

MSP PROJECT BRIEF

Project Identifiers	
1. PROJECT NAME: Support to the implementation of the National Biosafety Framework for Kenya	2. GEF IMPLEMENTING AGENCY: UNEP
3. COUNTRY/IES IN WHICH THE PROJECT IS BEING IMPLEMENTED: Kenya	4. COUNTRY ELIGIBILITY: Kenya ratified the Convention on Biological Diversity in 26 th July 1994 and signed the Cartagena Protocol on the 15 th May 2000
5. GEF FOCAL AREA: Biodiversity/Biosafety	6. OPERATIONAL PROGRAMME: 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, approved by the Council in November 2000.
7. PROJECT LINKAGE TO NATIONAL PRIORITIES, ACTION PLANS AND PROGRAMMES: <ul style="list-style-type: none"> • In 1987, the Government through the then Ministry of Research Science and Technology set up a committee under the National Council for Science and Technology (NCST), to determine the priorities for research in biotechnology. The committee known as the National Advisory Committee on Biotechnology Advances and their Applications (NACBAA) made the first reference to the need for a policy on biosafety. The committee, consisting of the directors of Research Institutes, produced a report which recommended that the NCST develops a policy on biohazards and ethics in biotechnology. • In 1994, the Kenya National Environment and Action Plan which was approved by Cabinet, made the following recommendations pertaining to biosafety: <ul style="list-style-type: none"> – Establish a National Commission on biotechnology and biosafety. – Formulate a scientific criteria for the safe use genetically modified organisms including methods of hazard identification and exposure assessment before GMOs are released into the environment and also design measures for biological and Physical containment of GMOs and mechanisms to monitor the organisms, genetic material and processes exposed to GMOs. – Make Prior Informed Consent a Pre-requisite for all field-testing. – Formulate a biosafety policy and regulations. • In 1997, The Kenya Agricultural Research Institute produced Biosafety Guidelines and formed the Institutional Biosafety Committee. • In 1998, the National Council for Science and Technology produced the regulations and guidelines for safety in biotechnology which provided a base for the establishment of the National Biosafety Committee (NBC) and Institutional Biosafety Committees as well as identifying the competent authority as the National Council for Science and Technology. • In 1999, under the framework of the UNEP/GEF Biosafety Enabling Activity, a National Biosafety Framework was produced based on an assessment of the status of biotechnology and biosafety in the country. A draft Biosafety Law was also prepared and it is currently under revision for submission to the authorities in charge. • In 2000, the National Biodiversity Strategies and Action Plans (NBSAP), published by the Ministry of Environment and Natural Resources, identified biosafety as an important area that required support for its advancement. • On 15th May, 2000, during the Fifth Conference of Parties to the CBD, the President of Kenya signed the Cartagena Protocol on Biosafety. Kenya was the first country to sign the Protocol. 	

<ul style="list-style-type: none"> • Kenya took part to the round table conference of Ministers held in May 2000 during the COP 5 and supported the need for providing assistance to developing countries for biosafety capacity building activities. • In 2000, the <i>National Environment Co-ordination and Management Act</i> was enacted. This Act also emphasizes the need to set regulatory framework for biosafety issues. 	
<p>8. GEF NATIONAL OPERATIONAL FOCAL POINT AND DATE OF COUNTRY ENDORSEMENT:</p> <p>Submitted: Acknowledged: Endorsed:</p>	
<p>9. Project Objectives and Activities</p>	
<p>GOAL: Support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries.</p> <p>OBJECTIVE: To support the Implementation of the National Biosafety Framework in Kenya as required by the Cartagena Protocol. The overall objective is to strengthen the needed capacity, which would enable the Country to implement the Cartagena Protocol on Biosafety. Specific objectives are:</p> <p>(A) To support the establishment of the regulatory and administrative basis for the implementation of the management and monitoring system related to the safe environmental release, commercial production and transboundary movement of living modified organisms (LMOs) in Kenya, in compliance of the obligations of the Cartagena Protocol;</p> <p>(B) Strengthen capacity building on biosafety policy, management, administration and risk assessment/management (in order to provide guidance and design risk management options and strategies);</p> <p>(C) Strengthen national facilities for LMOs managing, handling and monitoring activities.</p> <p>(D) Strengthen the national information system to serve as well for the purposes of the BCH</p> <p>(E) Strengthen national capacity to enhance public awareness and promote information sharing on biosafety related issues</p>	<p>➤</p> <p>➤ Indicators:</p> <p>➤ To strengthen national capacities for implementing the National Biosafety framework and meet the requirement of the Cartagena Protocol</p> <p>➤ Entry into force of the " Biosafety Act of Kenya" and related regulations and guidelines.</p> <p>➤ Start the Implementation the biosafety management system.</p> <p>➤ Main stakeholders trained</p> <p>➤ Laboratory facilities equipped for risk assessment.</p> <p>➤ Biosafety data information system and Biosafety Clearing House Mechanism for Kenya in-use.</p> <p>➤ National Capacity for public awareness purposes strengthened</p>

