1. Project Data

Summary project data			
GEF project ID		402	
GEF Agency project ID		N/A	
GEF Replenishment Phase		GEF-1	
Lead GEF Agency (include all for joint projects)		UNEP	
Project name		Pilot Biosafety Enabling Activity	
Country/Countries		Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Kenya, Hungary, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda, Zambia	
Region		Global	
Focal area		Biodiversity	
Operational Program or Strategic Priorities/Objectives		EA-Enabling Activities	
Executing agencies involved		UNEP	
NGOs/CBOs involvement		through consultation	
Private sector involvement		through consultations	
CEO Endorsement (FSP) /Approval date (MSP)		2/20/1998	
Effectiveness date / project start		2/27/1998	
Expected date of project completion (at start)		12/15/1999	
Actual date of project completion		4/30/2000	
Project Financing			
		At Endorsement (US $M)	**At Completion (US $M)**
Project Preparation Grant	GEF funding		
	Co-financing		
GEF Project Grant		2.744	2.739 (Trustee data)
Co-financing	IA own		
	Government		
	Other multi- /bi-laterals		
	Private sector		
	NGOs/CSOs		
Total GEF funding		2.744	2.739
Total Co-financing			
Total project funding (GEF grant(s) + co-financing)		2.744	2.739
Terminal evaluation/review information			
TE completion date		12/1999	
TE submission date			
Author of TE		Julian Kinderlerer	
TER completion date		10/03/2014	
TER prepared by		Nelly Bourlion	
TER peer review by (if GEF EO review)		Joshua Schneck	

2. Summary of Project Ratings

Criteria	Final PIR	IA Terminal Evaluation	IA Evaluation Office Review	GEF EO Review
Project Outcomes	N/A	N/A	N/A	S
Sustainability of Outcomes	N/A	N/A	N/A	MU
M&E Design	N/A	N/A	N/A	MS
M&E Implementation	N/A	N/A	N/A	UA
Quality of Implementation	N/A	N/A	N/A	S
Quality of Execution	N/A	N/A	N/A	S
Quality of the Terminal Evaluation Report	-	-	N/A	MS

3. Project Objectives

3.1 Global Environmental Objectives of the project:

The project is designed to improve and strengthen national instruments for environmental management. It is directed at "*promoting a comprehensive understanding and approach to biosafety issues by countries within their region in order to safeguard biological diversity in situ conservation against possible adverse impacts from LMOs (*living modified organisms) *with novel traits resulting from biotechnology*" (PD, pg.4).

Many scientists, after the invention of new techniques in biology, started thinking about the possible dangers that might result from the ability to move genetic information from one organism to another (TE, pg.23). Therefore, according to the TE, this project is designed to be of crucial importance in ensuring the safe use of the technology, and of assuring the safety of products imported into countries. (TE, pg27)

The project is also designed to take into account the possible risks and negative impacts, products such as LMOs and GMOs can have on the environment and the ecosystems, with respect to the biodiversity of a country and/or its subregion. (TE, pg.42)

3.2 Development Objectives of the project:

The development objectives of the project is to set up National Biosafety Frameworks in 18 countries and the development of systems for controlling cross boundary movement of living modified organisms (LMOs) (PD, pg.5). The project has two components:

(a) Preparation of National Biosafety Frameworks in each of eighteen participating countries, including a survey of capacity for both biotechnology and for safety assessment; and

(b) The organization of a series of eight workshops that explored both risk analysis and management and transboundary movement of LMOs. The workshops involved more countries than in the preparation of National Biosafety Frameworks.

The countries involved in the project were chosen because of their differences in size, geography and geographical locations, and level of socio-economic development (TE, pg.11). The 18 participating countries are Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, the Russian Federation, Tunisia, Uganda, and Zambia.

The expected result of this project is an harmonized approach to risk assessment and risk management of modified organisms both within the individual countries and within each region (TE, pg.11).

3.3 Were there any **changes** in the Global Environmental Objectives, Development Objectives, or other activities during implementation?

There was **no** changes in GEO, DO, and activities. However, Pakistan was unable to start the programme and withdrew (TE, pg.11). The reason why is not given in the TE.

4. GEF EO assessment of Outcomes and Sustainability

Please refer to the GEF Terminal Evaluation Review Guidelines for detail on the criteria for ratings.

