MSP PROJECT BRIEF

PROJECT IDENTIFIERS	
1. **PROJECT NAME:** Support for the implementation of the Uganda National Biosafety Framework (NBF) within the context of the Cartagena Protocol".	1. **GEF IMPLEMENTING AGENCY:** UNEP
3. **COUNTRY IN WHICH THE PROJECT IS BEING IMPLEMENTED:** Uganda.	*4*. **COUNTRY ELIGIBILITY:** Uganda ratified CBD on 8th August 1993 and signed the Cartagena Protocol on the 24 May 2000.
5. **GEF FOCAL AREA:** Biodiversity/biosafety	6. **OPERATIONAL PROGRAMME/SHORT-TERM MEASURE:** The project cross-cuts the Biodiversity Operational Programmes 1,2,3,4, and follows the Initial Strategy for the Entry into Force of the Cartagena Protocol adopted by the GEF Council in November 2000.

7. PROJECT LINKAGE TO NATIONAL PRIORITIES, ACTION PLANS, AND PROGRAMS:

- Uganda is richly endowment of resources. The country has a great variety of landscape and vegetation. There are semi arid areas in the Southwest and northeast and rain forests in the west and some parts of the central. The remainder of the landscape is savanna and swamps. The country is also rich in wild life, which inhabit six national parks, 12 game reserves 14 controlled hunting areas and 8 game sanctuaries. Ten major forest reserves are also wildlife protection areas. The above information have important impacts for biosafety considerations that the country has to adopt: its proximity to the Vavilonian centre where several crop origins in Ethiopia makes the risks posed by genetic engineering to the biodiversity of crops very real. As a landlocked country, issues of transboundary movement of LMOs will be very crucial and the issue of the AIA needs to be internalised by policy makers. The favourable climate and weather regimes in Uganda make invasion by alien species very easy. Against this background, there is a growing population, which has exerted a lot of pressure on land resources. Consequently, government has adopted decentralization, privatisation, and trade liberalization as key policies for socio-economic development. Government programmes like the PMA are emphasizing modernization of Agriculture. Government is also pushing for increased food production through biotechnology. Biotechnological research on Bananas and cassava are being undertaken at local institutions to ensure national food security and poverty eradication.
- Government has undertaken significant steps to promote sustainable development, including the adoption of legislation to establish guidelines for environment impact assessment. The National Environmental Act to protect the environment, conserve natural resources and promote sustainable development was approved in 1995. Other current ongoing efforts include the draft national biodiversity strategy and action plan, which has a specific chapter dedicated to biotechnology and biosafety. In addition, Uganda has ratified and has to comply with several international conventions including the CBD and WTO, which all impact on biosafety.
- In 1997, the UNEP/GEF pilot project supported Uganda in drafting and establishing its NBF, which was approved by the Ministry of Environment in March 2001. As part of that work, a Biosafety regulation under the Environment Act of 1995 to ensure safety in biotechnology was drafted. This regulation has to be still finalized.
- This project is therefore geared at strengthening capacity for the implementation of the Uganda Biosafety Framework in the context of the Cartagena protocol. This is crucial for the success of the NBF. A key issue is the strengthening and development of human resources in biosafety issues and the development of appropriate facilities involving the transfer of know-how. Several capacity building requirements in the area of biosafety regulation, scientific capacity and in monitoring enforcement are set to enhance the

process at local and national level. The rationale for this proposal is anchored on the following premises:

1. Uganda has realized the importance of biosafety regulatory structure in biotechnology transfer. Biosafety mechanisms ensure that the new biotechnologies are applied judiciously.
2. While biosafety issues have been discussed for over twenty years in the developed world, only in the last four years have the issues been extensively explored in the global arena. The establishment of an international protocol on biosafety under the Biological Diversity Convention is increasing the pressure on Uganda to formulate guidelines and build capacity to regulate development and transboundary movement of living modified organisms. Uganda has therefore established the National Biosafety Committee (NBC), but a major shortcoming of this committee is that the vast majority of the members lack the competence in biosafety issues, especially in risk assessment. It significantly slows the assessment process, which, in tum, retards technology transfer and development. The scientists have expertise in their own disciplines but lack the experience of applying their knowledge to risk assessment and management.

   During the last 5 years or so there has been a number of international training programs and regional workshops aimed at building capacity in the implementation of risk assessment and management. A prime objective of these workshops has been to build institutional and individual capacity by sharing industrialized country experience in biosafety regulations and field-testing of GMOs with scientists, policy makers, and special interest group representatives. However, the effort done is still not enough.
3. Once there is national capacity, the next stage the country has to get prepared for is the harmonization of guidelines, regionally but also worldwide.

8. GEF NATIONAL OPERATIONAL FOCAL POINT AND DATE OF COUNTRY ENDORSEMENT:

GEF operational Focal Point
Mr Kassami, Chris K.
Permanent Secretary, Ministry of Planning and Economic Development
P.O. Box 7086, Kampala, Uganda
Phone (256-41) 241529, Fax : (256-41) 233035/235051

Letter of endorsement enclosed.

9. **Project Objectives and Activities**	Indicators
Goal: To support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries.	
Objective: To provide support to strengthen capacity building for the implementation of the National Biosafety Framework in Uganda, compliance with the obligations of the Cartagena Protocol .	
Specific objectives:	
(A) Set up a regulatory and administrative system to enable an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, with a specific focus on transboundary movements in Uganda, and meet the obligations foreseen under the Cartagena Protocol;	➢ Biosafety regulatory and administrative system set up.
B) Strengthening, and when needed building, effective scientific human capacity in risk assessment/risk	➢ Capacity on biosafety legislation/ operational management, risk assessment/ management/monitoring strengthened.

management and monitoring capabilities through training.	
C) Strengthening national infrastructure for LMOs testing;	➢ National referral institutions with capabilities for LMOs testing strengthened.
D) Strengthening the information system to be linked to the Biosafety Clearing House Mechanism	➢ Information system strengthened.
E) Enhance public awareness and promote dissemination among the relevant stakeholders;	➢ Information material for public awareness disseminated
10. Project Outcomes	**Indicators**
(A.1) Biosafety Regulation enacted.	➢ Biosafety Regulation enacted.
(A.2) Two-days workshop for 75 participants organized on handling request for releases of LMOs into the environment, with the participation of representatives of the public, private sector and NGOs organised.	➢ 2 workshops held
(A.3) 2 workshops organized as follows: ➢ A two-days workshop for 75 participants, including members of the National Biosafety Committee, Institutional Biosafety Committees, political leaders, legislators and policy makers, senior government officials, university staff and executives of semi autonomous government bodies on issues of biosafety legislation and procedure ➢ 2 days national workshop on procedures involved transboundary movement of LMOs with 75 participants from Customs Department, Phytosanitary Division, and Ministry of Agriculture, Universities.	
(A.4) Manual on procedures for transboundary movement of LMOs in Uganda published.	➢ Manual on procedures for transboundary movement of LMOs in Uganda disseminated
(B.1) Training activities carried out as follows: ➢ 3 days training course for 45 participants among the members of the National Biosafety Committee staff and Institutional Biosafety Committees on biosafety legislation and management practices; ➢ 5 days training for 10 experts on risk assessment and risk management and monitoring; ➢ a 5 days training for 45 custom officials on national and neighbouring country biosafety practices.	➢ Training activities carried out as planned.
(B.2) One day training workshop for 20 local council chiefs/district on biosafety legal and administrative aspects as well as risk assessment and management procedures in the 5 districts of Busia, Kampala, Mpigi, Soroti, and Mbarara.	
C) Equipment of two laboratories for LMOs testing	