<p>10. Expected Outcomes:</p> <p>(A.1) Project team set up. (A.2) Assessment on the implementation of the biosafety framework as established by the National Biosafety Committee carried out. (A.3) 2 workshops held in order to review the draft Biosafety Bill, (A.4) Submitted and in force "Biosafety Act of Kenya" (A.5) Through the already established National Biosafety Committee (NBC), the Regulations and Guidelines for biosafety in Kenya will be reviewed and published for comments (A.6) One national workshop on handling request for LMOs release for 24 participants organized in Nairobi (a.7.1) One workshop on Article 11 of the Cartagena Protocol relating to the importation or export of living modified organisms intended for food or feed held (2 days, 40 participants) held. (A.7.2) Specific regulations and procedures for food safety as per article 11 of the Cartagena Protocol drafted.</p> <p>(B.1) One week training for two Officers in Data Management for the purpose of the BCH (B.2) 1 Seminars for training 30 participants, including NBC members, scientists and policy-makers/per course on risk assessment and management taking into account articles 15 and 16 of the Protocol. (B.3) 4 training courses for trainers (technicians, decision-makers, custom officials, institutional biosafety committees' members and inspectors) carried out by area of competence.</p> <p>(C.1) Office of the National Biosafety Committee to serve biosafety management activities and the BCH equipped. (C.2) Kenya Agricultural Research Institute (KARI) and the Botany department, University of Nairobi, equipped with facilities for handling and monitoring of LMOs.</p> <p>(D.1.1) Biosafety Database System to serve as Biosafety Clearing House Mechanism in Kenya set up</p>	<p>Indicators:</p> <ul style="list-style-type: none"> ➤ Proceedings of all the workshops made available. ➤ Biosafety Act of Kenya is passed through Parliament and comes into force. The Act provides for the making of appropriate regulations and guidance for the safe use of living modified organisms in Kenya ➤ Assessment published ➤ Survey on attendance and quality of the training courses ➤ Laboratory and office equipment purchased as per annex ➤ Database and Web site operational
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<p>(D1.2) Biosafety Website for Kenya to be linked to the BCH active</p> <p>(E.1) Teaching materials, brochures, manuals in order to strengthen capacity for public awareness purposes developed</p> <p>(E.2) Best practices and lessons learnt disseminated.</p>	<ul style="list-style-type: none"> ➤ Biosafety Database active. BCH established. Web site open. ➤ Teaching materials, brochures, manuals distributed to users
<p>Planned activities to achieve outcomes (including cost in US\$ or local currency of each activity):</p>	<p>Indicators:</p>
<p>(A.) Establish the project coordination team</p> <p>(A.1) Carry out an assessment on the implementation of the biosafety framework as established by the National Biosafety Committee, including calling for public (stakeholder) comment.</p> <p>(A.2) Organize 2 workshops in order to review the draft Biosafety Bill. One workshop is addressed to the main stakeholders to collect their view and comments on the draft Bill (1 day workshop, 50 participants), the second is addressed to the panel of experts (1 day, 20 participants) for finalization of the Bill to be submitted to Parliament;</p> <p>(A.3) Submission of the "Biosafety Act of Kenya" that provides for the making of regulations and publishing of guidance so as to ensure that safe use, import and export of living modified organisms in Kenya;</p> <p>(A.4) Review and Finalize, through the already established National Biosafety Committee (NBC), "the Regulations and Guidelines for biosafety in Kenya";</p> <p>(A.5) Organize workshop on handling request for LMOs release (Nairobi, 2 days, 24 participants)</p> <p>(a.6.1) Organize one workshop on Article 11 of the Cartagena Protocol (2 days, 40 participants).</p> <p>(A.6.2) Draft specific regulations and procedures for food feed and processing as per article 11 of the Cartagena Protocol. Publish draft regulations for public/stakeholder comment.</p> <p>(TOTAL: 118,016USD; GEF92,872USD)</p>	<ul style="list-style-type: none"> ➤ Minimum of 80% participants for each workshop ➤ Reviewed bill submitted for approval to Parliament ➤ Focal point appointed and his/her tasks identified. ➤ "The Regulations and Guidelines for biosafety in Kenya" drafted and published for consultation; ➤ Pilot study on the implementation of the biosafety regulations ➤ Regulations and procedures for food, feed and processing as per article 11 of the Cartagena Protocol drafted ➤ Establishment of Project Coordination and Management Team.
<p>(B.1) Train two Officers for one week in Data Management for the purpose of the Biosafety Clearing House</p>	<ul style="list-style-type: none"> ➤ 4 Training workshops and 3 seminars held. ➤ Minimum 80% of attendance

<p>(B.2) Organize a seminars (2 days) for training 30 participants, including NBC members, scientists and policy -makers on risk assessment and management;</p> <p>(B.3) Organize 4 training courses (4 days) as follows:</p> <ul style="list-style-type: none"> • 15 decision- makers and government officials on biosafety legislation and procedures, • 15 custom officials on procedures to be applied to LMO transboundary movements and information on regulation existing in neighbouring countries, • 15 technicians on safety measures in laboratories and LMOs inspection procedures, • 15 institutional biosafety committee members on the implementation of biosafety measures and risk monitoring as per the national guidelines. <p>(TOTAL :125,274USD; GEF:110,253USD)</p>	
<p>(C.1) Equip the office of the National Biosafety Committee to serve biosafety management activities requirements i.e. (BCH).</p> <p>(C.2) Equip the Kenya Agricultural Research Institute (KARI) and the Botany department, University of Nairobi, with facilities for LMOs handling and monitoring.</p> <p>(TOTAL:217,457USD;GEF:164,570USD)</p>	<ul style="list-style-type: none"> ➤ National Biosafety Office equipment purchased as per annexes ➤ Two laboratories equipped with facilities as per attached list.
<p>(D.1.1) Set up a Biosafety Database System to serve as Biosafety Clearing House Mechanism in Kenya</p> <p>(D1.2) Set up a Biosafety Website for Kenya to be linked to the BCH</p> <p>(TOTAL:73,553USD;GEF:60,921USD)</p>	<ul style="list-style-type: none"> ➤ Biosafety Database System set up and operational ➤ Website active and connected tot he BCH ➤ Number of hits on the website
<p>(E.1) Develop and disseminate teaching materials, brochures, manuals (e.g. inspection manuals) in order to strengthen capacity for public awareness purposes</p> <p>(E.2) Dissemination of best practices and lessons learnt</p> <p>(TOTAL:85,237USD; GEF: 82,263USD)</p>	<ul style="list-style-type: none"> ➤ Teaching materials, brochures, manuals published
<p>12. Estimated budget (in US\$ or local currency): (the budget should include an estimate of the GEF financed portion of project execution costs, the portion expected to be financed form other sources and the total)</p> <p>GEF: 510,879USD</p> <p>In-kind: 108,658USD</p>	

TOTAL: 619,537USD

13. **Information on project proposer:**

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National Council for Science and Technology (NCST) was established in 1970 by an Act of Parliament known as the Science and Technology Act. Its mandate is to advice on different areas of application of science and technology. Within the NCST, a special National biosafety Committee was established in 1998 as result of the recommendations of the Final Report on the "Development of a National Biosafety Framework" under the UNEP/GEF pilot project. The NCST constituted a National Biosafety Committee (NBC) that would embark on the implementation of the regulations and guidelines. The NBC comprises of representatives from:

- Government Ministries: Agriculture, Health, Office of President, Environment and Natural Resources, Research and Technology.
- Government Departments such as Kenya Industrial Property Office and Department of Resource Survey and Remote Sensing.
- Public Universities
- Research Institutions namely, Kenya Agricultural Research Institute (KARI), Kenya Medical Research Institute (KEMRI), and International Livestock Research Institute (ILRI).
- Stakeholders such as the Kenya National Farmers Union and the Kenya Agricultural Biotechnology Platform.
- The National Council for Science and Technology

The NBC is chaired by a representative of the Ministry of Agriculture while the Secretary of the committee is a representative of the NCST who is also a member of the Regional Biosafety Focal Point. Main tasks of the NBC are:

- To review and ascertain the suitability of both physical and biological containment and control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities. Main tasks of the NBC are:
- To review relevant proposals, except those that relate to research under contained laboratory conditions, and recommend any conditions under which the proposed work should be carried out.
- To ensure that adequate testing of genetically transformed materials developed elsewhere has been performed in the country of origin before it is introduced in a local trial programme.
- To establish contact and maintain liaison with other countries and organizations dealing with biosafety issues.
- To consult with relevant government institutions and non-governmental institutions as may be necessary.
- To establish a database for the purpose of facilitating collection and dissemination of information relevant to biosafety.
- To identify national requirements for manpower development and capacity building in

