

## MSP PROJECT BRIEF

<b>PROJECT IDENTIFIERS</b>	
<b>1. PROJECT NAME:</b> Support to the implementation of the National Biosafety Framework of Namibia	<b>2. GEF IMPLEMENTING AGENCY:</b> UNEP
<b>3. Country/ies in which the project is being implemented:</b> Namibia	<b>4. Country eligibility:</b> Namibia signed the Cartagena Protocol on the 24 May 2000
<b>5. GEF FOCAL AREA:</b> Biodiversity/biosafety	<b>6. OPERATIONAL PROGRAMME/SHORT-TERM MEASURE:</b> The project relates to biosafety issues and cross-cuts the Biodiversity Operational Programmes 1,2,3,4.and is in accordance with the Initial Strategy for the Entry into Force of the Cartagena Protocol, approved by the Council in November 2000.
<b>7. PROJECT LINKAGE TO NATIONAL PRIORITIES, ACTION PLANS AND PROGRAMMES:</b> <ul style="list-style-type: none"> <li>• The safe use of biotechnology is considered one of the key issues in Namibia's ten-year strategic plan of action for sustainable development through biodiversity conservation 2000-2010;</li> <li>• This national policy for the safe use of biotechnology was completed and approved by the Cabinet in November 1999 and has two objectives:               <ul style="list-style-type: none"> <li>a) to guide the judicious use of modern biotechnology in Namibia for sustainable development, in ways which do not in any way jeopardise human or environmental health, including Namibia's biodiversity and genetic resources;</li> <li>b) to ensure effective control of transboundary movements of living modified organisms or products thereof resulting from modern biotechnology, through the exchange of information and a scientifically-based, transparent system of advance informed agreement;</li> </ul> </li> <li>• A draft Biosafety Act on "the import, export, release into the environment, placing on the market, placing in transit and the contained use, of living modified organisms (LMOs and combinations of LMOs)" is going through the Parliament for approval.</li> <li>• Namibia is part of the South African Development Community (SADC), Southern African Economic Community and the Southern African Customs Union (SACU) that is attempting to remove barriers to trade amongst its members in line with the SADC-Protocol on trade and the recommendation of the SACU-Trade Commission. There is a need to set up a legal system for controlling the use, handling and transfer of Living Modified Organisms (LMOs).</li> <li>• The harsh environment experienced by most of Namibia has made the protection of the environment and sustainable use of land much clearer to those who live and work in the country than in many more developed countries.</li> <li>• The sustainable use of the environment in a protective manner becomes more and more recognised internationally and improves the reputation of Namibia</li> </ul>	
<b>8. GEF NATIONAL OPERATIONAL FOCAL POINT AND DATE OF COUNTRY ENDORSEMENT:</b>  The project was endorsed by the GEF Operational Focal Point of Namibia, Mr. Teofilus Nghitila Acting head of Environmental Affairs, Ministry of Environment and Toursim, Private Bag 13306, Windhoek, Tel. +264 61 249 015, Fax. +264 61 240 339, <a href="mailto:pb@dea.met.gov.na">pb@dea.met.gov.na</a> , on the 25 July 2001	
<b>Project Objectives and Activities</b>	
<b>9. Project rationale and objectives:</b>  <b>GOAL: To support the implementation of the</b>	<b>Indicators:</b>

<p><b>objective of the national policy on the safe use of biotechnology and the objective of the Cartagena Protocol on Biosafety in the signatory countries</b></p> <p><b>OBJECTIVE:</b> Implementation of the National Biosafety Framework for Namibia. Specific objectives are:</p> <p>(A) To support the establishment of the legal and administrative basis to 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 Namibia and the SADC region and to meet the obligations foreseen under the Cartagena Protocol</p> <p>(B) To improve the ability to screen LMOs in order to monitor and manage the risks associated to their handling, transport, use, transfer and release;</p> <p>(C) Strengthen capacity building of main stakeholders through training courses and workshops;</p> <p>(D) Strengthen information sharing of relevant stakeholders;</p> <p>(E) Enhance public awareness on biosafety-related issues;</p>	<p>➤ <i>Namibian Authorities approve the "Biosafety Act" and implement the related biosafety management system.</i></p> <ul style="list-style-type: none"> <li>• Namibian Authorities allocate funds for personnel at the implementing institution, hosting of the biosafety advisor, contribute towards the operational costs</li> <li>• Namibia authorities strengthen the cooperation and information exchange with similar authorities in the SADC region</li> <li>• Laboratory facilities equipped for risk assessment</li> <li>• Regional based acknowledged management data bank has been developed and is in use</li> <li>• Main stakeholders trained</li> <li>• Biosafety data information system and local BCHM established and in-use.</li> <li>• Public discussions and inputs concerning the sustainable use and implementation of LMOs take place</li> </ul>
<p><b>10. Project outcomes:</b></p> <p>(A.1) Project coordination and management set up (A.2) Submission for approval of the following regulations to implement the biosafety management mechanism in Namibia:</p> <ul style="list-style-type: none"> <li>- Safety levels and safety measures for contained use</li> <li>- Field testing of living modified organisms</li> <li>- Marketing of living modified organisms</li> <li>- Administrative procedures</li> <li>- Application forms (including guidance)</li> </ul> <p>(A.3) Three days workshop for 50 stakeholders concerning "National biosafety legislation and the Cartagena Protocol" organised.</p> <p>(B) Expanded and strengthened laboratory facilities for risk assessment and management</p> <p>(C.1) Training activities organised as follows :</p> <ul style="list-style-type: none"> <li>• One training for the registrar, support units and</li> </ul>	<p><b>Indicators:</b></p> <ul style="list-style-type: none"> <li>• Regulations approved;</li> <li>• Well equipped accredited laboratories in the country and the region are in place</li> <li>• Quality survey on the training courses available</li> <li>• 25 participants plus custom officials to attend the training</li> </ul>