Centre strengthened. Laboratories are placed at: ➢ Makerere University Institute of Environment and Natural Resources (MUIENR). ➢ Genomics unit at the National Foundation for Research and Development's Centre for Biotechnology and Biomedical Research	➢ LMO testing centres equipped.
(D.1) Information databases set up and linked to the BCH. The database will contain the following information as required by the Biosafety Protocol to satisfy the BCH requirements: ➢ Relevant existing laws, regulations including those applicable for the approval of LMOs; ➢ Bilateral, regional or multilateral agreements or arrangements relevant to biosafety in Uganda. ➢ Cases when imports take place at the same time as the movement is notified. ➢ Checklist of imports of LMOs into Uganda that are exempted from the Advance Informed Agreement (AIA) procedures. ➢ Specifications of when domestic regulations shall apply to specific imports. ➢ Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Article 15. ➢ Information on cases of illegal transboundary movements. ➢ The National Roster of Biosafety and Biotechnology experts in Uganda (D.2) Open and activate a website for the National Biosafety Committee, accessible from the general public. (D.3) Set up National Roster of experts in biosafety.	➢ Databases set up according to the requirements of the BCH and in operation.
(E.1) Awareness material prepared and disseminated to main users, i.e. politicians, community leaders private sector, consumer protection association, chambers of commerce and general public. (E.2) Some awareness material translated into local indigenous languages. (E.3) Best practices and lessons learnt disseminated	➢ Awareness materials available and disseminated.
11. Planned activities to achieve outcomes	**Indicators**
(A) Set up the project coordination and management team (A.1) Finalise the Biosafety Regulation under the Environmental Act of 1995.	➢ Biosafety Regulations finalised and submitted to the Minister responsible for Environment.
(A.2) Organize a two-days workshop for 75 participants organized on handling request for releases of LMOs into the environment, with the participation of representatives of the public, private sector and NGOs	➢ At least 70 participants attending the 2 workshops

(A.3) 2 workshops organized as follows: ➢ A two-days workshop for 75 participants, including members of the National Biosafety Committee, Institutional Biosafety Committees, political leaders, legislators and policy makers, senior government officials, university staff and executives of semi autonomous government bodies on biosafety regulation and procedure. ➢ 2 days national workshop on procedures related to transboundary movement of LMOs with 75 participants from Customs Department, Phyto-sanitary Division, and Ministry of Agriculture, Universities and NGOs. (A.4) Develop and publish a manual on procedures for transboundary movement of LMOs in Uganda. **(Total: 217,000USD; GEF:185,000)**	➢ Quality survey carried out at the end of each workshop among the participants. ➢ Proceedings of the two workshops available ➢ Manual of procedures for transboundary movement of LMOs in Uganda finalised.
(B.1) Training activities carried out as follows: ➢ 3 days training course for 45 participants including members of the National Biosafety Committee staff and Institutional Biosafety Committees on biosafety legislation and management practices; ➢ 5 days training workshop for 10 experts on risk assessment and risk management and monitoring; ➢ a 5 days training workshop for 45 custom officials on national and neighbouring country biosafety practices. (B.2) Three day training workshop for 20 local council chiefs/district on biosafety legal and administrative aspects as well as risk assessment and management procedures in 5 districts, Busia, Kampala, Mpigi, Soroti, and Mbarara. **(Total: 130,000 USD; GEF: 105,000)**	➢ Minimum of 80% of participants/training attending. ➢ Quality survey carried out at the end of each course among the participants.
C) Two laboratories for LMOs testing strengthened. Laboratories are placed at: ➢ Makerere University Institute of Environment and and Natural Resources (MUIENR). ➢ Genomics unit at NFRD's Centre for Biotechnology and Biomedical Research **(Total: 100,000 USD; GEF: 100,000 USD)**	➢ Equipment for 2 laboratories purchased
(D.1) Set up information databases, to serve also for the BCH. The database will contain the following information as required by the Biosafety Protocol: ➢ Relevant existing laws, regulations including those applicable for the approval of GMOs; ➢ Bilateral, regional or multilateral agreements or arrangements relevant to biosafety in Uganda. ➢ Cases when imports take place at the same time as the movement is notified.	➢ Information databases developed

➢ Checklist of imports of LMOs into Uganda that are exempted from the Advance Informed Agreement (AIA) procedures. ➢ Specifications of when domestic regulations shall apply to specific imports. ➢ Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Article 15. ➢ Information on cases of illegal transboundary movements. ➢ The National Roster of Biosafety and Biotechnology experts in Uganda (D.2) Open and activate a biosafety website for the National Biosafety Committee, accessible from the general public. (D.3) Set up National Roster of experts in biosafety. **(Total: 105,000 USD; GEF: 95,000 USD).**	➢ Website active and linked to the database. ➢ Roster of experts created.
(E.1) Prepare and disseminate awareness material to the main users, i.e. politicians, community leaders private sector, consumer protection association, chambers of commerce and general public, as well as best practices (E.2) Translation of some awareness material into local indigenous languages. (E.3) Dissemination of best practices and lessons learnt **(Total: 90,000 USD; GEF: 75,000)**	➢ Set of awareness material disseminated

12. Budget (in USD):

GEF: 560,000USD
Co-financing: 82,000USD
Total (USD) : 642,000USD

13. Information on Project Proposer:

Name: Uganda National Council for Science and Technology (UNCST), under the Ministry of Finance, Planning and Economic development
Type: Semi-Autonomous Government Institution
Address: P.O Box 6884 Kampala, Uganda
Location: Kampala Road, Plot 10, Uganda House, Floor 11
Contact person: Dr. Nyiira, Executive Secretary

14. Information on Proposed Executing Agency:

The Uganda National Council for Science and Technology was established by Statute 1 of 1990 as a corporate institution under the Ministry of Finance Planning and Economic Development to guide and coordinate research and experimental development throughout Uganda. The Councils mandate is to advise government in the formulation of policies, which enhance and foster the integration of Science and Technology (S&T) in Uganda's national economic and social development. Its mission is to develop strategies for the promotion and development of S&T for ensuring sustainable integration of S&T in national development process.

The Uganda National Council for Science and Technology (UNCST) activities are executed trough Programmes and Units and a set of specialised committees. Altogether there are 9 programmes and 6 specialised committees. The Council by its mandate is also expected to develop nucleus programmes and projects, which act as loci of future technology development institutions. The proposed project falls under the Biotechnology and Biosafety activity that falls under the Technology Promotion and Development Programme started in 1994. The project seeks to implement and operationalise the National Biosafety Framework within the context of the Cartagena Protocol.

15. Date of initial submission of project concept:

26th July 2000

16. Project Identification number:

Not yet assigned

17. Implementing Agency Contact Person:

Ahmed Djoghlaf, Executive Co-ordinator, UNEP/GEF Coordination Office, 30552, Nairobi, Tel.+254 2 624166, Fax. +254 2 624041.

18. Project linkage to Implementing Agency Program(s):

As the financial mechanism of the Convention on Biological Diversity, the GEF is also called upon to serve as the financial mechanism of the Cartagena Protocol on Biosafety.

GEF Council during its meeting in May 9-11, 2000, "welcomed the adoption of the Cartagena Protocol on Biosafety, including Article 28 of the Protocol which provides that "the financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol". The Council requested the Secretariat, in consultation with the Implementing Agencies and the Secretariat of the Convention on Biological Diversity, to inform the Council at its next meeting of its initial strategy for assisting countries to prepare for the entry into force of the Protocol. The Council also requests UNDP and the GEF Secretariat to take into account the provisions of the Cartagena Protocol in the on-going work of the Capacity Development Initiative".

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

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

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

Project Description

Project rationale and objectives.

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

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

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

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

4. The project "Implementation of the National Biosafety Framework" for Uganda is consistent with the *"Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"*(GEF/C.16/4) adopted by GEF Council in November 2000. Such strategy foresees that:

"In countries that …. have participated in the pilot project, it is proposed that the GEF undertake country-based demonstration projects to assist in the implementation of a country's national biosafety framework.

This type of assistance might best be provided to countries that have already ratified the Protocol, in much the same way that assistance through the financial mechanism of the Convention on Biological Diversity is to be provided to Parties to the Convention. However,

in the interest of gaining experience and developing good practices that may promptly and effectively be provided to assist Parties once the Protocol enters into force, it is proposed that the GEF finance a limited number of country-based demonstration projects (maximum of eight countries - two per region for Africa, Asia, Eastern Europe, and Latin America and the Caribbean)."

