment of, another country. The workshop/seminar will, therefore, cover issues pertinent to the exchange of general information about national biosafety mechanisms, generic research of value to risk assessment and risk management, and approvals given for the marketing of products containing or consisting of living modified organisms (LMOs)/organisms with novel traits (ONTs).

It will also cover the issues of data harmonization, data validation and mutual acceptance of data. Participants would examine and review the critical role of international databases as sources of information for risk assessment and risk

management since such databases provide detailed knowledge of and experience gained by countries/organizations and would also assist in the development of national, sub-regional or regional models.

Each of the workshops/seminars will be of 3-5 days duration and attended by all eligible countries of the respective region with each country represented by two/three government nominated experts. The venue of each of the workshops/seminars in a particular region will be determined in consultation with the relevant UNEP Regional Office.

The activities are reflected in the attached table.

The project activities to be conducted over a period of 12 months are reflected in the implementation plan shown in the following table.

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12
1. Project Coordination	x	x	x	x	x	x	x	x	x	x	x	x
2. Planning for RS 1*	x	x		x								
3. Regional Seminar (RS) 1 Africa			x									
4. Regional Seminar (RS) 1 Asia		x			x							
5. Regional Seminar (RS) 1 LAAC			x									
6. Regional Seminar (RS) 1 E. Europe		x			x							
7. Planning for RS 2*	x	x				x		x				
8. Regional Seminar 2 AF							x					
9. Regional Seminar 2 AS									x			
10. Regional Seminar 2 LA							x					
11. Regional Seminar 2 EE									x			
12. Monitoring & Evaluation			x	x	x	x	x	x	x	x	x	

RS1* Regional Workshop/Seminar on Risk Assessment and Risk Management of Living Modified Organisms (LMOs)/Organisms with novel traits (ONTs), including their environmental impact assessment.

RS2* Regional Workshop/Seminar on issues related to the transboundary transfer of living modified organisms (LMOs)/Organisms with novel traits (ONTs), including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of safety in biotechnology.

(iii) Best practice:

The methodology for implementation of this project will be based on the UNEP International Guidelines for Safety in Biotechnology (UNEP, 1996). The project will apply the lessons learned from the UNEP subregional/regional consultations on Biosafety Guidelines and Related Capacity Building Requirements (San Jose, Bangkok, Amman, Buenos Aires, Geneva, Cairo, Keszthely, 1995). The project will also fully utilize and benefit from the following: Buenos Aires International Workshop to follow up on the UNEP International Technical Guidelines for Safety in Biotechnology (1996); the African Regional Conference for International Cooperation on Safety in Biotechnology, Harare (1993); the Aarhus Workshop on Transboundary Movement of Genetically Modified Organisms (1996); the work of the OECD Expert Group on Harmonization of Oversight in Biotechnology (1995-1997) and reports of the CBD Open-ended *Ad-Hoc* Working Group on Biosafety Protocol and the Informal UNIDO/UNEP/WHO/FAO on Biosafety, among others. Most importantly, the project will establish linkages with the NBSAPs.

(iv) Cost effectiveness and consistency of approach and procedures:

The Regional Workshops/Seminars are adopted for this project in view of their cost-effectiveness. They will encourage the widest possible participation of the general public and the scientific community as well as the private sector involvement in national/regional level biosafety activities/initiatives. It is acknowledged and recognized that in developed countries, the private sector has played and continues to play an especially critical role to ensure and enhance safety in biotechnology. In developing countries, the private sector contribution could usefully be replicated because the Governments have serious resource constraints and cannot therefore mobilize adequate, if any, resources into the field of biosafety on a priority basis. Participation of the private sector will be encouraged since the sector is expected to contribute substantively to the sustainability of safety in biotechnology applications, research and development at national/regional levels.

Since stakeholder involvement both from the private and public sectors as well as from the general public at large will be crucial in the implementation and execution of national/regional biosafety initiatives, the workshops/seminars under this project will endeavour to inculcate the ethic of consultative/participatory approaches at national/regional levels. The workshops/seminars will stress the importance of involving the full array of stakeholders not only for information gathering but with regard to the formulation of principles, approaches and potential measures to be taken to address the biosafety issues and the national biosafety framework, and for the establishment of priorities for action, including the preparation of a list of priority areas. Eventual involvement of all the stakeholders at national/regional levels is therefore anticipated through the consultative approaches that will be adopted and stakeholder workshops/seminars that will be conducted by the countries/regions thereafter. Objectives of the project will thus be achieved in the long term.