Relevance can receive either a Satisfactory or Unsatisfactory rating. For Effectiveness and Cost efficiency, a six point rating scale is used (Highly Satisfactory to Highly Unsatisfactory), or Unable to Assess. Sustainability ratings are assessed on a four-point scale: Likely=no or negligible risk; Moderately Likely=low risk; Moderately Unlikely=substantial risks; Unlikely=high risk. In assessing a Sustainability rating please note if, and to what degree, sustainability of project outcomes is threatened by financial, sociopolitical, institutional/governance, or environmental factors.

Please justify ratings in the space below each box.

4.1 **Relevance**	Rating: **Satisfactory**

The project is relevant to both the GEF and participating countries, The project supports the objectives of the Convention on Biological Diversity and Agenda 21, especially Chapter 16 (TE, pg.22).

The Conference of the Parties to the Convention on Biological Diversity in 1995 had decided that that a Protocol to the Convention on biosafety should be developed. At that time, it was recognized that gaps in knowledge about modified organisms remained, especially about the interaction between these organisms and the environment. In May 1995, the Governing Council of UNEP "affirmed the desirability of contributing to international efforts on biosafety including the development of International Technical Guidelines for safety in Biotechnology" (TE, pg.25).

Moreover, the governments represented at the Earth Summit in Rio de Janeiro in June 1992 decided on "*international cooperation on issues relating to the safety of modern biotechnology in order to maximize the benefits that could accrue and minimize any risks to the environment and to human health*" (TE, pg.24). Their commitment included sharing experience, capacity-building and international agreement on principles for the safe use of the technology. Agenda 21, more specifically Chapter 16, defines

biotechnology in optimistic terms as the integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional biotechnology (TE, pg.24).

Finally, the countries involved in this project believed that this was the type of project that the countries would have had to undertake to contribute to their National Strategy (TE, pg.9).

4.2 **Effectiveness**	Rating: **Satisfactory**

The overall effectiveness of the project is rated Satisfactory. According to the TE, the project was successfully executed; all participating countries identified their needs, held national workshops, with representatives of other countries and international experts, and all the countries began the process of considering a possible legal framework for biotechnology research, development, commercialization and import and export (TE, pg.11).

Out of 18 countries in the pilot project, 17 prepared National Biosafety Frameworks (Pakistan withdrew from the project). The countries have identified the national systems needed to ensure the safe adoption and application of products of modern biotechnology. However, the TE states that many countries had not separated their role in promoting the technology from that of audit and safety assessment (TE, pg. 6).

All the regional workshops were held and many stakeholders were involved. According to the TE, these workshops were successfully conducted, productive, and worthwhile. They 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" (TE, pg.6).

However, one of the project's goals was not achieved. According to the TE, the identification of cost norms turned out to be very complex and perhaps virtually impossible (TE, pg.8). The TE states that variety in climate, physical and social geography, as well as the number of local languages needed to bring awareness of the benefits and risks of biotechnology to all stakeholders had not been considered, and therefore, the biosafety systems in some countries were not implemented (TE, pg8).

4.3 **Efficiency**	Rating: Satisfactory

Overall the efficiency of the project is Satisfactory. The project was ambitious and the timescale was limited however the achievements attained indicate a satisfactory efficiency.

The timescale for the project was limited and according to the TE (pg.6) 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"(TE, pg.6).

A framework for this project was given by the sub-projects documents and by the UNEP biosafety guidelines. Therefore, the countries had timetables and detailed guidance to achieve their objectives.

According to the TE (pg.7), UNEP instituted structures that ensured a flexible system; in case countries failed to meet their obligations money was withheld, or when small amounts of extra finance were required by the countries UNEP could provide it. The TE says that task managers at UNEP were clearly willing to talk with country representatives and provide flexibility in interpreting the needs of countries within the framework set by the project (TE, pg.9).

4.4 **Sustainability**	Rating: **Moderately Unlikely**

The sustainability of the project is rated Moderately Unlikely.

Additional support is needed by the countries involved to be able to implement the biosafety frameworks. These frameworks were developed during this project, however they were not implemented, therefore additional funding, and support for capacity-building initiatives is needed (TE, pg. 6). According to the TE, there is a need "for development and strengthening of national as well as subregional capacities, including the development of human resource infrastructure to attempt risk assessment, management and monitoring of LMOs at national, subregional and regional levels" (TE,pg.6)

Moreover, the importance of extending the UNEP/GEF financial and technical support was mentioned at the regional workshops and at the Consultative Meeting of the Participating Countries by the steering committee members of the pilot project. This would allow the project to continue, as well as being developed in additional eligible countries (TE, pg.9).

Nothing indicates in the TE, that this project will be able to be sustained, no additional funding or technical support have been dedicated yet.