The strategy was further supported in the Final Decisions of 21st Governing Council of UNEP. The GC21 has:

- *Congratulated the 18 countries that participated in the United Nations Environment Programme/Global Environment Facility Pilot Enabling Activity Project for their exemplary execution of the national component of the pilot project, and*

- *Invited the Global Environment Facility to provide further financial support to these and other countries for the implementation of national biosafety frameworks (or similar policy administrative, legislative biosafety frameworks) they have developed in preparation for the entry into force of the Cartagena Protocol on Biosafety and for the first phase of the Biosafety Clearing House.*

4. Uganda has signed the Cartagena Protocol on 24 May 2000. To date, as also identified in the final recommendations of the enabling activity carried out under UNEP/GEF for the "Development of a National Biosafety Framework", Uganda needs to build its capacity in the key areas in order to proceed further and implement its NBF. This project sets therefore as main objectives:

(A) Set up a regulatory and administrative system to enable an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, with a specific focus on transboundary movements in Uganda, and meet the obligations foreseen under the Cartagena Protocol;
(B) Strengthening, and when needed building, effective scientific human capacity in risk assessment/risk management and monitoring capabilities through training.
(C) Strengthening national infrastructure for LMOs testing;

(D) Strengthening the information system to be linked to the Biosafety Clearing House Mechanism

(E) Enhance public awareness and promote dissemination among the relevant stakeholders;

Current situation

1. Uganda has established the National Biosafety Committees (NBCs) in 1997 under the decision of the Council of Science and Technology Act of 1990. The NBCs are key players in the risk assessment/management process. A major shortcoming of the NBC committee is that the vast majority of its members lack competence in biosafety risk assessment. This significantly slows the assessment process, which, in addition, retards technology transfer and development. The scientists have expertise in their own disciplines but lack the experience of applying their knowledge to risk assessment and management.

2. During the period April 1998 to September 1999, the Uganda National Council for Science and Technology (UNCST) undertook a country study with support from the Global Environment Facility (GEF) through the United National Environment Programme to develop a National Biosafety Framework for Uganda. In the context of this project, a National Biosafety Framework was prepared. The Framework was adopted by the Ministry of Environment in March 2001.

   Overall, the pilot project resulted in:

   - Starting and providing an incentive for a debate in Uganda for the first time on issues of safety when using biotechnology.
   - Drafting of the National Biosafety Guidelines (further adopted by the Ministry of Finance and Planning in 1999) and regulations based on the International Technical Guidelines on Safety in Biotechnology.
   - Catalysing action, and international co-operation, mobilisation of resources.
   - An awareness of the potential and relative benefits and risks of the environmentally sound application of biotechnology among the public and key decision makers.

3. The signing of the Cartagena Protocol by Uganda at the Conference of parties to the CBD in Nairobi in May 2000 galvanised more impetus at national level to have the National Biosafety Framework implemented. The Biosafety Protocol is indeed an important international agreement, especially for developing countries. This is due to the recognition of the fact that LMOs carry special risks and hazards and need therefore to be regulated.

4. As a signatory to the Protocol, Uganda has taken steps to properly and effectively implement the protocol. A Biosafety regulation was therefore drafted and needs currently to be finalised. This prompted UNCST to submit a new project concept on 26th July 2000 to UNEP expressing the desire to seek additional GEF support to implement the National Biosafety Framework. Thus, during the official launch of the National Biosafety Framework by the Ugandan Minister of State for the Environment in a workshop organized by UNCST on 20th March 2000, several capacity building needs were identified by the workshop participants as critical in the implementation of the NBF in accordance with the Cartagena Protocol. These needs are currently addressed under this proposal.

Status of other ongoing biosafety efforts in the region

There are also some programs operating at regional or international levels. The East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) was founded in 1998, to facilitate a concerted effort in Agricultural, Industrial, Environmental and Food Biotechnology research in the countries of the Eastern Africa comprising of Ethiopia, Kenya, Tanzania and Uganda. Without applying itself specifically to the Biosafety Protocol, the programme focuses on some of the major problems and opportunities for biotechnology in East Africa in the agricultural, environmental, industrial areas; and combines biotechnology R&D, biosafety and biotechnology policy development thereby facilitating a close collaboration between scientists, policy makers and the private sector and acting as a catalyst in stimulating regional collaboration between research and policy institutions.

The ASARECA has recently initiated a biotechnology program, which will address policy issues in biotechnology, and biosafety issues at regional level for ASARECA countries in Eastern and Central Africa region. Several CGIAR centres are also actively working with the National Agricultural Systems (NARS) in the region on important biotechnology programmes.

The African Biotechnology Stakeholders Forum (ABSF) programme in Kenya is a forum for sharing and exchanging experiences and practices in biotechnology with view of strengthening its applications and lobbies for active implementation of biosafety systems.

The Rockefeller Foundation Research Capacity Building Program on Agricultural Biotechnology is under development in order to develop capacities in developing countries including biosafety procedures.

The IITA and INIBAP in Uganda are working on banana biotechnology to address pests especially the banana weevil and nematodes and the Black Sigatoka disease. CIMMYT is working closely with KARI in Kenya to develop enhanced insect resistant maize varieties. In another project they are working towards developing effective strategies to reduce Striga infestations on maize. CIAT is working with NARO in Uganda on the diseases of *Phaseolus* beans. None of these projects address requirements proposed in this proposal.

Finally, WWF and GTZ have offered to provide support for the implementation of some aspects of the Cartagena Protocol. This initiative is still at a very conceptual stage.

The GEF Alternative

The establishment of an international protocol on biosafety under the Convention and its acceptance for signature by Uganda has increased the pressure on country with respect to strengthening its national capacities due to the rapid development of technology involving more and more LMOs. This increases as well the risk for transboundary movements. In addition, the practical integration of biotechnology into our national research and development programmes has started, especially in the field of agricultural research.

A key step in the process is the strengthening and/or development of human resources in biosafety issues and the development of appropriate facilities. However Uganda is lacking the needed financial resources to cover in adequate manner all the above issues and match the requirements of the Cartagena Protocol. GEF intervention and financial support is indeed considered essential.

The project sets therefore the following outcomes:
(A.1) Biosafety Regulation enacted.
(A.2) Two-days workshop for 75 participants organized on handling request for releases of LMOs into the environment, with the participation of representatives of the public, private sector and NGOs organised.
(A.3) 2 workshops organized as follows:

- A two-days workshop for 75 participants, including members of the National Biosafety Committee, Institutional Biosafety Committees, political leaders, legislators and policy makers, senior government officials, university staff and executives of semi autonomous government bodies on issues of biosafety legislation and procedure
- 2 days national workshop on procedures involved transboundary movement of GMOs of LMOs with 75 participants from Customs Department, Phytosanitary Division, and Ministry of Agriculture, Universities.

(A.4) Manual on procedures for transboundary movement of LMOs in Uganda published.

(B.1) Training activities carried out as follows:

- 3 days training course for 45 participants among the members of the National Biosafety Committee staff and Institutional Biosafety Committees on biosafety legislation and management practices;
- 5 days training for 10 experts on risk assessment and risk management and monitoring;
- a 5 days training for 45 custom officials on national and neighbouring country biosafety practices.

(B.2) One training day workshop for 20 local council chiefs/district on on biosafety legal and administrative aspects as well as risk assessment and management procedures in the 5 districts of Busia, Kampala, Mpigi, Soroti, and Mbarara.

C) Two laboratories for LMOs testing strengthened. Laboratories are placed at:
- Makerere University Institute of Environment and Natural Resources (MUIENR).
- Genomics unit at NFRD's Centre for Biotechnology and Biomedical Research

(D.1) Information databases set up and linked to the BCH. The database will contain the following information as requested by the Biosafety Protocol to satisfy the BCH requirements:

- Relevant existing laws, regulations including those applicable for the approval of LMOs;
- Bilateral, regional or multilateral agreements or arrangements relevant to biosafety in Uganda.
- Cases when imports take place at the same time as the movement is notified.
- Checklist of imports of LMOs into Uganda that are exempted from the Advance Informed Agreement (AIA) procedures.
- Specifications of when domestic regulations shall apply to specific imports.
- Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Article 15.
- Information on cases of illegal transboundary movements.
- The National Roster of Biosafety and Biotechnology experts in Uganda

(D.2) Open and activate a website for the National Biosafety Committee, accessible from the general public.
(D.3) Set up National Roster of experts in biosafety.