- biosafety.
- To maintain a directory of experts in biotechnology and biosafety, as well as a directory of project supervisors approved by institutional biosafety committees.
 - To keep a record of biotechnology and biosafety activities in the country.
 - To advise the Institutional Biosafety Committee (IBCs), relevant institutions and persons, on mitigation measures to be undertaken in case of an accident.
 - To initiate diplomatic actions as may be necessary for appropriate compensation to Kenyan inhabitants or organizations who may suffer damage as a consequence of the exposure to imported biotechnology products.
 - To review and amend these regulations and guidelines from time to time as necessary.
- The National Biosafety Committee has already started its work and has developed procedures for assessing application for introduction of GMOs. Already the committee has assessed one application for introduction of transgenic sweet potato which is resistant to yellow mottle virus.

14. **Information on proposed executing agency (if different from above):** NA

15. **Date of initial submission of project concept:**

16. **Project Identification number:**

17. **Implementing Agency contact person:**

Ahmed Djoghlaif, Executive Co-ordinator, UNEP/GEF Coordination Office

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 Kenya, 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 Montpellier on 11-15 December 2000. The UNEP/GEF projects were further discussed during a side event held on 13th December at the margins of the meeting. The Montpellier Declaration 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 the methods, techniques, standards, guidelines, indicators for assessing and monitoring the risks, and control and regulatory measures for those risks likely caused by the transportation, release, commercialization 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 understanding and concern of the public and major decision makers of the potential benefits and risks of biotechnology application;
 - Enhance international cooperation and communication on scientific research, legislation, information exchange and personnel training in the field of biosafety.
4. Kenya completed in 1999 its project entitled “National Biosafety Framework of Kenya (NBFC)”, supported by UNEP/GEF. Under the pilot enabling activity it was found that some institutions had put in place biosafety measures in place. However these measures were general and they only fitted within the category of Good Laboratory Practices. Besides, most the organizations surveyed explained that they had no institutional biosafety committees and hence they had no direction on what kind of risk assessment and risk

management measures were in commensurate with their types of work. Hence, reinforcement of the safety measures were left to individuals.

The results of the survey also indicated that only a few institutions had any persons who were adequately trained to assess risks or even to manage risks should these occur either through intended or unintended releases of living modified organisms. This situation may pose great danger to biodiversity as well as risks to humans. Hence, the low levels of risk assessment and risk management in biotechnology that characterize most institutions in the country call for capacity building in both personnel and infrastructure including information resources. In line with this, most institutions indicated their need for support in activities that would increase their capacity. The gaps, needs, priorities and the way forward for the various categories of institutions were identified in the four workshops held during the 1998-99 period under UNEP/GEF enabling activity.

This project therefore addresses therefore the recommendations for follow-up activities identified in the final report of the pilot project for the "Development of the National Biosafety Framework for Kenya" as per Annex 1.

Objectives

There is no doubt that biosafety is a subject that merits an adequate capacity for its implementation. This means, when viewed from a larger context, that capacity building is required as far as human resources are concerned, infrastructure and material resources such as information. In particular, biosafety deals with risk assessment and risk management, which can only be assessed and managed when there is competence in the relevant fields, and confidence in an ability to apply disciplinary knowledge to risk assessment and management. An adequately well-trained human resource will not only develop and use safe modern biotechnology products but will be able to monitor the release of living modified organisms as well as assess the related ecological impacts.

A step-by-step approach in building competence and developing techniques while interacting with the regulatory authorities such as the National and Institutional Biosafety Committees will be an important and worthwhile endeavour.

The main goal of the project is therefore to support the implementation of the objective of the Cartagena Protocol in the country by establishing a biosafety management system, strengthening capacity building and infrastructure for LMOs development, import/export, handling, transport and release in the country. The National Biosafety Framework will be established through the approval of the Biosafety Act, and the implementation of the national regulations and guidelines for safety in biotechnology as recommended by the fifth Conference of Parties to CBD and the Ministerial Round Table on capacity building in developing countries to facilitate the implementation of the Protocol held in Nairobi in May 2000. Kenya has already designated the focal point for the Intergovernmental Committee for the Cartagena Protocol (ICCP), but still needs to establish a biosafety clearing house mechanism which will facilitate the implementation of the Protocol. In this respect, efforts will be made to build a national infrastructure to meet the requirements for effective implementation of biosafety mechanisms.

The specific objectives of this project are therefore set as follows:

- (A) To support the establishment of the regulatory and administrative basis for the implementation of the management and monitoring system related to the safe environmental release, commercial production and transboundary movement of living modified organisms (LMOs) in Kenya, in compliance of the obligations of the Cartagena Protocol;
- (B) Strengthen capacity building on biosafety policy, management, administration and risk assessment/management (in order to provide guidance and design risk management options and strategies);
- (C) Strengthen national facilities for LMOs managing, handling and monitoring activities.
- (D) Strengthen the national information system to serve as well for the purposes of the BCH
- (E) Strengthen national capacity to enhance public awareness and promote information sharing on biosafety related issues

Current situation

Over the last thirty years, biosafety issues have steadily received recognition at national, regional and globally. The impetus for this recognition was generated by the discovery of recombinant DNA and the subsequent utilization of the DNA to produce Biotechnology products through genetic engineering as opposed to the conventional techniques. The fact that the new biological techniques are able to break the natural genetic barriers and hence facilitate horizontal gene transfer and also facilitate the development of living modified organisms, has raised concerns on the risks on the genetic resources, the human and animal health that could arise.

To address these issues, the Convention on Biological Diversity has given priority to biosafety and the Cartagena Protocol on Biosafety, focusing on only living modified organisms that may have adverse effect on the conservation and sustainable use of biological resources and humans has been agreed. At the same time eighteen countries have attempted to address biosafety issues through the support of the UNEP/GEF Pilot Enabling Activity. At the National level the National Biosafety Focal Point based at National Council for Science and Technology addressed biosafety issues and currently the National Biosafety Framework for Safety in Biotechnology was prepared. Draft regulations and guidelines were developed in order to facilitate development, application and safe use of biotechnological products.

In addressing the issues of biosafety and the ecological impact assessment, it is necessary to take cognizance of the fact that there are 35,000 known species of plants and animals and microorganisms in Kenya. We also take cognizance that in spite of the well intentioned

policies to make Kenya an industrial country, the current situation is that Kenya with its 36 million people largely depends on rain fed agriculture which is found in 20% of the land. Efforts to increase human and financial capacity in biotechnology and biosafety will enable the country to add value to the genetic resource through appropriate technologies. This calls for cooperation in all the activities including information sharing.