5. Processes and factors affecting attainment of project outcomes

5.1 Co-financing. To what extent was the reported co-financing essential to the achievement of GEF objectives? If there was a difference in the level of expected co-financing and actual co-financing, then what were the reasons for it? Did the extent of materialization of co-financing affect project's outcomes and/or sustainability? If so, in what ways and through what causal linkages?

According to the TE, the country representatives believed that this project would have been undertaken in absence of GEF funding. However, they believed that if it had been left entirely to Governments for funding, it would have been delayed, and probably much slower and less effective (TE, pg. 48). This project was financed by GEF and UNEP only. There was no cofinancing from other parties. The TE believes that a majority of the project activities at national level would not have taken place without the

UNEP/GEF support because most developing countries have not provided significant funding for research about biosafety or for setting up mechanisms that ensured the safe use of the technology (TE, pg.48).

5.2 Project extensions and/or delays. If there were delays in project implementation and completion, then what were the reasons for it? Did the delay affect the project's outcomes and/or sustainability? If so, in what ways and through what causal linkages?

The project was planned to be accomplished in 12 months, and it actually took 16 months. The timescale was limited and therefore most countries were unable to complete and adopt a framework. Only, the preliminary work towards producing legal systems for safe biotechnology was accomplished (TE, pg. 30).

According to the TE, the time limitation was the primary criticism. All the work had to be completed within one year. For example, Kenya mentioned to the evaluator that "the first three months of the one-year project were used simply to organize and get it started" (TE, pg30).

5.3 Country ownership. Assess the extent to which country ownership has affected project outcomes and sustainability? Describe the ways in which it affected outcomes and sustainability, highlighting the causal links:

Public participation and involvement in the project was strong, however it differed among countries. According to the TE, this is a reflection of differing traditions, difficulties caused by the size and geographical conditions of the countries, the number of languages and educational deficiencies (TE, pg.7).

Representatives from countries within each region were nominated to attend workshops. The workshops were also attended by government representatives of developed countries, the scientific community, United Nations organizations, the biotechnology industry and other organizations. All key stakeholders attended regional workshops which show a high level of commitment (TE, pg.15).

According to the TE, the enthusiasm of most countries involved, was such that countries present at the meeting of Central and Eastern European countries in Bulgaria not involved in the project indicated some jealousy (TE, pg.28). All the countries recognized the importance of publicly available information, and underlined the importance of continuing the UNEP/GEF Pilot Biosafety Enabling Activity Project. (TE, pg.28).

6. Assessment of project's Monitoring and Evaluation system

Ratings are assessed on a six point scale: Highly Satisfactory=no shortcomings in this M&E component; Satisfactory=minor shortcomings in this M&E component; Moderately Satisfactory=moderate shortcomings in this M&E component; Moderately Unsatisfactory=significant shortcomings in this M&E component; Unsatisfactory=major shortcomings in this M&E component; Highly Unsatisfactory=there were no project M&E systems.

Please justify ratings in the space below each box.

6.1 **M&E Design at entry**	Rating: **Moderately Satisfactory**

In the PD (pg.38) the M&E system is shortly described. The monitoring and evaluation of the project should be done by UNEP. This should include feedback from participants on how the next workshop has to be adjusted for more effective attainment of the objectives. A review of the overall pilot biosafety proposal should be conducted by STAP, to provide the GEF with strategic guidance for extending assistance to other eligible countries. A budget for those activities is given in the PD. Moreover, the activities that are to be realized are described in detail, and some indicators are given to measure the achievements. These indicators and targets are not given as such, they are given very detailed in the budget lines, but they are not synthetized in a logframe.

6.2 **M&E Implementation**	Rating: **Unable to Assess**

There is insufficient information in the TE about M&E implementation to provide a rating..

7. Assessment of project implementation and execution

Quality of Implementation includes the quality of project design, as well as the quality of supervision and assistance provided by implementing agency(s) to execution agencies throughout project implementation. Quality of Execution covers the effectiveness of the executing agency(s) in performing its roles and responsibilities. In both instances, the focus is upon factors that are largely within the control of the respective implementing and executing agency(s). A six point rating scale is used (Highly Satisfactory to Highly Unsatisfactory), or Unable to Assess.

Please justify ratings in the space below each box.

7.1 **Quality of Project Implementation**	Rating: **Satisfactory**

The project was implemented by UNEP in association with National Executing Agencies (NEAs) of the respective countries (for the national level component). A task manager, in collaboration with the programme officer, Division of Environmental Conventions of UNEP, implemented the pilot project. (TE, pg.10).