(E.) Awareness material prepared and disseminated to main users, i.e. politicians, community leaders private sector, consumer protection association, chambers of commerce and general public.

ACTIVITIES

1. LEGISLATIVE COMPONENT

- ***Finalization of the Draft National Biosafety Legislation***

This will involve the finalization of a specific biosafety regulation under the Environment Act of 1995. The regulation will also take into account the following factors:
- Fulfilment of Cartagena Protocol
- Institutional arrangements
- Application and Approval
- Participatory/advisory process
- Scientific inputs (Risk assessment and Risk Management)

- Enforcement process
- Delegation of Authority
- Liability/redress
- Penalties
- Appeal Process
- Timeframe for decision making
- Flexibility
- Accountability
- Predictability
- Coordination
- Transparency
- Cost of Compliance
- Definitions
- Consideration of socio-economic issues
- Public participation
- Transboundary movement,
- Risk assessment and Management

Once finalized, the Biosafety Regulation will be submitted to the Minister of Environment for approval. Through such a Regulation, the national biosafety administrative system will became fully operational.

As part of the project, three workshops will be held. A steering committee will be set up, to hold meetings which will identify participants, draw up workshop programs, make site visits, commission papers and be responsible for the production of proceedings. The workshops are:

- In order to finalize the Biosafety Regulation, a specific workshop will be held and will aim at collecting views and opinions on specific aspects of mentioned regulation. The workshop will also assist participants in familiarizing them with the biosafety regulatory agencies (NBC, IBC, etc.), and biosafety regulatory procedures. The workshop will lasts 2 days and will be attended by 75 participants comprising Members of Parliament, Senior government officials, Administrators from Universities and semi autonomous government bodies.

- A second workshop on Procedures for the transboundary movement of LMOs and their impact in Uganda will be held. The aim of this workshop is to outline in a stepwise manner, procedures involved transboundary movement of LMOs as well as their risks and potential impacts in Uganda. 45 participants drawn from Customs Department, Phytosanitary Division, and Ministry of Agriculture, Universities and NGOs conducting research will attend the 2-days workshop. An organising committee will be set up to hold meetings, which will identify participants, draw up workshop programs, make site visits, commission papers and be responsible for the production of proceedings.

A Manual on transboundary procedures will be compiled, taking into consideration the issues arising from mentioned workshop.

A two-days workshop on handling requests for releases of LMOs into the environment with the participation of 75 participants will be organised. The workshop will deal with the main features for handling requests, i.e.:

- Providing information to stakeholders;
- Handling request, i.e. processing, screening for completeness, etc;

- Public participation in the process preceding decision-making;
- Follow-up (inspections to insure compliance, reviewing reports, etc)

TRAINING

During the last decade, integration of biotechnology into national research and development programmes has started, especially in the field of agriculture. In accordance with article 19 of the Protocol Uganda has established the National Biosafety Committee (NBC) as the competent authority for biosafety in Uganda. The NBC members will soon be key players in the risk assessment/management process. In fact, as requested by article 15 and 16 of the Cartagena Protocol, the Committee will have to evaluate the risk assessment submitted by the exporting party as part of the information supplied along with the notification to the importing party. It could also conduct its own risk assessment or instruct the exporting party to undertake another risk assessment if it is not fully satisfied with the risk assessment supplied by the exporting party. Where scientific information about potential adverse effects is made available, the NBC may have to review its decision. All this requires biosafety capacity that is currently lacking. In addition, an inadequately trained committee slows the assessment process, which, in turn, means delay in technology transfer and development.

The NBC will further need the backing of local scientific capacity to screen applications and make decisions on import. Training and capacity building of local scientists in biosafety assessment is also critical. Scientists from key organizations should become part of the local scientific pool of expertise.

The same applies to the national monitoring and enforcement capacity. The best laws, regulatory mechanisms, and scientific expertise will be of little use if there is no effective monitoring and enforcement capability to ensure sound biosafety regulation. As required in article 17 of the Cartagena protocol, monitoring and enforcement will be carried out by Customs officials as well as the NBC but at different levels. Given the above, three training courses and training workshops will be held as follows:

- *Training course on biosafety regulation and administrative procedures for members of the NBC and IBC and scientists.*

The three days training course is aimed at providing members of the NBCs, IBCs and scientists with information on the implementation of the biosafety regulation and administrative procedures. It will include handling of application and theory and practice of risk assessment and management.

- *Training course on risk assessment/risk management*

The aim of this 5 days training course is to train 10 lawyers on legal issues involved in biosafety. Because biosafety implementation is not yet taught in schools and colleges and has not yet been incorporated in the curriculum of the law school at Universities, it will be important to expose lawyers to the subject.

- *Training course for customs officials on national, regional and selected international Biosafety practices, procedures for the transboundary movement of LMOs and their impact in Uganda.*

The 5 days training is aimed at providing customs officials with the necessary knowledge of transboundary practice in Uganda and in the neighbouring countries and will involve 45 participants.

In addition, a set of 5 training workshops will be held in the districts of Kampala, Mpigi, Mbarara, Masindi and Soroti in order to promote capacity for decision making purposes at local level. The three days training (per district) will include local authorities as well as town/city councils farmers associations and NGO's and Media. An organizing committee will be set up to hold meetings, which will identify participants, draw up workshop programs, make site visits, commission papers and be responsible for the production of proceedings.

3. Strengthen capacity of LMO testing centres

Uganda is on the alert that LMOs may slip through its borders. Article 25 of the Cartagena Protocol requires parties to adopt appropriate domestic measures to prevent LMOs entering the country without permission.

A substantial part of the current food aid offered to Uganda comprises genetically engineered seeds and food. This could bypass the procedures and mechanisms for regulating the transboundary movement of LMOs. Uganda needs therefore to strengthen its facilities and improve its testing capacities. This activity consist therefore in identifying and equipping the molecular biology laboratory at MUIENR and the Genomics Centre at NFRD, National Foundation for Research and Development, with affordable basic diagnostic equipment for verifying the presence of LMO in commodities.

The Molecular Biology laboratory at the Makerere Institute of Environment and Natural Resources is affiliated to the Faculty of Science and its current research activities are centered around DNA and genetic studies on natural populations of wild life. The National Foundation for Research and Development (NFRD) is affiliated to the Uganda National Council for Science and Technology: its new Genomics Unit is intended to serve initially as a laboratory with research portfolio covering the area of early warning systems related to LMOs Risk Assessment and management: LMOs inspection is therefore also part of its activities.

The type of equipment required for LMO inspection services under the risk assessment and management procedure prescribed by the Protocol is listed in Annex 3. These facilities will also help in strengthening the capacity of the Makerere Institute of Environment and Natural Resources for teaching purposes.

Strengthening the information system.

This activity involves the setting up of databases linked to the Biosafety Clearing House Mechanism in accordance with the Cartagena Protocol. This will contain the following information:

- Relevant existing laws, regulations or guidelines, including those applicable for the approval of LMOs.
- Bilateral, regional or multilateral agreements or arrangements;
- Cases when the import may take place at the same time as the movement is notified;
- Imports of LMOs exempted from the AIA procedures;
- Specifications of when domestic regulations shall apply to specific imports;
- Notification of the point of contact in case of transboundary movements;
- Summaries of risk assessments or Environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Article 15;
- Information on cases of illegal transboundary movements.

A user-friendly website to serve as a point source of all information concerning all GMO work in Uganda will also be set up. It will contain scientific, environmental legal, and all documents concerning approval process of LMOs in Uganda.

5. Public awareness

Article 23 of the Cartagena Protocol requires parties to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs. The project will aim at strengthening capacity for public awareness by developing material to be disseminated across the country.