<p>NBI members (National Biosafety Inspectorate), on biosafety management procedures and the need to handle applications (9 participants, 4 days);</p> <ul style="list-style-type: none"> <li>• Three training courses for, 16 from NABA/NBAC including the registrar on risk assessment procedures and 20 from personnel in sectoral regulatory and administrative positions, on risk assessment by applicants, the Advance Informed Agreement procedures and issuing of import permits (36 participants, 4 days);</li> <li>• Two training courses for NBEC members on decision making related to biosafety issues (6 participants, 4 days);</li> <li>• Two courses for 70, of which 50 personnel at ports of entry (5 for each point of entry) on identification of products and certification, 10 Officials at Customs and Excise, 10 Namibian Police in conjunction with the NBI (70 participants, 4 days);</li> <li>• One training for technicians to enable them to carry out laboratory activities in relation to biosafety and the implementation of the Protocol at the University (10 technicians, 4 days)</li> <li>• Two training courses for Information Management Officers on the BCHM (4 Officers, 4 days).</li> </ul> <p>(C.2) Two training workshops held on biosafety issues for farmers and consumer groups representatives (25 participants, 2 days)</p> <p>(C.3) Exchange programmes for technicians, including training, in view of their professional/academic advancement;</p> <p>(D) Set up a Biosafety Database System to serve for the Biosafety Clearing House Mechanism in Namibia to organize, integrate and develop existing information. Website opened.</p> <p>(E) Public awareness material prepared and disseminated.</p>	<ul style="list-style-type: none"> <li>• Database and Web site established and continuously upgraded</li> <li>• Free access to the information on web-site and communiqué from Registrar to main stakeholders</li> <li>• Public awareness material disseminated</li> </ul>
<p><b>11. Planned activities to achieve outcomes (cost in US\$ of each activity):</b></p> <p>(a.1) Set up the project office and select the project coordinator, project coordination and management</p> <p>(a.2) Finalisation of the following regulations to activate the operational mechanisms for biosafety management in Namibia</p> <ul style="list-style-type: none"> <li>- Safety levels and safety measures for contained</li> </ul>	<p><b>Indicators:</b></p> <ul style="list-style-type: none"> <li>• Identification and selection of the Project coordinator, office set up;</li> <li>• Regulations ready for approval;</li> </ul>

<p>use</p> <ul style="list-style-type: none"> <li>- Field testing of living modified organisms</li> <li>- Marketing of living modified organisms</li> <li>- Administrative procedures</li> <li>- Application forms</li> </ul> <p>(a.3) Three days workshop for 50 stakeholders concerning legislation and policies: “National biosafety legislation and the Cartagena Protocol”</p> <p><b>TOTAL: 331,000; GEF: 170,000</b></p>	
<p>(b.1) Purchase of laboratory facilities, kits, reagents and consumables for risk assessment and management as needed for upgrading the University of Namibia laboratory and the Central Veterinary Laboratory;</p> <p>(b.2) Purchase of the basic equipment for taking and collecting samples needed for personnel working at the country’s port of entry to identify Living Modified Organisms (LMOs) and for in-country inspectors controlling their use</p> <p><b>TOTAL:180,000; GEF: 170,000</b></p>	<ul style="list-style-type: none"> <li>• Equipment for laboratory and sample taking purchased</li> </ul>
<p>(c.1) Organise training activities as follows :</p> <ul style="list-style-type: none"> <li>• One training for the registrar, support units and NBI members (National Biosafety Inspectorate), on biosafety management procedures and the need to handle applications (9 participants,4 days);</li> <li>• Three training courses for, 16 from NABA/NBAC including the registrar on risk assessment procedures and 20 from personnel in sectoral regulatory and administrative positions, on risk assessment by applicants, the Advance Informed Agreement procedures and issuing of import permits (36 participants,4 days);</li> <li>• Two training courses for NBEC members on decision making related to biosafety issues (6 participants, 4 days);</li> <li>• Two courses for 70, of which 50 personnel at ports of entry (5 for each point of entry) on identification of products and certification, 10 Officials at Customs and Exc ise, 10 Namibian Police in conjunction with the NBI (70 participants, 4 days);</li> <li>• One training for technicians to enable them to carry out laboratory activities in relation to biosafety and the implementation of the Protocol at the University (10 technicians, 4 days)</li> </ul>	<ul style="list-style-type: none"> <li>• Minimum of 80% participants attending the courses and the workshops;</li> <li>• Proceeding of the workshops available</li> </ul>