Kenya signed the Biosafety Protocol in May 2000, and is currently pursuing ratification of the Protocol, but like many other developing countries has limited capacity for the implementation of the Protocol itself. The needed capacity is generally understood as availability of well trained critical mass of persons, availability of information which is relevant to biosafety activities and properly equipped facilities for handling safety modern biotechnology products and processes.

According to UNEP Technical Guidelines on Safety in Biotechnology, biosafety capacity building has been defined as:

“The strengthening and/or development of human resources and institutional capacities. It involves the transfer of know-how, the development of appropriate facilities, training in sciences related to safety in biotechnology and in the use of risk assessment and risk management.”

In Kenya, there has been a significant amount of research work involving the use of biotechnology. This is notable in universities and at some research institutes such as Kenya Medical Research Institute and Kenya Agricultural Research Institute where medical biotechnology, animal biotechnology and agricultural biotechnology is undertaken.

In 1999, a pilot enabling activity was supported by UNEP/GEF for the development of a National Biosafety Framework for Kenya. Under that project, it was found that some institutions had put in place biosafety measures. However these measures were general and they only fitted within the category of Good Laboratory Practices. Besides, most the organizations surveyed explained that they had no institutional biosafety committees and hence they had no direction on what kind of risk assessment and risk management measures were in commensurate with their types of work. Hence, reinforcement of the safety measures was left to individuals. The gaps, needs, priorities and the way forward for the various categories of institutions were identified and reported in the National Biosafety Framework as reported under paragraph *“Stakeholders involvement and social assessment”*. In addition, a draft Biosafety Act was also draft.

This Act was drafted before the Cartagena Protocol was agreed. Kenya is therefore seeking support for matching those requirements and submitting the Act to the authorities in charge for entry into force.

The GEF Alternative: expected project outcomes, with underlying assumptions and context

In the light of the, The proposed GEF project has been designed to address the gaps and needs as described above. This intervention is in fact assuring that the biosafety framework worked out during the Pilot Project phase becomes fully operational through

the strengthening of the national capacities, playing therefore an important role in launching biosafety management in Kenya.

In this respect, the following outcomes are expected:

(A.1) Project team set up.

(A.2) Assessment on the implementation of the biosafety framework as established by the National Biosafety Committee carried out.

(A.3) 2 workshops held in order to review the draft Biosafety Bill,

(A.) Submitted and in force "Biosafety Act of Kenya"

(A.5) Through the already established National Biosafety Committee (NBC), the Regulations and Guidelines for biosafety in Kenya will be reviewed and published for comments

(A.6) One national workshop on handling request for LMOs release for 24 participants organized in Nairobi

(a.7.1) One workshop on Article 11 of the Cartagena Protocol relating to the importation or export of living modified organisms intended for food or feed held (2 days, 40 participants) held.

(A.7.2) Specific regulations and procedures for food safety as per article 11 of the Cartagena Protocol drafted.

(B.1) One week training for two Officers in Data Management for the purpose of the BCH

(B.2) 1 Seminars for training 30 participants, including NBC members, scientists and policy -makers/per course on risk assessment and management taking into account articles 15 and 16 of the Protocol.

(B.3) 4 training courses for trainers (technicians, decision- makers, custom officials, and institutional biosafety committees' members) carried out by area of competence.

(C.1) Office of the National Biosafety Committee to serve biosafety management activities and the BCH equipped.

(C.2) Kenya Agricultural Research Institute (KARI) and the Botany department, University of Nairobi, equipped with facilities for handling and monitoring of LMOs.

(D.1.1) Biosafety Database System to serve as Biosafety Clearing House Mechanism in Kenya set up

(D1.2) Biosafety Website for Kenya to be linked to the BCH active

(E.1) Teaching materials, brochures, manuals in order to strengthen capacity for public awareness purposes developed

(E.2) Best practices and lessons learnt disseminated.

ACTIVITIES

1. LEGISLATION AND COORDINATION

Through the project, the draft Biosafety Act for Kenya will be finalised. In this respect, two workshops will be held. A one day workshop will be addressed to the main stakeholders (around 50 participants) to collect their views and comments on the Bill. The recommendations will be further presented and discussed at the second one day workshop, where a panel of experts, selected by the National Biosafety Committee, will finalise the Bill before submission to Parliament.

The Act provides for the making of appropriate regulations and guidance for the safe use of living modified organisms in Kenya. Workshops will identify and assist in the review of the current regulations and guidance in order to ensure the safe use living modified organisms in Kenya.

During the development of the project, an assessment of the operation of the National Biosafety Committee as well as the Institutional Biosafety Committees will be carried out.

A specific workshop on mechanism for handling requests for LMOs releases into the environment will be held for 24 participants (government officials, research institutes and universities, companies, NGOs, etc.) . 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)

A specific part of this component will be devoted to article 11 of the Protocol on "Procedure for Living Modified Organisms intended for direct use as food or feed, or for processing" and to the drafting of the related detailed regulations and procedures. A two days workshop will be held to address this issue. This need for specific food and feed regulations was, in fact, identified in the NBF recommendations under the UNEP/GEF pilot project.

A project coordination team will be established. The focal point, as part of the coordination team, will convene meetings and co-ordinate activities to undertake this work.

TRAINING COMPONENT

To strengthen capacity in biosafety, a set of training and seminars will be held by area of competence as follows:

Training courses

- 4 days training for 15 decision makers and government officials on biosafety legislation and procedures
- 4 days training for 15 custom officials on transboundary movements requirements,
- 4 days training for 15 technicians on safety measures in laboratories and LMOs inspection procedures,

- 4 days training for 15 institutional biosafety committees' members on the implementation of biosafety measures as per the guidelines and risk monitoring.

Seminars

1 seminars (2 days) for training 20 participants/per course, including NBC members, policy-makers and scientists will be held on risk assessment and management;

Finally, under this project, two Officers will be trained for one week in Data Management for the purpose of the Biosafety Clearing

EQUIPMENT COMPONENT

NBC Office equipment for the BCH related activities

The office of the National Biosafety Committee needs support in upgrading its current equipment to fulfil its project tasks in terms of activities in relation to the Biosafety Clearing House requirements. In particular, computer and related accessories, as well as software and Internet connection are of particular urgency.

Laboratory equipment

The laboratory at KARI and Botany department, at the University of Nairobi, are now building capacity in handling biosafety issues. Currently KARI is conducting research on GM in agricultural crops, identification and use of molecular markers, genetic transformation, while the Botany department at the University of Nairobi conducts genetic analysis and risk assessment of transgenic products. These laboratories need to be upgraded with:

- 1) equipment for inspections purposes in the context of the risk assessment and management procedure;
- 2) equipment for protection against accidental release of organisms to the environment and for ensuring the safe use, import and export of living modified organisms that may have a negative impact on the environment or on human health (see Annex 4).