The aim is to develop easily accessible pamphlets, brochures and abridged series of the Biosafety Guidelines and National Biosafety Framework for address the main information needs of the different users (government institutions, NGOs, private associations, general public, etc.). Also more reprints of the Ugandan Biosafety regulations for dissemination and Framework will be updated and made available at workshops. Some of the awareness materials will be translated and published in local languages.

Best practices and lessons learnt will be disseminated for replication in other countries of the region.

Sustainability Analysis and Risk Assessment

The project has strong government support, in particularly from the Ministries of Finance, Planning and Economic Development, Ministry of Lands Water and Environment and Agriculture. The UNCST, which is under the Ministry of Finance Planning and Economic Development, will be responsible for coordinating the project in the Country. The Council houses the National Biosafety Committee and is also responsible for the overall clearance and approval of all GMO work. The council operates both foreign and local bank accounts and has an efficient accounting and purchasing system that are vetted by the government appointed independent auditors. The Ministry of Environment will provide technical inputs to the activities being undertaken. Social assessments will analyse the costs and benefits of decentralized decision-making about biosafety in Uganda.

NGOs, community based-organizations and other interest groups will be involved through their representatives in the National biosafety Committee.

Stakeholder involvement and social assessment

Several stakeholders who attended the workshops held in conjunction with the National Biosafety Framework contributed with important inputs and ideas that have been used in the formulation of this current proposal. These stakeholders include:

- Members of the National Biosafety Committee,
- Members of the R& D institutions (Universities)
- Representatives of International CGIAR institutions in Uganda (IITA, INIBAP)
- Senior government officials from ministries of Agriculture, Health, Environment, Trade and commerce, education and local government,
- Uganda Manufacturers association,
- Members of Parliament,
- Lawyers,

- Customs officials,
- Uganda Revenue Authority Officials
- National Farmers association,
- National Drug Authority,
- Uganda Chemist,
- National environment management Authority
- National Agricultural Research Organization (NARO)
- Farmers representatives
- The Consumer Protection association,
- Media people.

The Uganda National Council of Science and Technology has then put together all recommendations that has resulted into the current proposal. These recommendations were refined and then incorporated in the project on the occasion of \ the final workshop held on 20th January 2001, when the Minister of Environment officially launched the National Biosafety Framework.

INCREMENTAL COST ASSESSMENT

Uganda has signed the Cartagena Protocol on the 24 May 2000. In 1997, the UNEP/GEF pilot project supported Uganda in drafting and establishing its NBF, which was approved by the Ministry of Environment in March 2001. As part of that work, a Biosafety regulation under the Environment Act of 1995 to ensure safety in biotechnology was drafted. This regulation has to be still finalized.

Uganda is currently highly exposed to a random introduction of modern biotechnology, given that government has adopted decentralization, privatisation, and trade liberalization as key policies for socio-economic development to ensure national food security and poverty eradication. The need for implementing the National biosafety framework is therefore extremely urgently. However, despite the efforts, the country lacks the main capacities and facilities to address these issues.

Besides UNEP/GEF support, Uganda has benefited of funds for biotechnology R & D and related training by the Swedish Co-operation, SIDA, for an amount equal to *110,000USD*, and of a contribution of *50,000USD* by ACTS (African Centre for Technology Studies) for a Ugandan Representative to take part in 3 regional workshops on biosafety. The SIDA component related to training is included in the baseline.

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

Project components	Baseline	Alternative	Increment
Legislation and coordination	The Biosafety Act is in draft. Ugandan institutional capacity is still poor.	Finalisation and enactment of the Biosafety Act, manual on procedures for transboundary movement of LMOs published, institutional capacity further strengthened through workshops	The implementation of the Cartagena Protocol is supported by the consolidation of the the National Biosafety framework and its implementing regulations
Training	Need for strengthening capacity among those involved in the biosafety management system in order to adequately implement the National biosafety Framework and therefore the Cartagena Protocol	Capacity strengthened through specific training courses and workshops organized for government and technical staff	Strengthened national capacity to service commitments under the Cartagena Protocol
Strengthening national facilities for risk assessment and management	Uganda's laboratory facilities are in their early stage of development with respect to screening LMOs and monitor/ manage the risks associated to their transfer, handling and use.	The Makerere University Institute of Environment and Natural Resources (MUIENR), and the Genomics unit at the National Foundation for Research strengthened with specific laboratory equipment needed for inspection purposes in relation to the risk assessment procedure. These	Risk assessment and management improved through the strengthening of national facility and therefore capacity to screen LMOs

		facilities will also help in strengthening the capacity of the Makerere Institute of Environment and Natural Resources for teaching purposes.	
Strengthening the information system to serve for the purposes of the BCH	An organized database system to serve for the purpose of the Biosafety Clearing House is still missing.	A national information system as required by the Protocol for the purpose of the BCH (database as well as web site) set up with all the information required by the Cartagena Protocol (Article 20 and Articles 6, 10, 11, 12, 13, 14, 17, 19, 23, 24 and 25), i.e. applications for permits, laboratory and field trails, permits for the release of GMO to environment/market, product containing GMO, transboundary movement of LMO (import and export), GMO risk assessment, management monitoring and control	The setting up of the national database, the collection of the related information, the opening of a web site are the basic activities needed to make the Central BCHM as structured in the Protocol operational
Public awareness and dissemination	Current capacity for public awareness purposes is still poor	Capacity for public awareness purposes strengthened through the preparation and dissemination of awareness material, best practices and lessons	National capacity for public awareness capacity enhanced

As shown in the table below, the cost of the increment is of ***642,000USD*** of which ***560,000USD*** is being requested from the GEF; the remaining ***82,000USD*** is provided as in-kind contribution by Uganda.

Project components	**Baseline**	**Alternative**	**Increment**	**Cost to GEF (Global Benefit)**	**Co-financing (in-kind contributions)**
Legislation and coordination	10,000	227,000	217,000	185,000	32,000
Training	50,000	180,000	130,000	105,000	25,000
Strengthening national facilities	60,000	160,000	100,000	100,000	-
Strengthening the information system	15,000	120,000	105,000	95,000	10,000
Public awareness and dissemination	5,000	95,000	90,000	75,000	15,000
Total	**140,000**	**782,000**	**642,000**	**560,000**	**82,000**

PROJECT BUDGET (in 000 USD)

	Project Component	Year 1	Year 2	Year 3	Total GEF Contribution	In kind by Uganda	Total
A1	Finalisation of draft regulations.	30	15	-	40	5	45
A2	Workshop on handling requests for releases of LMOs in the environment including Foreign expert participation/consultancy costs	35	-	-	30	5	35
A3.1	Workshops on Biosafety Regulations and Procedures.	25	5	-	25	5	30
A3.2	Workshops on Procedures for the transboundary movement of LMOs	15	-	15	25	5	30
A4	Development and Publication of a manual on procedures for transboundary movement of LMOs in Uganda	5	10	5	15	5	20
SUBTOTAL A		110	30	20	**135**	**25**	**160**
B1.1	Training course on biosafety legislation and management practices for lawyers.	-	20	-	15	5	20
B1.2	Training course on risk assessment and management and monitoring for scientists, NBC and IBC's	-	30	-	25	5	30
B1.3	Training course on national and neighbouring country biosafety practices			30	25	5	30
B2	District Workshops on Biosafety in Biotechnology	10	30	10	40	10	50
SUBTOTAL B		10	80	40	**105**	**25**	**130**
C	Strengthening capacity of LMO testing centres at MUENR and	-	50	50	100	-	100

	NFRD						
SUBTOTAL C		-	50	50	**100**	**-**	**100**
D1	Set up information databases	30	10	10	50	-	50
D2	Open and activate a biosafety website for the NBC	20	10	10	35	5	40
D3	Set up a national roster of experts in Biosafety	5	5	5	10	5	15
SUBTOTAL D		55	25	25	**95**	**10**	**105**
E1	Prepare and disseminate awareness material on biosafety, dissemination of best practices and lessons learnt	20	20	20	50	10	60
E1	Translate and publish awareness materials in local languages	10	10	10	25	5	30
SUBTOTAL E		30	30	30	**75**	**15**	**90**
F1	Office Equipment	5	-	-	5	-	5
F2	Project Personnel	4	3	3	10	-	10
F4	International experts	5	6	4	15	-	15
F5	Stationery	5	5	5	10	5	15
F6	Communication	4	4	4	10	2	12
SUBTOTAL F		20	16	16	50	**7**	**57**
	GROSS TOTAL	**228**	**233**	**181**	**560**	**82**	**642**