<ul style="list-style-type: none"> <li>• Two training courses for Information Management Officers on the BCHM (4 Officers, 4 days).</li> </ul> <p>(c.2) Two training workshops on biosafety issues for farmers and consumer groups representatives (25 participants, 2 days)</p> <p>(c.3) Exchange programmes for technicians, including training, in view of their professional/academic advancement</p> <p><b>TOTAL: 226,000; GEF: 158,000;</b></p>	
<p>(d.1.) Upgrading the Biosafety Web-page to serve as a tool for the Biosafety Clearing House Mechanism</p> <p>(d.2) Setting up a database on LMO field trials, commercial use or release, import and export in Namibia with an adequate mechanism for information sharing and security and confidentiality management. It will be linked to the BCH. It will contain the following information as required by the Cartagena Protocol</p> <ul style="list-style-type: none"> <li>- Any relevant existing laws, regulations or guidelines, including those applicable for the approval of LMOs –FFPs</li> <li>- Any bilateral, regional or multilateral agreements or arrangements</li> <li>- Cases when the import may take place at the same time as the movement is notified</li> <li>- Imports of LMOs exempted from AIA procedures</li> <li>- Specifications of when domestic regulations shall apply to specific imports</li> <li>- Notification of the point of contact in case of transboundary movements</li> <li>- Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with article 15</li> <li>- Information on cases of illegal transboundary movements</li> <li>- National, regional and international experts to be consulted for supporting NBAC with risk assessment and other biosafety related issues</li> <li>- Authorities in charge of LMOs origin and content</li> </ul> <p><b>TOTAL: 120,000; GEF: 120,000;</b></p>	<ul style="list-style-type: none"> <li>• Biosafety web page active</li> <li>• Counting hits on the website</li> <li>• Database operational, with all information included</li> </ul>
<p>(e.1.3) Information available on the biosafety web site and other electronic means printed in</p>	<ul style="list-style-type: none"> <li>• Survey of the main information users</li> <li>• Brochure for main users translated and</li> </ul>

<p>order to be distributed as hard copies;  (e.1.2) Preparation and dissemination of relevant information material for personnel working at the ports of entry;  (e.2.1) Translation of the national policy and biosafety act into various indigenous languages;  (e.3) Developing and disseminating brochures for different users (decision-makers, the general public, custom-clearance officials, etc.) on biosafety related issues;  (e.4) Design and develop TV and radio interactive programmes;  (e.5) Development and dissemination of a twice year released newsletter updated by Registrar and support unit.  (e.6) Dissemination of best practices and lessons learnt</p> <p><b>TOTAL:54,000;GEF:54,000</b></p>	<p>disseminated</p>						
<p><b>12. Estimated budget (in US\$):</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">GEF:</td> <td style="text-align: right;">672,000.00</td> </tr> <tr> <td>Co-financing-Namibia</td> <td style="text-align: right;">239,000.00</td> </tr> <tr> <td><b>Total:</b></td> <td style="text-align: right;"><b>961,000.00</b></td> </tr> </table>		GEF:	672,000.00	Co-financing-Namibia	239,000.00	<b>Total:</b>	<b>961,000.00</b>
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Co-financing-Namibia	239,000.00						
<b>Total:</b>	<b>961,000.00</b>						
<p><b>12. Information on project proposer:</b>  Dr. Martha Kandawa-Schulz,  Chairperson,  Namibian Biotechnology Alliance (NABA),  University of Namibia, Faculty of Science, Private Bag 13301, Windhoek , Namibia  Telephone: +264 61 2063635; Fax: +264 61 2063791;  email: <a href="mailto:kschulz@unam.na">kschulz@unam.na</a>  <a href="mailto:mschuly@polytechnic.edu.na">mschuly@polytechnic.edu.na</a></p>							
<p><b>13. Information on proposed executing agency (if different from above):</b></p> <p>The Namibian Biotechnology Alliance (NABA) proposes the project on behalf of the Ministry of Higher Education, Training and Employment Creation, which shall act as the competent authority.</p> <p>The elected Management Committee of the Namibian Biotechnology Alliance (NABA) as the <i>interim</i> technical review and advisory body, process the applications to import or use biotechnology products or procedures and consult international and/or local experts as required to reach sound decisions on the desirability and risks of all applications.</p>							
<p><b>14. Date of initial submission of project concept:</b>  November 2000</p>							
<p><b>15. Project Identification number:</b>  16. Not yet assigned</p>							
<p><b>17. Implementing Agency contact person:</b>  Ahmed Djoghlaif, Executive Co-ordinator, UNEP/GEF Coordination Office. Po. Box 30552 ,  Gigiri, Nairobi, Kenya</p>							
<p><b>18. Project linkage to Implementing Agency program(s):</b></p> <p>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.</p>							

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 welcome the commitment of **GEF to support a second phase of the UNEP/GEF Pilot Biosafety Enabling Activity project**". The need for capacity-building was also emphasized at the GEF workshop on the UNEP/GEF Pilot Biosafety Enabling Activity held on 24<sup>th</sup> May 2000 in the margins of CBD COP5 with the participation of more than 150 delegates.

12. 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".