The laboratories will be further involved with LMOs intended for food and feed, including the issue related to the labelling.

Due to the above, the University of Nairobi will be therefore also strengthened as training centre on LMO detection

INFORMATION SYSTEM

A National Biosafety database will be set up and linked to the Biosafety Clearing House Mechanism. In particular, the following information as per the Cartagena Protocol Requirements, will be collected:

- Any relevant existing laws, regulations or guidelines, including those applicable for the approval of LMOs-FFPs
- Any 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;

The Internet website so established will be also linked to the BCH and will facilitate the access to other regional and international databases such as those from CBD, IRRO, ICGEB, BIOTRACK etc. The web site (except confidential information) will also be open to the general public.

The National Biosafety Focal Point (NBFP) will work through the National Biosafety Committee already in place in order to establish infrastructure for information exchange within the country. The NBFP will gather, collect and disseminate information related to risk assessment and risk management. The focal point will also in charge of co-ordinating the establishment of the national biosafety website and the communication network to be available to all users.

PUBLIC AWARENESS

The project will develop a set of teaching materials, brochures and manuals to be published and distributed to the main users and be used for capacity building purposes.

This information material will be shaped according to the needs that will be expressed during the public debate that will be carried out as national own activity before the approval of the Biosafety Act.

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

Sustainability analysis and risk assessment

The project is shaped on already on-going national activities in the biosafety field, and is basically strengthening the needed capacity to fulfill the requirements of the Cartagena Protocol. In fact, the NBF was established before the Cartagena Protocol was agreed. The Biosafety Act for Kenya will therefore be finalised according to those requirements. The Act will be legally binding and its entering into force will guarantee the continuity of the biosafety initiatives. Institutional arrangements already in place (National Biosafety Committee and the Institutional Biosafety Committees) will be further improved to suit all the needs of functional biosafety management system.

The main risk associated to the project is mainly related to the lack of capacity in implementing the biosafety legislative framework. Decision-makers, technicians, custom-officials may not gain the skills needed for proper and safe application of the regulation. Therefore, this project is proposing training courses and workshops in order to reach the broadest audience.

The public plays an important role in application or adoption of technologies involving LMOs, therefore attention is given to their participation through the national debates. Information materials will also be prepared for distribution.

Stakeholder involvement and social assessment

The project is based on the recommendations of the pilot phase. As part of that project, the needs of the main stakeholders were identified through surveys and are now addressed within the frame of this current activity. The gaps, needs and priorities are:

Universities and Research Organizations

- Gaps:** Lack of proper linkages among the institutions.
Needs: Personnel training in safety and bio-policy issues. This should also include risk assessment and risk management
Priorities: A course in biotechnology and biosafety be introduced in the syllabus.
To hold a series of workshops biotechnology and biosafety in order to create awareness on biotechnology and biosafety. This also to serve as a way of capacity building.
Way Forward: To encourage international organizations to interact with the local institutions.

NGOs and Private Companies

- Gaps:** Lack of awareness on the part of the companies on the products that they deal with.
Needs: To build capacity in risk assessment and management that will also eradicate ignorance amongst users of the products.
Priorities: To carry out short term training on personnel on biosafety matters.
Way Forward: To encourage training on risk assessment and management
The public should be sensitized on biotechnology and biosafety through media, press conference and stakeholder workshops
Information to companies to be targeted through their representatives e.g. Agrochemical Association of Kenya.
NCST to act as a one stop center for information in biotechnology and biosafety.

Hospitals

- Gaps:** There is general lack of awareness to Biotechnology and Biosafety issues
Needs: To build capacity and improve training and awareness programs.
Priorities: To encourage capacity building
To ensure the availability of storage and disposal facilities with a trained biosafety officer to oversee the activities .

Government Ministries

- Gaps:** There is lack of sensitization and harmonization of all regulatory, advisory and legal instruments
- Needs:** There should be capacity building and co-ordination in biosafety issues in order to enhance technology transfer.
- Priorities:** To encourage capacity building, training and exchange of experts and information.
- Way Forward:** To enhance public awareness on Biotechnology and Biosafety issues across the board.
NCST to be aggressive and play a major role on public awareness campaigns both to the public and target institutions. NCST be responsible for the acquisition of information and repackage it for dissemination.

INCREMENTAL COST ASSESSMENT

Kenya was signed the first country to sign the Cartagena Protocol on Biosafety on the 24th of May 2000 and is preparing for its ratification. In 1999, under the UNEP/GEF Biosafety Enabling Activity, a National Biosafety Framework was established and a Biosafety Act drafted. However, being the draft prepared before the Cartagena protocol was adopted, Kenya is seeking for support to match those requirements and submit the Draft Law to the authorities in charge for its approval and entry into force.

Already since 1987, the Government of Kenya through the then Ministry of Research Science and Technology set up a committee under the National Council for Science and Technology (NCST), to determine the priorities for research in biotechnology. The committee known as the National Advisory Committee on Biotechnology Advances and their Applications made the first reference to the need for a policy on biosafety. The committee, consisting of the directors of Research Institutes, produced a report known as the National Advisory Committee on Biotechnology Advances and their Application (NACBAA) and this recommended that the NCST develops a policy on biohazards and ethics in biotechnology.

In 1994, the Kenya National Environment and Action Plan which was approved by Cabinet, made the following recommendations pertaining to biosafety:

- Establish a National Commission on biotechnology and biosafety.
- Formulate a scientific criteria for the safe use genetically modified organisms including methods of hazard identification and exposure assessment before GMOs are released into the environment and also design measures for biological and Physical containment of GMOs and mechanisms to monitor the organisms, genetic material and processes exposed to GMOs.
- Make Prior Informed Consent a Pre-requisite for all field-testing.
- Formulate a biosafety policy and regulations.

In 1997, The Kenya Agricultural Research Institute produced Institutional Biosafety Guidelines and formed the Institutional Biosafety Committee while in 1998, the National Council for Science and Technology produced the regulations and guidelines for safety in biotechnology which provided a base for the establishment of the National Biosafety Committee (NBC) and Institutional Biosafety Committees as well as identifying the competent authority as the National Council for Science and Technology.