IMPLEMENTATION PLAN

The project consist of 5 main activities to be carried out over a period of three years according to the following schedule:

	ACTIVITY	YEAR 1												YEAR 2												YEAR 3											
A	Establishment of coordinating office and recruitment of project officer																																				
A1	Finalise the Biosafety regulations																																				
A2	Organise a workshops on biosafety regulations and Procedures																																				
	Organise a workshop on procedures related to transboundary movement of LMOs.																																				
A3	Develop and Publish a manual on procedures for transboundary movement of LMOs in Uganda.																																				
A4	Organise a workshop on handling request for releases of LMO's into the environment.																																				
B1	Training course on biosafety legislation and management practices.																																				
	Training course on risk assessment, risk management and monitoring.																																				
	Training Course on national and neighbouring country biosafety practices.																																				
B2	District training workshop on biosafety legal and administrative aspects as well as risk assessment and management procedures.																																				
C	Strengthen the Molecular Biology Laboratory at Makerere and the Genomics laboratory at NFRD with LMO testing equipment.																																				
D1	Set up information databases, open and activate a biosafety website for the NBC.																																				
D2																																					
D3	Set up a national roster of experts in Biosafety.																																				
E1	Prepare and Disseminate awareness material on Biosafety.																																				
E2	Translate some of the awareness material in local languages.																																				

PUBLIC INVOLVMENT PLAN

Several stakeholders are involved in the implementation of the proposed framework these include the NBC, IBC, senior government officials, members of parliament, lawyers, customs officials, scientists, farmers, NGOs media, local government officials, etc.

The NBC and IBCs will be the target for training in various capacity building activities. In addition, they will also provide biosafety advice, approvals of applications and will also monitor implementation of the framework. They will also in addition be trained in vetting applications ensuring biosafety compliance with regard to the national biosafety guidelines and to participate in national workshops and training activities.

Members of Parliament will be targeted for training on the biosafety regulatory framework and will be sensitised to offer political support to the biosafety regulation drafting process

Customs officials will be trained in monitoring and enforcement of biosafety regulations and monitor implementation of the framework and to participate

Legal officers (Lawyers) will trained in technical aspects in relation to the biosafety regulations so as to develop their capacity to understand the legal basis of the biosafety in biotechnology.

Plant Health Inspectors will be trained in risk assessment and management partic ipate in workshops and training courses

Policy makers (senior government officials) will be trained and to offer legal and policy guidance and implementation of the biosafety processes as well as administrative structure.

Researchers and Scientists will be trained in risk assessment and management. They will manage the laboratories and participate in workshops and training courses.

Farmers will be trained/sensitised to the issues and participate in decision making with respect to socio-economic considerations as well as transfer of technology

NGOs and civic organizations will be consulted, provided with information and assisted with the technical expertise and information on new advances in biotechnology and biosafety.

The Private sector (Industry) will be invited to form partnerships with public sector and where possible contribute to the funding of emerging R&D needs in biosafety. They will also be trained in biosafety, be sensitised on regulatory and administrative procedures on transboundary movement of GMOs and participate in the national dialogue.

Consumer Protection Associations will be involved when making decisions regarding imports of GMOs as well as in sensitisation of their members.

The media will play an important role at workshops and training courses. They will be responsible for summarising information generated during all activities for the newspapers in various local languages. Targeted media people will include those mainly from the New Vision and Monitor (English), Bukedde (Luganda), Etop (Ateso), Orumuri (Runyankole) Rupiny (Acholi) and Arupet (Lango) will be invited to translate information in those local languages. All

radio stations will be invited to participate in workshops and training courses and therefore encouraged to disseminate information to the general public.

Local Council authorities (LCs) 1, 2, 3, 4 and 5 will be trained and sensitised on current developments in biosafety and biotechnology. They will also participate in decision making and will be assisted in setting up district biosafety committees which will be integrated in the administration structures of the decentralized districts for implementation of the framework.

As per activities E.1 and E.2 of the project, materials, abridged booklets and brochures will be prepared and disseminated.

MONITORING AND EVALUATION

Monitoring of the progress of all activities will be undertaken by UNEP in accordance with its Monitoring and Evaluation procedures.

The indicators identified in the project will be used for monitoring the development of the project activities.

A mid-term independent evaluation will be undertaken. The evaluation will include an assessment of on-going activities including a diagnosis of possible problems and recommend any corrective measures. A final evaluation of the project will be undertaken in accordance with UNEP.

Dissemination of results will take place via the stakeholders meetings, via periodic meetings between the project management team and the government departments, publications and via the public media.

Recommendations and best practises will be disseminated for replication to other countries in the region.

IMPLEMENTATION ARRANGEMENTS

- A National Coordination committee is being installed. As appropriate, UNEP, as leading agency, and the World Bank and UNDP, as collaborating agencies, will provide recommendations and assess the achievements done during the implementation of this project.
- A Steering Co-ordination Committee for the eight projects will be chaired by UNEP and will comprise the representatives of the National Executing Agency, the two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. In addition, experts selected on their personal capacity will be part of the Steering Committee as well as the representative of STAP when the Steering Committee will be addressing technical and scientific issues arising from the implementation of the MSPs.

LIST OF ANNEXES

ANNEX 1

Summary of the Uganda Biosafety Framework

Background

Following the signing and ratification of the Convention on Biological Diversity (CBD), Uganda has been involved in a number of measures to implement the various obligations under the convention. These measures however lacked a national framework under they operated. Conscious of this gap, the Uganda National Council for Science and Technology took the leadership in formulating a national biosafety framework with support from the GEF and UNEP. The need for the framework were identified as follows:

- The need to enhance/ensure safety in biotechnology in order to protect human health and enhance the well being of the environment while maximizing the benefits from the potentials of biotechnology and avoiding to the maximum extent possible the adverse effects on conservation/sustainable use of biological resources.
- The need to facilitate smooth and rapid progress of the work initiated by the conference of parties to the Convention on Biological Diversity on the need for and modalities of a biosafety protocol within the context of the Convention.
- The need to facilitate the development and wide use of harmonized globally acceptable principles and technical guidelines that offer appropriate and wide adequate guidance to governments, institutions, organizations, companies and various stakeholders etc in their efforts towards development of and application of biological risk assessment and management procedures and processes at national, regional and international level.
- The need to set the stage for appropriate and adequate endogenous capacity building including human resources development in the area of safety in biotechnology at national, regional and international levels. This need is recognized as a prime element requiring urgent global attention . Its fulfillment will greatly facilitate effective implementation of the technical guidelines and any future international agreement on biosafety.
- The need to enhance technology assessment capacity at national and regional level for the management of environmentally sound biotechnology, including environmental impact and risk assessment, with due regard to safeguards on the transfer of technologies.
- The need for consensus building at national and regional levels and greater awareness among the public and key decision makers regarding the potential and relative benefits and risks of environmentally sound application of biotechnology.
- The need for human resources development in the area of safety in biotechnology, particularly risk assessment and management of biotechnology applications.
- for regional cooperation for harmonization, data validation and mutual acceptance of data.

The framework involved a number of surveys and commisioned studies which included:

1. Survey existing biotechnologies and status of safety in biotechnology applications.
2. Survey existing national, bilateral and multilateral cooperative programmes in R&D and application of biotechnology.
3. Survey existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation.
4. Survey of extent and impact of release of LMOs and commercial products.
5. To identify monitoring and enforcement mechanisms for biosafety implementation.

The resulting biosafety framework document is made up of 6 chapters, appendix annexes.