13. The GEF Initial Biosafety Strategy as well the UNEP/GEF biosafety projects, including the results of the pilot project, which involved Namibia, 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 13<sup>th</sup> 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 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, covering 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia, Malawi), consisted of the following two components:
  - a *National Level Component* aiming at assisting eighteen eligible 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 (US\$ 0.8 million).
3. Each country in the pilot project went through some important stages needed to provide the foundation for the implementation of the National Biosafety Frameworks (and its modification to take account of the terms of the Cartagena Protocol), and included requirements 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 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 understanding and concern of the public and major decision makers of the potential benefits and risks of biotechnology application;
  - Enhance international co-operation and strengthen SADC and South African Custom Union (SACU) cooperation and communication on scientific research, legislation, information exchange and personnel training in the field of biosafety.
4. As one of the first pilot countries, Namibia benefited from funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project. A country study on the status of biotechnology in Namibia was undertaken and technical guidelines for work with genetically modified organisms were compiled. The country study Biosafety and Biotechnology in Namibia: “A country study; Namibian Biotechnology Alliance (NABA) 1999, identified a number of needs and recommendations for a National Biosafety Framework in Namibia. The study assessed the local capacity with regard to human resources and institutions to implement a National Biosafety Framework, and found that there was very limited institutional and human resource capacity within Namibia to safely and effectively implement a biosafety framework with the above objectives and proposed principles. It was recognised that:



- There is limited institutional capacity at two institutions, the National Forensic Science Institute and the Central Veterinary Laboratory;
- There is very limited human resource capacity, particularly in the regulatory functions pertaining to regulation of biotechnology due to the lack of familiarity with the subject;
- Namibia's arid marginal environment needs particular protection;
- The level of public awareness of issues pertaining to biosafety is very low.

4. This project proposal is a follow-up to the pilot project “Assistance for Developing a National Biosafety Framework” and tailored to meet these requirements as well as the following needs:

- Capacity building in many areas and sectors
- Training for the registrar and the biosafety unit
- Training for the NBAC and the NBEC
- Training of the border post personnel and country inspectors and the legal administrative and technical status
- Format information exchange amongst main trade in the region by using the existing platforms of SADC and SACU
- Upgrading of the laboratory facilities to enable screening of genetic material.

5. The main objectives of the project are:

- (A) To support the establishment of the legal and administrative basis to 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 Namibia and the SADC region and to meet the obligations foreseen under the Cartagena Protocol
- (B) To improve the ability to screen LMOs in order to monitor and manage the risks associated to their handling, transport, use, transfer and release;
- (C) Strengthen capacity building of main stakeholders through training courses and workshops;
- (D) Strengthen information sharing of relevant stakeholders
- (E) Enhance public awareness on biosafety-related issues.

### **Current situation**

1. The Government of Namibia signed and ratified the Convention on Biological Diversity (CBD) in 1992 and 1997 respectively. The CBD in its articles 8 (g) and 19 (3) states that “Parties shall establish and maintain means to regulate, manage or control the risks associated with the use and release of Living modified organisms (LMOs), resulting from modern biotechnology, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biodiversity, taking also into account the risks to human health”. The Cartagena Protocol was signed on the 24 May 2000.

2. The Namibian Biotechnology Alliance initiated a project to establish a National Biosafety Framework, which was submitted to GEF/UNEP for funding and benefited from this financial support. A variety of activities have been carried out under this project and the results are shown below:

- The country assessment on the status of biotechnology use, including modern biotechnology
- National technical guidelines for the safe use of biotechnology,
- National Policy, which was approved by Cabinet in November 1999. This national policy was approved before the Cartagena Protocol on Biosafety was agreed in January 2000 and before

the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"(GEF/C.16/4) was adopted in November 2000 by the GEF Council

- A draft act on the safe use of biotechnology submitted to the government legal drafters
- Drafting of regulations on administrative procedure, general procedure for registration and authorization, application for trial or experimental release of LMOs, application of placing on the market, transit of LMOs/LMOs-FFPs); regulations on safety levels and safety measures for contained use; application form: establishing and operating a laboratory or production facility for the contained use of LMOs.

It was realised later that the act could not include all the necessary procedures and as a result it was decided to have regulations separately to go along with the biosafety act. Funding was then sought from other institutions for this activity. Workshops were organised and experts from the country, region and developed countries took part. Namibia benefited from their experience and continues to work together with them.

During this pilot phase, awareness on biotechnology/biosafety was raised and continues to be raised although, due to other difficulties, this can only happen at a slow pace. NABA has succeeded in getting both farmers' representative and someone from the consumer lobby to be part of the committee.

3. The National Biosafety Framework was approved by the Ministry of Higher Education, Training and Employment Creation in consultation with the Namibian Biotechnology Alliance and other Ministries. This has been done on the bases of the draft act and regulations, which still have to go to Parliament after the government legislative draftsmen have completed their work.

Having succeeded in developing the national biosafety framework and signing the Cartagena Protocol on Biosafety, Namibia is now facing problems with the implementation of this developed framework and changes that must be made due to agreement on the Cartagena Protocol. The problem identified in all the workshops held is that Namibia does not have the capacity to deal with all the activities required.

It will have to rely also on experts outside Namibia and preferably from the region with similar ecosystems. Harmonisation of the regional acts, regulations and guidelines is an important issue that needs to be tackled by all countries involved.

The Ministry of Higher Education, Training and Employment Creation (the implementing institution) has already appointed an individual to look into the issues of the implementation of the National Biosafety Framework. The Ministry has also allocated funds to enable him to take part in international meetings and workshops in the area of biosafety.

The Ministry of Agriculture has also realised the importance of building capacity in the area of biotechnology and biosafety, and travel money is set aside to send these people to related biosafety meetings.