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
<i>Legislation and coordination</i>	The draft Biosafety Act is currently under revision by the technical committees. Some implementing regulations and guidelines have been developed, but need to be reviewed.	Biosafety Act finalized, submitted and in force, regulations and guidelines reviewed and published, institutional capacity further strengthened through workshops	The implementation of the Cartagena Protocol is supported by the consolidation of the National Biosafety framework and its implementing regulations
<i>Training</i>	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 meet the requirements coming from the Cartagena Protocol
<i>Strengthening national facilities for risk assessment and management</i>	The laboratories at KARI and Kenya Agricultural Research Institute (KARI) and the Botany department, University of Nairobi are now building capacity in handling biosafety issues. They carry out basic research but lack equipment for carrying out inspections as required in the context of the risk assessment and management procedure and facilities insuring protection against accidental release.	The laboratories at KARI and Kenya Agricultural Research Institute (KARI) and the Botany department, University of Nairobi, strengthened with: 1) Equipment for inspections purposes in the context of the risk assessment and management procedure; 2) equipment for protection against accidental release of organisms to the environment and for ensuring the safe use, import and export of living modified organisms that may have a negative impact on the environment or on human health. Due to the above, the University of Nairobi will be consequent strengthened as training centre on LMO detection.	Risk assessment and management as well as protection against accidental release improved through the strengthening of national facility and therefore ability to screen LMOs
<i>Strengthening the information system to serve for the purposes of the BCH</i>	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 trials, permits for the release of GMO to environment/market, product containing GMO, transboundary movement of	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

		LMO (import and export), GMO risk assessment, monitoring and control	
<i>Capacity building for public awareness</i>	Current capacity for public awareness purposes is still poor	Capacity for public awareness strengthened through development of educational programmes, published teaching materials, dissemination of best practices and lessons learnt	National capacity for public awareness capacity enhanced

An estimate of the baseline activities amounts to **107,531USD**. The proposed GEF alternative complements these national activities and, as shown in the table below, the cost of the increment is of **619,537USD**, of which **510,879USD** is being requested from the GEF; the remaining **108,658USD** is provided as in-kind contribution by Kenya.

Table 1 - Incremental Cost Table (US\$)

Activity	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing (in-kind contributions)
<i>Legislation and coordination</i>	44,545	162,561	118,016	92,872	25,144
<i>Training</i>	15,584	140,858	125,274	110,253	15,021
<i>Strengthening national facilities</i>	----	217,457	217,457	164,570	52,887
<i>Strengthening the information system</i>	12,987	86,540	73,553	60,921	12,632
<i>Public awareness and dissemination</i>	34,415	119,652	85,237	82,263	2,974
Total	107,531	727,068	619,537	510,879	108,658

PROJECT BUDGET

	SUPPORT TO THE IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORK	GEF	In Kind Kenya	Total
A	LEGISLATION, COORDINATION			
A1	Project coordination team	4,223	855	5,078
A2	Assessment on the implementation of the biosafety framework	6,067	2,563	8,630
A3	2 Workshops to review of the draft biosafety law: ➤ 1st workshop, 1 day, 50 participants, ➤ 2 nd workshop, 1 day, 20 experts,	11,118	3,947	15,065
A4	Submission of the bill to parliament for enactment (finalization, publication, distribution)	3,333	666	3,999
A5	Revision of the biosafety regulations and guidelines to comply with the Cartagena protocol.	5,526	6,105	11,631
A6	Organize one national workshop for handling requests for LMOs release into the environment (24 participants, out timings)	11,040	520	11,560
A7.1	Organize one workshop on Article 11 of the Cartagena Protocol 30 participants (2 days) (16 residents)	10,276	1,579	11,855
A7.2	Develop specific regulations and procedures for food safety	15,500	6,804	17,304
	Subtotal	67,083	23,039	90,122
B	TRAINING			
B1	Train two officers for one week in Data Management for NBC and CHM	10,053	2,842	12,895
B2	One seminar (1 day) for 30-40 participants on risk assessment and management	13,200	4,579	17,779
B3	4 Training courses (4 days) for 15 decision policy makers, Government officials, custom officers, and scientists, and National Biosafety Committee members	67,000	7,600	74,600
	Subtotal	90,253	15,021	105,274
C	EQUIPMENT			
C1	N.B. Office equipped (for BCH)	50,609	25,256	75,865
C.2	Office Equipment (see list)	24,013	4,605	28,618
C.3	Laboratory equipment for KARI & Botany dept. U.O.N (See list)	89,948	23,026	112,974
	Subtotal	164,570	52,887	217,457
D	COMMUNICATION			
D1	Establishing Database, BCHM linkages, network	46,579	6,316	52,895
D2	Set up website by consultancy	14,342	6,316	20,658
	Subtotal	60,921	12,632	73,553
	PUBLIC AWARENESS			
E.1	Develop and publication of teaching materials, brochures, manuals	32,263	2,974	35,237
E.2	Dissemination of best practices and lessons learnt	50,000	-	50,000
	Subtotal	82,263	2,974	85,237
F	International and local experts	40,000	-	40,000
G	Project coordination, monitoring and evaluation	5,789	2,105	7,894
	TOTAL	510,879	108,658	619,537

MONITORING AND EVALUATION PLAN

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 as collaborating agency, will 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** "National Needs and Critical gaps",
from the final report on "Kenya Biosafety Framework" under the
UNEP/GEF Pilot Project
- ANNEX 2** Summary of the National Biosafety Framework
- ANNEX 3** Matrix showing the relation between the project activities, the
Cartagena Protocol and the National Biosafety Framework
- ANNEX 4** Provisional list of equipment needed in the Biosafety office for
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- ANNEX 5** UNEP Response to the STAP Technical Review

ANNEX 1

"National Needs and Critical gaps", from the final report on "Kenya Biosafety Framework" under the UNEP/GEF Pilot Project

- Capacity building in personnel and infrastructure is important in both public and private sectors so as to cater for the risk assessment and management.
- It is imperative that the country increases her biosafety measures especially in connection with establishment of containment facilities and also in data acquisition.
- It is important to create public awareness on issues of Biotechnology and Biosafety.
- NCST should develop a catalogue of various Research and Development activities going on in the country.
- Currently there exists only one Institutional Biosafety Committees. This is the Kenya Agricultural Research Institute Committee which ensures that GMOs released for trials are properly contained and the release of the same is as recommended by the National biosafety committee. Most of the research institutions in Kenya and universities do not have biosafety institutions. However, there are efforts to establish such committees in the near future.
- NCST should take the initiative of publicizing the trends and implications of Biosafety through diverse fora like press conferences, pamphlets, media, National agricultural shows, science congresses etc.

ANNEX 2

Summary of the National Biosafety Framework

1.0 Biotechnology and Biosafety

In Kenya, the application of biotechnology in research and development is taking place in various public, international and private organisations. Among these are organisations such as Kenya Agricultural Research Institute (KARI), Kenya Medical Research Institute (KEMRI), International Centre for Insect Physiology and Ecology (ICIPE), International Livestock Research Institute (ILRI), and various Universities. Some private companies involved in horticulture and flower industry are also practising biotechnology.