According to the TE, the participants at the regional workshops and the officials and experts in the participating countries were very pleased with UNEP conceptualization and implementation of the project (TE, pg.6). According to them, a majority of the project activities at national level would not have taken place without the UNEP/GEF support (TE, pg.9).

UNEP/GEF provided a framework for the work involved in this project, and in consultation with individual participating countries provided timetables for delivery of aspects of the project. The TE states that the flexibility of the system implemented by UNEP was very important in achieving the objectives (TE, pg.33). The task managers were talking with country representatives and therefore could provide flexibility in interpreting the needs of countries within the framework set by the project.

UNEP representatives attended all of the national workshops, and provided important assistance during the process when approached. UNEP representatives were also involved in the regional workshops, providing the basis on which national frameworks could be built (TE, pg.32).

Overall, according to the TE, the achievements within the year indicate a well-managed project (TE, pg.33).

7.2 **Quality of Project Execution**	Rating: **Satisfactory**

The project was executed by National Executing Agencies of respective countries. UNEP collaborated with the International Information Resource on the Release of Organisms into the Environment Microbial Strain Data Network (IRRO/MSDN) and four institutions designated by respective host Governments for the organization of regional workshops (TE, pg.6).

The quality of execution seems to have been appropriate, governments and executing agencies were highly involved in the project and enthusiastic about it (TE, pg.28). However, there is not much information in the TE apart from an issue with the national biosafety committees.

The national biosafety committees often included promotion of the use of biotechnology as well as either performing a risk assessment on products produced in the country or imported, or auditing the risk assessment performed by applicants to produce or release modified organisms into the environment. Therefore, there were juxtapositions of supporting and judging products which impaired the project execution (TE, pg 30).

8. Assessment of Project Impacts

Note - In instances where information on any impact related topic is not provided in the terminal evaluations, the reviewer should indicate below that this is indeed the case. When providing information on topics related to impact, please cite the page number of the terminal evaluation from where the information is sourced.

8.1 Environmental Change. Describe the changes in environmental stress and environmental status that occurred by the end of the project. Include both quantitative and qualitative changes documented, sources of information for these changes, and how project activities contributed to or hindered these changes. Also include how contextual factors have contributed to or hindered these changes.

There is no environmental change mentioned in the TE.

8.2 Socioeconomic change. Describe any changes in human well-being (income, education, health, community relationships, etc.) that occurred by the end of the project. Include both quantitative and qualitative changes documented, sources of information for these changes, and how project activities contributed to or hindered these changes. Also include how contextual factors have contributed to or hindered these changes.

There is no socioeconomic change mentioned in the TE.

8.3 Capacity and governance changes. Describe notable changes in capacities and governance that can lead to large-scale action (both mass and legislative) bringing about positive environmental change. "Capacities" include awareness, knowledge, skills, infrastructure, and environmental monitoring systems, among others. "Governance" refers to decision-making processes, structures and systems, including access to and use of information, and thus would include laws, administrative bodies, trust-building and conflict resolution processes, information-sharing systems, etc. Indicate how project activities contributed to/ hindered these changes, as well as how contextual factors have influenced these changes.

a) Capacities

Several regional workshops and biosafety Protocol negotiations were held and raised awareness (TE, pg.8). Eight regional workshops in each region were held, namely Africa (Nairobi), Asia/Pacific (New Delhi), Latin America and the Caribbean (Havana) and Central and Eastern Europe (Bled, Slovenia). Two back-to-back workshops were held in each of the four centres. The workshops were attended by representatives from a large number of countries in each region (see TE, Table 1), many more than participated in the capacity-building segment of the project. They addressed risk assessment and management of LMOs concentrating primarily on their impact on the environment. Issues of transboundary movement of the organisms, including mechanisms for the supply and exchange of information between importing and exporting nations, constituted a major part of the workshop agenda. The workshops aimed to provide a clear understanding and appreciation of biosafety issues and to place the UNEP International Technical Guidelines for Safety in Biotechnology in perspective (TE, pg.15).

Subregional and regional centers of expertise were established, to supply and exchange information, to train scientists to use the technology safely, and to think about the consequences of their work (TE, pg.9).

Finally, national Biosafety Organizations were formed (TE, pg.31).

b) Governance

The project provided countries with the possibility of establishing a regulatory framework to start using biotechnological techniques (TE, pg.6).

The majority of the countries involved in the project have drafted new legislation to control the use of LMOs/GMOs within their borders (TE, pg.7). However, at the end of the project, only Cuba and Hungary had formal new laws in place (TE, pg.12)

8.4 Unintended impacts. Describe any impacts not targeted by the project, whether positive or negative, affecting either ecological or social aspects. Indicate the factors that contributed to these unintended impacts occurring.