Chapter 1 mentions Institutional structures mechanisms for biotechnology and biosafety in Uganda. Other aspects described include:

- Nature and kind of biotechnological activities conducted at various institutions and related biosafety status.
- Institutions involved in biotechnology applications and biosafety.
- Current Biotechnology applications in Public and private institutions.
- Bilateral and Multilateral Cooperative Research and Development (R&D) Programmes.
- Capacity building requirements including infrastructural needs and data management facilities.
- In-country net works.

Chapter 2 describes institutional administrative procedures for biotechnology and biosafety in Uganda and mentions the public institutions and private institutions involved in active biotechnology and existing Biotechnologies and Status of Safety in Biotechnology Applications in Uganda. The National Biosafety Committee under UNCST is described as the national administrative arm on matters concerning biotechnology and biosafety. Mechanisms for the implementation of the Biosafety guidelines are also briefly highlighted. A summary of the Biosafety Guidelines and Regulations is provided.

Chapter 3 describes mechanisms for biosafety risk assessment and management Uganda with respect to healthcare, agriculture and forestry and environmental protection. A review of extent and impact of release of LMOS and commercial products in Uganda is also given including a survey of future possible areas of application of biotechnology in Uganda. A review is made of the extent and impact of release of LMO's and commercial Products in Uganda. Containment facilities and biosafety practices are detailed including:

- Biological containment;
- Physical containment;
- Biosafety levels;
- Transport and handling, transfer and shipment of specimens;
- Health and medical surveillance;
- Emergency procedures;
- Decontamination and disposal
- Chemical, electrical, fire and radiation safety
- Safety considerations for genetically modified organisms
- Basic considerations for risk assessment of microorganisms
- Use of rDNA technology in vaccine development
- Procedures for release and commercialisation of GMO's, animals, plants.
- Risk assessment factors on environmental release of GMO's
- Familiarity, assessment and management of risks

In chapter 4, the framework gives policy and regulatory regime for biotechnology and biosafety in Uganda. Generally, none of the laws in Uganda explicitly covers LMO's and biosafety and such scattered provisions may be very difficult to enforce. The issues are usually piecemeal and are hidden in provisions of several sectoral laws relating to natural resources conservation, preservation and utilization, science and technology, industrial development, environmental protection including biodiversity and sustainable use of natural resources. An assessment of the effectiveness of various existing is therefore made with respect to biotechnology and biosafety. The framework concludes that, in practice these laws do not adequately cover the

biotechnology/biosafety requirements relating to biodiversity and its enactment of new laws is proposed. A proposed draft national regulation and policy measures are highlighted.

Chapter 5 gives strength's and opportunities for biotechnology and biosafety in Uganda including, strategies for biotechnology and biosafety, action plans constraints and specific needs and priorities to address biotechnology and biosafety in Uganda.

Strengths and Opportunities for Biotechnology and Biosafety in Uganda

These are given as follows:

- There is good political will from the Uganda government to support initiatives on all matters related to biosafety development. Uganda is signatory to and has ratified the convention on biodiversity.
- There is a conducive administrative/political environment i.e. local councils. Hence it is relatively easy to get community involvement and empowerment in biotechnology as one of the development programs.
- There is good international good will. There are currently major international biotechnology companies like Monsanto, Novartis Pioneer, etc who are ready to support the developing countries. There are also universities in the USA and Europe which have established collaboration linkages with institutions in Uganda . Bilateral donor programs sponsored by SAREC, NORAD, FAO, WHO, etc could be requested to finance these collaborations. Infrastructure development and some funding in biotechnology could be funded by bilateral donor programs.
- Regional co-operation already in existence i.e. E.A.C, COMESA, IGAD, e.t.c. This will make regional collaboration and networking in biotechnology easier. Already some collaboration does exist, such as the regional biosafety focal point in Harare and the East African Research Network in Biotechnology and Biosafety (BIO-EARN).
- Some infrastructure for biotechnology is already available and some modernization of our institutions is already taking place e.g. Makerere University, UVRI, JCRC, Medbiotech Labs, and local research institutes.
- There is already some institutional partnership/ collaboration at national and international level.
- Biotechnology is already in use in Uganda i.e. both traditional and modern biotechnology e.g. maize, cassava, beverages, tomatoes, passion fruits, compost and biogas production, etc.
- Biotechnology is a new field, innovative and promising, therefore attractive.
- There is already a National Biosafety Committee (NBC) under UNCST in existence.
- A legally binding instrument on biotechnology use in Uganda is in advanced stages.
- Existence of statutory bodies like UNCST, NEMA, NARO NDA which can be used to advance and entrench biotechnology.

Constraints and Gaps for Biotechnology and Biosafety in Uganda

The fact that biotechnology is increasingly becoming useful cannot be over emphasized. Biotechnology however has some potential risks to public health, environment and social aspects of the countries involved. Biotechnology and biosafety require knowledge in science and technical issues which require specialized knowledge. The management of biotechnology in Uganda is an issue of institutional development and governance requiring new institute values and standards, new capabilities at the policy making level and experimentation. Constraints being faced are given as follows:

- Lack of regulations to provide guidelines on the use of biotechnology.

- Shortage of highly trained manpower to handle biotechnology work.
- Limited institutional capacity for training in biotechnology.
- Insufficient funding to develop biotechnology and biosafety in Uganda.
- Inadequate of awareness on the importance and potential use and applications of biotechnology and the related safety needs which leads to limited or lack of community involvement in biotechnology activities.
- Inadequate national systematic policy and structures (e.g. legal instruments) regulating biotechnology use in Uganda, coupled with the lack of a clear-cut policy on intellectual property rights .
- Inadequate institutional collaboration and consultation in biotechnology which results in minimal pooling of resources and sharing of experience/expertise.
- Poor utilization of political infrastructure for effective management and sustainable use of biotechnology.
- Weak regional collaboration and coordination on matters related to biotechnology and biosafety.

Strategies and Action Plans for Biotechnology and Biosafety in Uganda

Strategies and action plans are presented as follows:

- Utilize article 20 of the CBD to provides a financial mechanism to increase national capacity (both human and institutional) for biotechnology and biosafety.
- Engage public debate before release of GMO's and ensure continuous scrutiny after release.
- Undertake effective monitoring of new biotechnologies should be done through regional and international cooperation, which ensures utmost good faith and transparency. This could be handled under the international biosafety protocol clearing house mechanism.
- Harness scientific tools to enhance farm productivity per unit area without causing ecological harm.
- Undertake public awareness and education on risks and dangers of new biotechnologies.
- Promote the Internet for searching information.
- Encourage the private sector to develop a culture of safety.
- Finalise our national biosafety law, which would empower the regulatory mechanism to oversee the development and transfer of biotechnology.
- Promote capacity building in biotechnology and biosafety particularly in product R&D, in areas of risk assessment and risk management by training and institutional strengthening in GLP and GMP.
- Promote linkages between academia and the private sector in Uganda. The universities are traditionally the manpower resource pool which the private sector provide the environment for acquiring experience in good laboratory and manufacturing practices.
- Encourage government to provide tax exemptions on imported scientific equipment and reagents, write off some taxes to offset losses incurred by the private sector.
- Seek mechanisms for Ugandan private sectors to gain access to technologies protected by patent rights in the North.

Action plans for biotechnology and biosafety

Action plans are given as follows:

- Put together a consortium of donors/philantrophists to create financial resources for costs related to training, institutional strengthening and product R&D in Uganda.