Some of the work in biotechnology involves the use of tissue culture for micropropagation for rapid multiplication and disease elimination, development of molecular markers in tea, genome mapping and development of transgenic sweet potato. Other efforts relate to production of vaccines for the control of livestock diseases such as rinderpest, contagious Bovine Pleuropneumonia and food and mouth diseases. In human health, production of monoclonal antibodies and diagnostic kits has been carried out. Studies on vaccine development for malaria and leishmaniasis are in progress. As far as research with genetically modified organisms is concerned there is already a capripox virus rinderpest recombinant vaccine and a transgenic sweetpotato which are ready for field evaluations. Furthermore research is being undertaken on *Anopheles gambiae* mosquito, recombinant vaccine against ticks and Bt resistant maize plant.

2.0 Development of Kenya Regulations and Guidelines

The development of regulations and guidelines for safety in biotechnology in Kenya was triggered during the First African Regional Conference for International Cooperation on Safety in Biotechnology which was held in Harare in 1993. A year before that, the Convention on Biology Diversity had highlighted the issue of biotechnology development, its safety implications and the need for countries to develop mechanisms of handling biotechnology safely. It is along this line that a committee of the National Council for Science and Technology (NCST) known as the Biological Sciences Specialist Committee embarked on activities which would eventually lead to the preparation of the current guidelines and regulations for safety in biotechnology for Kenya. Milestones on the development of the guidelines are:

- The NCST with support of the Kenya Agricultural Biotechnology Platform received assistance from the Special Programme Biotechnology Development and Cooperation of the Netherlands Government to convene a multidisciplinary task force which comprised of experts in areas such as crop production, livestock development, human health, biochemistry, law and policy development. This task force was mandated to produce the final version of the regulations and guidelines.
 - The final version of the regulation and guidelines from the task force was presented to a workshop held between 10th and 11th September, 1996 where submissions were made in support of the regulations.
 - The NCST constituted a National Biosafety Committee (NBC) which would embark on the implementation of the regulations and guidelines. The NBC comprises of representatives from:

- Government Ministries viz: Agriculture, Health, Office of President, Environment and Natural Resources, Research and Technology.
- Government Departments such as Kenya Industrial Property Office and Department of Resource Survey and Remote Sensing.
- Public Universities
- Research Institutions namely, Kenya Agricultural Research Institute (KARI), Kenya Medical Research Institute (KEMRI), and International Livestock Research Institute (ILRI).
- Stakeholders such as the Kenya National Farmers Union and the Kenya Agricultural Biotechnology Platform.
- The National Council for Science and Technology

The NBC is chaired by a representative of the Ministry of Agriculture while the Secretary of the committee is a representative of the NCST who is also a member of the Regional Biosafety Focal Point.

3.1 Scope

The guidelines and regulations cover areas of research and development involving GMOs, genetic transformation of plants, the use of all aspects of recombinant DNA technology, the release of microbes, plants, animals or biological products derived by genetic modification.

3.2 Objectives

There are three main objectives of the guidelines and regulations. These are:

- (a) to promote opportunities for the application and exploitation of products of biotechnology for the general well being of humanity.
- (b) to ensure public and environmental safety particularly in accident prevention, containment and waste disposal when GMOs are used in research development or industrial processes;
- (c) to determine the measures for risk assessment, management and monitoring of operations involving GMOs, recombinant DNA technology and products arising from the use of these.

3.3 Contents of the regulations and guidelines

(a) Background to Biotechnology Developments

This section gives a highlight of some of the important developments which have taken place in agriculture, animal biotechnology, plant biotechnology, food and feed industry; environment, health including human and animal health. These developments are given from the global point of view.

(b) **Institutional Framework**

The need to establish an institutional framework which would oversee the coordination and implementation of the regulations and guidelines was considered as a crucial factor for meaningful progress to be made.

As such it was recommended that one authority be designated to play the coordinating role and the body which was identified was the National Council for Science and Technology. Under this body a National Committee known as National Biosafety Committee had to be established with the following mandates:

(i) **National Biosafety Committee (NBC)**

Terms of reference of NBC

- To review and ascertain the suitability of both physical and biological containment and control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.
- To review relevant proposals, except those that relate to research under contained laboratory conditions, and recommend any conditions under which the proposed work should be carried out.
- To ensure that adequate testing of genetically transformed materials developed elsewhere has been performed in the country of origin before it is introduced in a local trial programme.
- To establish contact and maintain liaison with other countries and organizations dealing with biosafety issues.
- To consult with relevant government institutions and non-governmental institutions as may be necessary.
- To establish a database for the purpose of facilitating collection and dissemination of information relevant to biosafety.
- To identify national requirements for manpower development and capacity building in biosafety.
- To maintain a directory of experts in biotechnology and biosafety, as well as a directory of project supervisors approved by institutional biosafety committees.
- To keep a record of biotechnology and biosafety activities in the country.
- To advise the Institutional Biosafety Committee (IBCs), relevant institutions and persons, on mitigation measures to be undertaken in case of an accident.
- To initiate diplomatic actions as may be necessary for appropriate compensation to Kenyan inhabitants or organizations who may suffer damage as a consequence of the exposure to imported biotechnology products.

- To review and amend these regulations and guidelines from time to time as necessary.

The National Biosafety Committee has already started its work and has developed procedures for assessing application for introduction of GMOs. Already the committee has assessed one application for introduction of transgenic sweet potato which is resistant to yellow mottle virus.

Likewise it was recommended that institutional biosafety committees be established.

(ii) Institutional Biosafety Committee (IBC)

Terms of reference of IBC

- To assist the respective institutions in drawing up proposals that take cognisance of the applicable biosafety measures.
- To advise their respective institutions on cases where biotechnological activities should be reported to NBC.
- To assist their institutions in establishment of appropriate monitoring mechanisms for risk assessments and risk management.
- To collaborate with NBC through their respective institutions, in ensuring the implementation of the safety measures stipulated in the guidelines.
- To advise their respective institutions regarding safety measures to be taken in relation to the working environment.

4.0 Safety measures

4.1 Risk Assessment

The risk assessment and risk management in the context of safety in biotechnology is a new approach aimed at facilitating safe use and application of the modern biotechnology tools. This is because there are concerns that genetically modified organisms or products with novel traits may pose a danger to the environment, plants, animals and humans. Although GMOs have been released, especially those which are used in agricultural productions, there is little information regarding the ecological effects that are likely to occur when such organisms are released in centres of biological diversity where wild relatives of the GMOs exist.

The purpose of risk assessment is to produce a basis for decision making either on:

- i) transboundary movement of living modified organisms for all purposes
- ii) safe transfer and management of living modified organisms
- iii) ensuring minimal level of harmonisation in decision making.