There is no unintended impact reported in the TE.

8.5 Adoption of GEF initiatives at scale. Identify any initiatives (e.g. technologies, approaches, financing instruments, implementing bodies, legal frameworks, information systems) that have been mainstreamed, replicated and/or scaled up by government and other stakeholders by project end. Include the extent to which this broader adoption has taken place, e.g. if plans and resources have been established but no actual adoption has taken place, or if market change and large-scale environmental benefits have begun to occur. Indicate how project activities and other contextual factors contributed to these taking place. If broader adoption has not taken place as expected, indicate which factors (both project-related and contextual) have hindered this from happening.

There is no adoption of initiatives at scales reported in the TE.

However, the TE mentions that the "UNEP International Technical Guidelines for Safety in Biotechnology, which were used by the participating countries as a guide, may also need updating or reviewing to take into account the Biosafety Protocol provisions" (TE, pg.6). And that many more countries should benefit from similar input of funds and expertise as are available through this project. Many of these countries have applied for funding for their own National Biosafety Frameworks (TE, pg.9)

9. Lessons and recommendations

9.1 Briefly describe the key lessons, good practices, or approaches mentioned in the terminal evaluation report that could have application for other GEF projects.

The following main lessons are given in the TE (pg.37 and 38):

(1) A clear separation has to be maintained between assessing or auditing risk and promoting the use of biotechnology in order to maintain public acceptance of governments' objectivity.
(2) No country is isolated from its neighbors, and in many of the countries participating in the project there were very extensive land borders. The use of LMOs in any country cannot be isolated, and there is clearly a need to identify risks to neighboring countries and to inform those countries of risks about which they may have been unaware.
(3) Area and size of population must clearly be part of the consideration for criteria for funding. Variety in climate, physical and social geography must be taken into account in deciding on

expenditure. The number of local languages needed to bring an awareness of the benefits and dangers of biotechnology to all stakeholders may have a significant effect on the design of any framework.

9.2 Briefly describe the recommendations given in the terminal evaluation.

The TE gives several recommendations:

(1) 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, consideration has to be given to the review of the UNEP International Technical Guidelines for Safety in Biotechnology (TE, pg.9).
(2) If countries 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 (TE, pg.34).
(3) The experience of the large relatively developed countries has been very different from that of less developed but more homogenous countries. The experience gained by all these countries should not be lost, but should be transferred in a coherent manner to other countries that will face similar problems. The diversity of legal systems used in developed countries to ensure biosafety should provide a range of models on which all countries can base their own new guidelines or legal structures (TE, pg.35).
(4) In order that countries are able to decide on the mechanisms most appropriate for their circumstances, the project must provide training in techniques of risk analysis, assessment management and impact analysis. This training needs to be directed at scientists who would bear the brunt of the assessment requirements (TE, pg.36).
(5) In an extended or expanded future programme or project, more realistic timescales 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 (TE, pg.35).

10. Quality of the Terminal Evaluation Report

A six point rating scale is used for each sub-criteria and overall rating of the terminal evaluation report (Highly Satisfactory to Highly Unsatisfactory)

Criteria	**GEF EO comments**	Rating
To what extent does the report contain an assessment of relevant outcomes and impacts of the project and the achievement of the objectives?	The TE provides a strong assessment of relevant outcomes and achievements. However, impacts are not fully described and analyzed.	**S**
To what extent is the report internally consistent, the evidence presented complete and convincing, and ratings well substantiated?	The report is consistent and evidences are presented with detailed examples. However, there is no rating for any of the categories.	**MS**
To what extent does the report properly assess project sustainability and/or project exit strategy?	The project does not assess project sustainability with enough details. It only mentions the additional funding and technical needs of the countries; however it does not give information about the institutional or environmental sustainability. There is no exit strategy described.	**MU**
To what extent are the lessons learned supported by the evidence presented and are they comprehensive?	The lessons are well described and detailed. They are supported by the evidences and they are comprehensive.	**HS**
Does the report include the actual project costs (total and per activity) and actual co-financing used?	The report includes the actual project costs by activity. There was no co-financing in this project.	**S**
Assess the quality of the report's evaluation of project M&E systems:	The M&E system is not discussed at all in the TE.	**HU**
Overall TE Rating		**MS**

0.3*9+0.1*14 = 2.7+1.5= 4.2

11. Note any additional sources of information used in the preparation of the terminal evaluation report (excluding PIRs, TEs, and PADs).