In addition to these initiatives, Namibia approached the Commonwealth and the German Government for assistance in the implementation of the Cartagena Protocol and the National Biosafety Framework. An advisor on biosafety from the Commonwealth and an expert in biotechnology/biosafety has been approved by the above mentioned authorities/institutions as reflected in the budget under specific personnel contribution to the project.

## **Expected project outcomes, with underlying assumptions and context**

Namibia shall not permit the importation of biotechnology products or the use of procedures which do not meet minimum safety standards in countries with strong regulatory frameworks. Namibia shall endeavour to implement local field trials of such products or procedures to the extent of its ability where existing data are regarded as inapplicable to local circumstances.

Systems will be put into place to ensure compliance with these requirements, and to ensure that Namibia complies with the requirements of the Protocol. This project proposal is considered highly important in order to ensure that Namibia adopts the principles enunciated in its national policy, proceeds with the finalisation of its drafted Biosafety Act and meets therefore its obligations under the Cartagena Protocol.

Implementation of the project is focused on capacity building activities that will therefore lead to the following outcomes:

(A.1) Project coordination and management set up

(A.2) Submission for approval of the following regulations to implement the biosafety management mechanism in Namibia:

- Safety levels and safety measures for contained use
- Field testing of living modified organisms
- Marketing of living modified organisms
- Administrative procedures
- Application forms

(A.3) Three days workshop for 50 stakeholders concerning “National biosafety legislation and the Cartagena Protocol” organised

(B) Expanded and strengthened laboratory facilities for risk assessment and management

(C.1) Training activities organised as follows :

- One training for the registrar, support units and NBI members (National Biosafety Inspectorate), on biosafety management procedures and the need to handle applications (9 participants, 4 days);
- Three training courses for, 16 from NABA/NBAC including the registrar on risk assessment procedures and 20 from personnel in sectoral regulatory and administrative positions, on risk assessment by applicants, the Advance Informed Agreement procedures and issuing of import permits (36 participants, 4 days);
- Two training courses for NBEC members on decision making related to biosafety issues (6 participants, 4 days);
- Two courses for 70, of which 50 personnel at ports of entry (5 for each point of entry) on identification of products and certification, 10 Officials at Customs and Excise, 10 Namibian Police in conjunction with the NBI (70 participants, 4 days);
- One training for technicians to enable them to carry out laboratory activities in relation to biosafety and the implementation of the Protocol at the University (10 technicians, 4 days)
- Two training courses for Information Management Officers on the BCHM (4 Officers, 4 days).

(C.2) Two training workshops held on biosafety issues for farmers and consumer groups representatives (25 participants, 2 days)

- (C.3) Exchange programmes for technicians, including training, in view of their professional/academic advancement;;
- (D) Set up a Biosafety Database System to serve for the Biosafety Clearing House Mechanism in Namibia to organise, integrate and develop existing information. Website opened.
- (E) Public awareness material prepared and published, best practices and lessons learned disseminated.

## **Activities and financial inputs needed to enable changes**

### **1. Establishment of the operational mechanism for biosafety management in Namibia**

Namibia has already drafted its "Biosafety Act" and the biosafety regulations to be applied to the *import, export, placing in transit, release, contained use, handling, use and placing on the market, of all LMOs* and it is ready to approve it. The Act designs a well-modelled biosafety management system, which mainly foresees the appointment of

- 1) The Namibian Biosafety Advisory Council (NBAC), an independent, transparent technical advisory body in charge of advising on the development of policy and strategy in charge of reviewing applications and conducting risk assessments, advising on the granting or refusal of applications the Registrar (the interim advisory body to the Government is the Namibian Biotechnology Alliance (NABA);
- 2) The NBEC, the National Biosafety Executing Council, will be making the decision on behalf of the Minister of Higher Education, Training and Employment Creation and communicate this to the biosafety registrar. Members of the NBEC are appointed by the Minister from different government institutions
- 3) The Registrar will be appointed within the Ministry of Higher Education, Training and Employment Creation, Directorate of Science and Technology. The Registrar will be in charge of taking measures to notify affected States of any unintentional release of GMOs, liaising with the national focal point, requesting risk assessment/management through the national biosafety Inspectorate (NBI), networking with the national biosafety clearing-house-mechanism to provide information. The registrar/biosafety unit will screen the applications for correctness of the information provided before sending this to the NBAC.
- 3) In addition, two support units, the Regulatory Administration Unit and National Biosafety Inspectorate (NBI), are to be set up in order to oversee the regulatory and administrative processes, supported by regulatory administration units e.g. application screening, notification and information transfer.

These institutions will be set up during the development of the project by the Government of Namibia (NABA, as interim body, is already operational). The project will focus on the finalisation of the following regulations to activate the operational mechanisms for biosafety management in Namibia

- Safety levels and safety measures for contained use;
- Field testing of living modified organisms;
- Marketing of living modified organisms;
- Administrative procedures;
- Application forms for LMOs to enter the country.

A specific 4 days workshop involving 50 government representatives and other stakeholders will be held in order to discuss mentioned regulations, and more in general, the implementation of the legislative/administrative framework in Namibia.

### **2. Expand and strengthen laboratory facilities in order to improve the ability to screen LMOs and monitor/ manage the risks associated to their transfer, handling and use.**

Namibia is lacking the needed basic infrastructure. This intervention is therefore very much concentrated on supporting the country in purchasing and upgrading of equipment which are not available in the existing laboratories (research laboratory at the University of Namibia,

department of Chemistry, and the Central Veterinary Laboratory), but are necessary to screen materials (laboratory facilities, including consumables: kits, enzymes, primers, chemicals, etc).