INSTITUTIONAL FRAMEWORK:

The executing agency for this project will be the Information Resource on the Release of Organisms into the Environment (IRRO) in collaboration with the Scientific & Industrial Research & Developmen Centre (SIRDC), Zimbabwe, Instituto Interamericano de Cooperacion para la Agricultura (IICA) and the University of Malaysia, Department of Genetics & Plant Breeding (Universiti Kebangsaan).

Information Resource on the Release of Organisms into the Environment (IRRO)

The IRRO is a not-for-profit global referral service supported by the World Federation of Culture Collections (WFCC). It serves as an information resource on issues pertinent to the release of organisms into the environment. It has an international Steering Committee which provides guidance and direction for the development of its programmes. Its Secretariat, based in the U.K, is responsible for putting the various programmes into practice.

The IRRO Secretariat offers consultancy services and is available to answer enquiries from any persons or institutions with specialized requests (surveys, etc). Upon request, training can be given to individuals or groups on such topics as networking, e-mail, and location and use of information resources. IRRO runs special one week training courses aimed at users in developing countries. The scope of the IRRO covers introductions of non-indigenous plants, animals and microorganisms into new environments as well as releases of genetically modified organisms (GMOs)/Organisms with novel traits (ONTs).

The IRRO provides online access to resources on environmental releases. A simple search system is available on the host computers at Base De Dados Tropical (Brazil) and World Conservation Monitoring Centre (UK). There are links to other relevant/related networks. The types of information available include:

- Links to resources on species diversity, repositories of biological materials, taxonomy, health, nutrition, etc.
- Laboratory and field testing protocols
- Location and environmental parameters of release site
- Purpose of release/introduction
- Donor/host organism and vector used
- Methods for monitoring effects of releases
- Biological control
- Risk assessments
- Guidelines, regulations, contact details for national authorities authorizing releases

There is no fee for using IRRO databases, although some of the linked networks or databases may make a charge. Users may have to pay for local telecommunications and for use of the public data networks if access is by this route.

The World Federation of Culture Collections (WFCC) which provides support to the IRRO is a multidisplinary body that also supports two other major interelated initiatives, among others, that complement and facilitate the objectives of the project, namely the Microbial Strain Data Network (MSDN) and the World Data Centre for Micro-organisms (WDC). They are all deeply concerned and involved with improving and providing access to information on genetic resources, especially in respect of developing countries and countries with economies-in-transition.

PROJECT FINANCING:

Project Budget (US$)

Activity		Product	Process	Total
I.	**Project Coordination and support services/materials**	15 000	90 000	105 000
II.	**Regional Workshops in Africa** on (a) Risk Assessment and Risk Management of LMOs/ONTs, including their environmental impact assessment and (b) issues related to the transboundary transfer of LMOs/ONTs, including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of safety in biotechnology	15 000	150 000	165 000
III.	**Regional Workshops in Asia/Pacific** on (a) Risk Assessment and Risk Management of LMOs/ONTs, including their environmental impact assessment and (b) issues related to the transboundary transfer of LMOs/ONTs, including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of safety in biotechnology	15 000	150 000	165 000
IV.	**Regional Workshops in Latin America** on (a) Risk Assessment and Risk Management of LMOs/ONTs, including their environmental impact assessment and (b) issues related to the transboundary transfer of LMOs/ONTs, including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of safety in biotechnology	15 000	150 000	165 000
V.	**Regional Workshops in East Europe** on (a) Risk Assessment and Risk Management of LMOs/ONTs, including their environmental impact assessment and (b) issues related to the transboundary transfer of LMOs/ONTs, including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of safety in biotechnology	10 000	110 000	120 000
VI.	**Project Monitoring and Evaluation**	15 000	30 000	45 000
Total		85 000	680 000	765 000

MONITORING AND EVALUATION:

Monitoring and evaluation of the project will be undertaken by UNEP as the Implementing Agency. This will include feedback from participants on how the next workshop/seminar could be adjusted for more effective attainment of the objectives of the project.

In a separate exercise, STAP will conduct a review of the overall pilot biosafety proposal (this component together with the 18 country level proposals implemented in parallel concerning the preparation of national biosafety frameworks) in order to provide the GEF with strategic guidance for extending assistance to other eligible countries for biosafety related activities.