- Sdet up facilities for basic research and subsequently product research and development e.g. cloning and expression of drug targets or vaccines; creation of plant transgenes with the desired traits.
- UNCST should expand and equip the national biosafety committee to increase its role in delivering public education and awareness if the public is to be involved in a meaningful way.
- Provide tax exemptions on imported scientific equipment and reagents.
- Set up laws which protect intellectual property rights in Uganda.
- The NBSAP to sensitize government to set a side a reasonable proportion of the national budget for product R&D as well as reasonable salaries to national scientists.
- Enact and strengthen biosafety legislation to ensure development with safety. These regulations however should not stifle the creativity and motivation of scientific entrepreneurs and investors in the biotechnology
- Subject any trans-boundary movement of an LMO and /or their products to the advance informed agreement (AIA) procedure as suggested in Article 19.3 of the CBD.
- Establish National registers of past and present genetic engineering experiments/projects should be set up in order to establish an effective monitoring system as part of standard safety measures.
- Undertake Risk/benefit analyses for new biotechnologies should be done locally basing its criteria on a case-by –case basis e.g. an anti-HIV drug, a transgenic banana expressing malaria vaccine constructs.
- Label transgenic materials, be they foodstuffs, feeds, or pharmaceutical products by law, so that the consumer makes an informed decision whether to take them or not.
- Review mechanisms by which GM crop plants could be monitored in the environment so as to make recommendations for long-term monitoring of impact on ecosystems.
- Review possible effects of insect tolerant crops on the ecosystem and provide guidelines for growth of such crops and recommendations for further research.
- Review the effects of GM crops in comparison with the effects of current agricultural practices in general on ecosystems and the environment as a whole should be considered.
- Undertake research on the following topics
    - alternative markers to antibiotic resistance genes and methods of removal of marker genes when they are no longer needed.
    - Possible impact of virus resistant plants on the ecosystem
    - Pleiotropic effects and transgene instability in GM plants
    - Optimisation of pest control using insect tolerant plants in conjunction with minimisation of resistance development and study of likely impacts of insect tolerant plants on the ecosystem.

Specific Biosafety Needs and Priorities to Address Biotechnology and In Uganda

Specific biosafety needs are given as follows:

- Need for highly trained manpower to handle biosafety research.
- Need to create a fund to develop infrastructure for biosafety assessment capacity.
- Need for awareness on the importance of and potential use and applications of biotechnology and the related safety needs.
- Need community involvement in biosafety activities.
- Need for an explicit policy and regulatory structures for handling the needed biotechnology and biosafety requirements in Uganda.
- Need to strengthen institutional collaboration and consultation in biosafety.

- Need for utilization of existing political machinery e.g. the introduced decentralized system of governance to safely integrate biotechnology and biosafety concerns.
- Need to strengthen regional collaboration and coordination on matters related to biosafety.

Finally Chapter 6 gives references cited in the text and several appendices which include notification and application forms, a checklist of containment/laboratory facilities, categorization of microorganisms and annexes of participants/ institutions that participated in various workshops during the framework exercise.

ANNEX 2

Matrix showing the relation between the project activities, the Cartagena Protocol and the National Biosafety Framework

Proposed activity	Relevant Cartagena Protocol Article	Uganda Biosafety Framework
Finalization of the Draft National Biosafety Legislation	Article 2	In chapter 4 of the NBF, the need for finalizing the Biosafety regulations is spelt out. It is also mentioned in Chapter 5 among the strategies for Biosafety in Uganda and among the action plans for biosafety in Uganda.
Workshops on Biosafety Regulations and Procedures	Articles 20,22,23	The need for workshop on Biosafety regulations is a strategy to achieve the objective of setting up a regulations as spelt out in Chapter 4.
Development and Publication of a manual on procedures for transboundary movement of LMOS in Uganda	Articles 6, 7, 8 9,10, 14, 15, 16, 17, 18, 22,23, 25,26	This is in fulfillment of the needs expressed in Chapter 3 of the NBF particularly with respect to the capacity building needs for risk assessment and risk management.
Workshop on Procedures for the transboundary movement of LMO's	Articles 4,6,7, 8, 9, 10, 11, 13, 20, 23	The need for this workshop is spelt out in the action plans of the NBF.
Workshop on handling requests for releases of LMO's in the environment	Articles 15,16,18,19	The need for this workshop is spelt out in the action plans of the NBF as well as in the specific needs to address biosafety in Uganda
Training Course on risk assessment and management and monitoring for scientists, NBC and IBC's	Articles 15,16,18,19, Annexes 1,2,3	The need for this workshop is spelt out in Chapter 3 of the NBF, in the action plans of the NBF as well as in the specific needs to address biosafety in Uganda.
Training Course on national and neighboring country biosafety practices	Articles 14, 15,16, 18, 19,22,23,25	The workshop will address the capacity building requirements expressed in chapter 3, 4 and particularly in strengthening of regional collaboration and coordination on matters related to biosafety.
District Workshops on Biosafety in Biotechnology	Articles 6, 7, 8 9,10, 14, 18,21,22,25,25,27,33	District workshops are geared at addressing the NBF specific need of utilizing existing political machinery to safely integrate biosafety concerns in development.
Strengthening capacity of LMO testing centers at MUENR and NFRD	Article 7, 22, 25	The need for this workshop is spelt out in the specific needs to address biosafety in Uganda, with respect to developing infrastructure for biosafety assessment.
Setting up information databases	Article 20	This will compliment information provided in Chapter 3 on all technical aspects of biosafety.
Open and activate a biosafety website for the NBC	Article 20,23	This is mentioned in the strategies and action plans of the NBF namely the promotion of internet for information exchange.
Set up a national roster of experts in Biosafety	Article 20	This is geared at adding value to the information given in Chapter 1 of the NBF

		with respect to names of individuals in various institutions who are involved on biosafety.
Prepare and disseminate awareness material on biosafety	Article 20	This is in fulfillment of NBF strategy of using all possible mechanisms to communicate biosafety information to the general public
Translate and publish awareness materials on biosafety	Article 20	This is mentioned in the strategies and action plans of the NBF in respect to the communication of biosafety information to the general public

ANNEX 3

Provisional list of laboratory equipment needed at the Molecular Biology laboratory at the Makerere Institute of Environment and Natural Resources and at the Genomics Unit at NFRD Centre for Biotechnology and Biomedical Research

ITEM

2 - DNA Digital Documentation System

2 - Protein Gel and DNA Electrophoresis equipment

2 - Thermocycler (PCR Machine)

2 - Elisa machine (Reader)

2 - Photodocumentation System

ANNEX 4

UNEP Response to the STAP Technical Review

The STAP Technical Review provided that "the implementation of these 8 projects needs to be co-ordinated and assisted by an experienced facilitator or facilitators… What is needed is an expert - and preferably a group of experts - who have long experience in this highly complex legal and technical field and who have good connections with similar capacity building activities in the regions. The need for assistance is even stronger with these first 8 countries, as these are demonstration projects from which others have to learn". In addition, the STAP Review made a strong case to enhance regional collaboration. To respond to these requirements, and after consultation with the GEF Secreatariat, UNEP will establish a overarching Steering Committee for the implementation of the 8 Medium Size Projects.

The Steering Committee for the eight projects will be chaired by UNEP and will comprise the representatives of the National Executing Agency, the two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. In addition, experts selected on their personal capacity will be part of the Steering Committee as well as the representative of STAP when the Steering Committee will be addressing technical and scientific issues arising from the implementation of the MSPs.

UNEP fully agree on the STAP review on promoting regional collaboration. This request is in line with priorities identified by the National Governments during the development phase of the MSPs, but will require additional financial resources. UNEP will consult with the participating countries, during the implementation phase, on the ways and needs to address this issue.

Country's Specific Issues

The STAP comments relate mainly to the implementation of the projects. They have therefore been noted and will be fully taken into account during the development of the projects.

STAP Reviewer's comments on specific issues have been addressed in the revised version as evidenced in the attached table. They will be further taken into account during the appraisal phase of the MSPs.

Issue	Response
Kenya • *Capacity building should also be addressed to inspectors, for example by organising training workshop and developing inspection manuals.*	• Capacity building for inspectors in training workshop is now explicitly mentioned in the project proposal. It will be further addressed during the implementation of the project.

Poland • *One important element that is missing, is the development of implementing regulations.* • *The proposed training activities are very fragmented and it is recommended to merge some of the training activities.* • *Further clarification is needed as to how the proposed activities will be co-ordinated with the activities under the EU twinning project for which Poland has applied.*	1) The EU covers the regulatory component and therefore Poland didn't ask for any further financing from GEF. 2) In the Polish project proposal there is a table under the paragraph "Budget" showing what is financed by the EU and what should be financed by the GEF. That's why the activities may appear as fragmented, because they complement current EU ones.
Uganda • *It is recommended to include training activities on topics such as "other international obligations".*	• Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.