The research laboratory at UNAM, under the responsibility of the biosafety registrar, will be in charge of transgenic plants, food, feed and processed products. This laboratory will be conducting inspections under the Biosafety Act and for the sampling itself, analysis of selected samples, sample storage and documentation, validated test systems and standardised and reliable conditions are of utmost importance. This will require a physical separation of this biosafety laboratory from other research labs, the separation of DNA-sampling and -preparation from PCR-based analytical testing as well as restricted access to the laboratory and safe storage of samples and material. The University of Namibia will be therefore further strengthened in its role of training centre on LMO detection.

The central veterinary laboratory will take care of the any sampling and sample processing related to animals, veterinary therapeutics and diagnostics. The CVL is already quite well equipped and will need only small equipment (set of automated pipets, lockable refrigerator,) and validated test kits (the list of the equipment requested under this project is presented in Annex 3).

Equipment is also needed for personnel working at the country's port of entry to be able to collect samples of Living Modified Organisms (LMO) entering or transiting the country and send them for inspection. The upgraded laboratory will perform independent analysis as requested by NBAC as part of the risk assessment and management procedure.

Specific training activities to strengthen capacity and assure the country with its own independent evaluation ability are foreseen under the following paragraph.

### **3. Strengthen national capacity of main stakeholders**

Different sets of training activities have been foreseen to face the needs of the personnel that will be involved in the biosafety management mechanism defined in the Biosafety Act. It is highly important to build capacity and expertise to allow the personnel to perform its task, ensuring therefore the correct implementation of the legislative system set up for the safe use, import or export of LMOs in the country. Some training activities will be held twice during the three-years duration of the project in order to ensure the updating of the personnel and the establishment of biosafety management practices as needed.

Training activities will be therefore organised as follows:

- One training for the registrar, support units and National Biosafety Inspectorate members, on biosafety management procedures and the need to handle applications (9 participants, 4 days);
- Three training courses for, 16 from NABA/NBAC including the registrar on risk assessment procedures and 20 from personnel in sectoral regulatory and administrative positions, on risk assessment by applicants, the Advance Informed Agreement procedures and issuing of import permits providing for the certification of origin of products, e.g. Animal health control, Phyto-sanitary control, Environmental Assessment Unit, Resource Management (36 participants, 4 days).
- Two training courses for NBEC members on decision making related to biosafety issues (6 participants, 4 days).

- Two courses for 70, of which 50 personnel at ports of entry (5 personnel for each point of entry) on identification of products and certification, 10 Officials at Customs and Excise, 10 Namibian Police in conjunction with the NBI (70 participants, 4 days);
- One training for 10 technicians to enable them to carry out laboratory activities in relation to biosafety and the implementation of the Protocol at the University for 4 days
- Two training courses for 4 Information Management Officers on the BCHM for 4 days.

In addition, two training workshops on biosafety issues for 25 farmers and consumer group representatives (2 days). Farmers have an extremely important role in the economy of the country and their involvement is considered essential.

Finally, exchange programmes for technicians, including ad hoc training and participation to international forums, are thought for professional/academic advancement. They are therefore specifically addressed to universities and research centres.

#### **4. Strengthen the national information system**

This activity involves the setting up of integrated databases as follows:

- a database on LMOs field trials, commercial use or release, import and export in Namibia with an adequate mechanism for information sharing and security management
- a database containing national, regional and international experts to be consulted for supporting NBAC with risk assessment and other biosafety related issues;
- a database of the competent authorities in charge of certifying LMOs origin and content;

The above information will be used for the purposes of the Biosafety Clearing House Mechanism in accordance with the Cartagena Protocol.

The above-mentioned information related activities aim to be a user-friendly system where all information is accessible and exchange of information, through inputs and comments from governmental and non-governmental actors, granted. The biosafety clearing house mechanism is to be linked to the Biodiversity one and the CBD Secretariat as well as to the web site that will be created. The web site is to be maintained by the biosafety unit.

#### **5. Public awareness on biosafety related issues**

The project will aim at strengthening capacity for public awareness by developing material to be disseminated across the country. Information available on the biosafety web site and other electronic means printed in order to be distributed as hard copies.

The national policy and biosafety act will be translated into various indigenous languages. Brochures for different users (decision-makers, the general public, custom-clearance officials, etc.) on biosafety related issues will be prepared and disseminated as well as TV and radio interactive programmes designed.

Additionally, a twice year released project newsletter ,updated by Registrar and the support unit, will be produced.

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

## **10. Sustainability analysis and risk assessment**

Line Ministries (Ministry of Higher Education, Training and Employment Creation, Ministry of Environment and Tourism, Ministry of Agriculture, Water and Rural Development, Ministry of Health and Social Services, Ministry of Trade and Industry, Ministry of Fisheries and Marine Resources) in Namibia are all aware of the importance of the biosafety framework and the Cartagena Protocol on Biosafety. The biosafety Act and the related regulations design a well-modelled biosafety management system, and therefore insure the correct implementation of the national biosafety framework. They state clearly the responsibilities of each ministry and the needed steps to proceed forward.