At the level of the NBC a technical sub-committee of risk assessment experts assesses applications for the introduction of transgenics

4.2 Risk Management

Risk Management is the process of weighing alternatives to select the most appropriate regulatory strategy or action. Once risk assessment has been undertaken there is a need to establish whether the risk is high, moderate, minimal or negligible.

The NBC uses the experts' reports to implement risk management and issues conditions for compliance to the scientists wishing to work with transgenics.

5.0 Use of Natural Organisms and GMOs

The development and use of GMOs and natural organisms is based on the exemption categories. In the Kenya Biosafety regulations, four types of categories are identified. These are exemption category, and three non-exemption categories. Non-exemption category (A) includes work which may cause a hazard to the researchers, community and the environment. Non-exemption category (B) includes work which carries low level of risk. The non exemption category (C) includes work which could be given special exemption. All the four categories and their containment measures are indicated in the regulations and guidelines.

6.0 Importation of Biotechnology Products

The guidelines and regulations have provided details on this subject and have specified that the standard procedures governing, packaging and transport/shipping should be complied with.

All institutions wishing to import any products of Biotechnology seek approval and permission from the NBC

- Once applications are received they are sent within 2 weeks to the experts for review and risk assessment
- On receiving the reports of the technical subcommittee the secretary NBC convenes a meeting of the NBC to discuss the application.
- Constant supervision of the field and laboratory where work involving GMO is being undertaken is carried out by the Kenya Plant Health Inspectorate service

7.0 Notification

In case of accident the matter should be handled through established procedures such as reporting to IBC, NBC and disaster management organisations. Control measures must be instituted immediately.

8.0 Compliance with the Guidelines and Regulations

The need to comply with the regulations and guidelines and a list of sanctions to ensure compliance with safety measures in biotechnology are covered by the regulations. The penalties for offences under the regulations and guidelines have not yet been made into law but a draft law has been prepared and is awaiting public inputs and legislation. Currently the guidelines state that these penalties would be specified in orders made by the Minister by virtue of powers conferred by an Act of Parliament. Recently, November 2000 the Environmental Management and Co-ordination Act was enacted. This act recognises the need for biosafety regulations to be covered under the law.

9.0 Follow Up Activities

In order to implement the regulations effectively, a project under GEF-UNEP enabling activities was proposed in 1999. The aim of this project was to build a national capacity to meet the requirements

for effective implementation of the biosafety mechanisms. Further, the project is expected to create awareness by sensitising the public on issues related to safety in biotechnology.

ANNEX 3

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

ACTIVITY	LINKAGE TO THE NATIONAL BIOSAFETY FRAMEWORK	LINKAGE TO CARTAGENA PROTOCOL
<ul style="list-style-type: none"> 2 Workshop to review the drafted Biosafety Bill for parliament approval 	Appendix 4 of the KBF proposed Kenya Legal framework for safety in Biotechnology	Article 2 and 3 of the protocol Article 11 (2) Article 11 (5)
Submission and in force Biosafety Act of Kenya	Gaps noted in the laws and regulations on biosafety and amended.	“
<ul style="list-style-type: none"> Review and finalize through the already established National Biosafety Committee (NBC) the Regulations and Guidelines for biosafety in Kenya. 	Regulations and guidelines a publication by NCST.	Article 10 (3C) Article 11 (5)
<ul style="list-style-type: none"> One workshop and handling request for LMOs 	Part of the Regulation and guidelines for Biosafety regulations and guidelines.	Article 6 (1and 2) Article 18
<ul style="list-style-type: none"> Conduct an assessment on the implementation of the biosafety regulations 	Roles and functions of NBC as given in the KBF.	Article 2 (5) Article 33
<ul style="list-style-type: none"> 2-day workshop on Article of the Cartagena protocol. 	Function of NBC to amend the KBF regulations and guidelines as necessary	Article “
<ul style="list-style-type: none"> Draft specific regulation and procedures for safety as re-article 11 of the Cartagena protocol 	“	Article “
<ul style="list-style-type: none"> Establish a project co coordinating team 	KBF Recommendations to have an institutional framework for Co ordination and implementation of regulations 2 guidelines.	Article22
<ul style="list-style-type: none"> 4 train courses held for decision makes, customs officials technicians, IBC 	Identified in the national needs and critical gaps	Article22
<ul style="list-style-type: none"> 3 Workshop for training 20 policy makes and scientist 	“	Article 22
<ul style="list-style-type: none"> Train two officers in Data management for the purpose 	“	Article 22

of the Biosafety clearing House.		
• Equip the office of NBC	KBF Recommends that NBC act as a one stop center for information in biosafety	Article 22
• Equip KARI, UoN (Botany depart) with facilities at Biosafety	KBF Recommends for the establishment of appropriate facilities to limit hazards.	Article 22
To set up a biosafety data base supreme to serve as a clearing house mechanism	See C1	Article 22
Set up a biosafety website for Kenya to link to BCH.	See C1	Article 22
Develop teaching materials, brochures manuals in order to strengthen capacity for public awareness	Clause 5. Of Legal framework The NCST on competence auctions make available the said information to public, research institutes, the private sector and government departments	Article 23

ANNEX 4

Provisional list of equipment needed in the Biosafety office for biosafety management activities (i.e. BCH) and laboratory equipment

- **Equipment needed in the Biosafety office for biosafety management activities (i.e. BCH).**

Computer and accessories
Software (Power point, etc.)
Scanner
Fax
Internet connectivity
Photocopier

- **List of laboratory equipment**

Botany department, University of Nairobi

Greenhouse
5 binocular microscopes
3 dissecting microscopes
5 calibrated ocular lenses
3 Refrigerators
2 Analytical weighing balances
3 top loading balances
Forced air ovens
1 incinerator
Autoclave
Centrifuge
Safety cabinets
Gelcam camera system for
Gel photography and 667 polaroid films
UV transilluminator – 20 x 35 cm

Laboratory at KARI

Safety cabinets
Gelcam camera system for
Gel photography and 667 polaroid films
UV transilluminator – 20 x 35 cm

ANNEX 5

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 Secretariat, 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.

<u>Issue</u>	<u>Response</u>
Kenya <ul style="list-style-type: none">• <i>Capacity building should also be addressed to inspectors, for example by organising training workshop and developing inspection manuals.</i>	<ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• <i>One important element that is missing, is the</i>	1) The EU covers the regulatory component and

<p><i>development of implementing regulations.</i></p> <ul style="list-style-type: none"> <i>The proposed training activities are very fragmented and it is recommended to merge some of the training activities.</i> <i>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.</i> 	<p>therefore Poland didn't ask for any further financing from GEF.</p> <p>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.</p>
<p>Uganda</p> <ul style="list-style-type: none"> <i>It is recommended to include training activities on topics such as "other international obligations".</i> 	<ul style="list-style-type: none"> Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.