By the creation of the biosafety registrar and the biosafety unit, in charge of overseeing the regulatory and administrative procedures, the sustainability and transparency of the project as well as of the whole process will be granted.

## **11. Stakeholder involvement and social assessment**

The Namibian Biotechnology Alliance (NABA) has presented the project on behalf of the Ministry of Higher Education, Training and Employment Creation, which shall act as the competent authority. Namibian Biotechnology Alliance (NABA) is the *interim* technical review and advisory processing the applications to import or use biotechnology products or procedures and consult international and/or local experts as required to reach sound decisions on the desirability and risks of all applications.

NABA is composed of representatives of the University of Namibia, Ministry of Agriculture, private sector (the consumer lobby will also be represented in the permanent structure of NBAC (National Biosafety Advisory Council), NEPRU (Namibian Economic Policy and Research Unit), Ministry of Health and social services, Ministry of Fisheries, Ministry of Trade and Industry, Ministry of Environment and Tourism, Namibian Breweries, Multidisciplinary Centre, Meat Board, Agronomic Board. Its composition ensures therefore high level acceptance and support to the project.

Government representatives in NABA management have been part of the pilot phase and continue to be on the management committee for the development of the implementation phase. They report to the management on a regular basis about NABA activities. NABA is one of the working groups under the National Biodiversity task force. Report on the progress and development of each group is done at regular meetings.

Other stakeholders who took part to the activities carried out to develop of National Biosafety Framework have contributed with important inputs to the formulation of this current proposal. NGOs as The Desert Foundation and the Namibia Nature Foundation were involved in the process. More specifically, they strongly supported the development of the national biosafety framework and helped in the identification of the current needs and gaps as reflected in this project proposal.

## **INCREMENTAL COST ASSESSMENT**



Namibia has signed the Cartagena Protocol on the 24 May 2000. Namibia benefited from funding through the UNEP/GEF Pilot Biosafety Enabling Activity Project. A country study on the status of biotechnology in Namibia was undertaken and technical guidelines for work with genetically modified organisms were compiled. The country study Biosafety and Biotechnology in Namibia: "A country study; Namibian Biotechnology Alliance (NABA) 1999, identified a number of needs and recommendations for a National Biosafety Framework in Namibia. The study assessed the local capacity with regard to human resources and institutions to implement a National Biosafety Framework, and found that there was very limited institutional and human resource capacity within Namibia to safely and effectively implement a biosafety framework with the above objectives and proposed principles.

Therefore, the Ministry of Higher Education, Training and Employment Creation appointed an individual to look into the issues of the implementation of the National Biosafety Framework. The Ministry allocated funds to enable him to take part in international meetings and workshops in the area of biosafety. As well, the Ministry of Agriculture has also realised the importance of building capacity in the area of biotechnology and biosafety, and travel money was set aside for representatives to biosafety related meetings.

Funding was then sought from other institutions. Namibia approached the Commonwealth and the German Co-operation for assistance in the implementation of the Cartagena Protocol and the National Biosafety Framework. An advisor on biosafety and an expert in biotechnology/biosafety were approved by the above mentioned authorities/institutions. Their support and expertise will be partly associated and used for the purpose of this project.

<b>Project components</b>	<b>Baseline</b>	<b>Alternative</b>	<b>Increment</b>
<i>Legislation and coordination</i>	The draft Act on Biosafety is in the last stages of preparation. The implementing regulations are under development.	Implementing regulations finalised 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	Capacity strengthened through specific training courses and workshops organised for government and technical staff	Strengthened national capacity to meet the requirements under the Biosafety Act and the Cartagena Protocol
<i>Strengthening national facilities for risk assessment and management purposes</i>	Namibia needs strengthen laboratory facilities in order to build its capacity with respect to the inspection, identification and characterisation of LMOs. The Department of Chemistry at UNAM, under the responsibility of the Biosafety registrar, is currently only equipped with instruments assigned to training and education purposes and used - in the interim phase- for getting	The laboratory at the University of Namibia and the Central Veterinary Laboratory strengthened for conducting inspections under the Biosafety Act and for the sampling itself, analysis of selected samples, sample storage and documentation, validated test systems the inspection, identification and characterisation of LMOs. The laboratory at the University of Namibia	Risk assessment and management improved through the strengthening of national facility that will perform inspections/analysis as requested by NBAC according to the Biosafety Act and the Cartagena Protocol requirements.

	familiar with available LMO detection kits.	will be in charge of transgenic plants, food, feed and processed products while the Central Veterinary Laboratory with sampling and sample processing related to animals. The University of Namibia will be consequently strengthened also in its role of training centre on LMO detection	
<i>Strengthening the information system</i>	An organised 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.	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
Capacity building for public awareness purposes and dissemination	Capacity building for public awareness is still very poor	Capacity for public awareness purposes strengthened through preparation and dissemination of relevant information; translation of the national policy and biosafety act into various indigenous languages; brochures for different users on biosafety related issues; design and development of TV and radio interactive programmes; a twice year released newsletter, dissemination of best practices and lessons learnt	National capacity for public awareness capacity enhanced

As shown in the table below, the cost of the increment is of **911,000USD** of which **672,000USD** is being requested from the GEF; the remaining **239,000USD** is provided as in-kind contribution by Namibia.

<b>Activity</b>	<b>Baseline</b>	<b>Alternative</b>	<b>Increment</b>	<b>Cost to GEF (Global Benefit)</b>	<b>Co-financing (in-kind contributions)</b>
Legislation and coordination	29,000	360,000	331,000	170,000	161,000
Training	20,000	246,000	226,000	158,000	68,000
Strengthening national facilities	8,000	188,000	180,000	170,000	10,000
Strengthening the information system	5,000	125,000	120,000	120,000	-

Public awareness and dissemination	5,000	59,000	54,000	54,000	-
<b>Total</b>	<b>59,000</b>	<b>970,000</b>	<b>911,000</b>	<b>672,000</b>	<b>239,000</b>

## BUDGET

Activity	GEF	Gov. in-kind contribution	TOTAL
<b>Project management</b>			
<b>Personnel component</b>			
• Project co-ordinator/project resource personnel	50,000		
• Other support Personnel		40,000	
• Communication		7,000	
• Local transportation		40,000	
<b>Personnel specific project contributions</b>			
• Contribution to NABA		5,000	
• Registrar and Administration Unit		30,000	
• National Biosafety Inspectorate		15,000	
• Other Ministries and University of Namibia		5,000	
• Commonwealth Advisory's office		12,000	
<b>Coordination Office -rent</b>			
<b>Office supplies</b>	3,000	7,000	
• Computer and printer for the coordinator	4,000		
• Insurance and maintenance of equipment	4 0000		
	5 000		
<b>SUBTOTAL</b>	<b>66,000</b>	<b>161,000</b>	<b>227,000</b>
<b>Regulatory component</b>	<b>104,000</b>		
a) Finalising of the following regulations:			
- Safety levels and safety measures for contained use			
- Field testing of living modified organisms			
- Marketing of living modified organisms			
- Administrative procedures			
- Application forms			
b)One workshop for 50 stakeholders on the regulations, the NBF and the CPB (4 days)			
<b>SUBTOTAL</b>			<b>104,000</b>

<p><b>Training component</b></p> <p>a-One training for the registrar, support units and NBI members (National Biosafety Inspectorate), on biosafety management procedures and the need to handle applications (9 participants,4 days);</p> <p>b-Three training courses for, 16 from NABA/NBAC including the registrar on risk assessment procedures and 20 from personnel in sectoral regulatory and administrative positions, on risk assessment by applicants, the Advance Informed Agreement procedures and issuing of import permits (36 participants,4 days);</p> <p>c-Two training courses for NBEC members on decision making related to biosafety issues (6 participants, 4 days);</p> <p>d-Two courses for 70, of which 50 personnel at ports of entry (5 for each point of entry) on identification of products and certification, 10 Officials at Customs and Excise, 10 Namibian Police in conjunction with the NBI (70 participants, 4 days);</p> <p>e-One training for technicians to enable them to carry out laboratory activities in relation to biosafety and the implementation of the Protocol at the University (10 technicians, 4 days)</p> <p>f-Two training courses for Information Management Officers on the BCHM (4 Officers, 4 days).</p> <p>g-Two training workshops on biosafety issues for farmers and consumer groups representatives (25 participants, 2 days)</p> <p><b>SUBTOTAL</b></p>	128,000	25,000	
<p><b>Experts (International, Local)</b></p> <p><b>SUBTOTAL</b></p>	30,000 <b>30,000</b>	43,000 <b>43,000</b>	<b>73,000</b>
<p><b>Equipment component</b></p> <p>a) <b>Laboratories (SEE Annex)</b></p> <p>b) <b>BCHM</b></p> <ul style="list-style-type: none"> <li>• Setting up of the BCHM</li> <li>• server</li> <li>• website</li> <li>• Software</li> <li>• Preparation and administration of related information material of people working at the port of entry</li> <li>• Upgrading of the website after setting up</li> <li>• Printing and distribution of hard copies where electronic means are not available</li> </ul> <p><b>SUBTOTAL</b></p>	170,000 120,000	10,000	
<p><b>SUBTOTAL</b></p>	<b>290,000</b>	<b>10,000</b>	<b>300,000</b>
<p><b>Miscellaneous component</b></p> <p>a) <b>Reporting and drafting costs</b></p> <ul style="list-style-type: none"> <li>i) Translation and dissemination of national policy, biosafety act and biosafety regulations</li> <li>ii) translation, printing and dissemination of information</li> <li>iii) drafting, printing and dissemination of brochures,</li> <li>iv) development and dissemination of a twice per year Newsletter</li> </ul> <p>b) <b>dissemination of best practices and lessons learnt</b></p> <p><b>Sundry (Communications, others)</b></p>	15,000		
	33,000 6,000		

<b><i>SUBTOTAL</i></b>	<b>54,000</b>	<b>-</b>	<b>54,000</b>
<b>TOTAL</b>	<b>672,000.00</b>	<b>239,000</b>	<b>911,000</b>

## 9. Project implementation Work plan/Timetable

Project activities, including those financed by the government of Namibia to be conducted over 36 months, are reflected below:

Project activities	3	6	9	12	15	18	21	24	27	30	33	36
1. Submission for approval of the biosafety act and the biosafety regulations	•	•	•									
2. Appointment of registrar		•	•									
3a) Creation of the biosafety unit b) Identification of the National Biosafety Inspectorate			• •	•	•							
4. Establishment of NBAC by the Minister in consultation with other line Ministries, institutions, etc					•	•						
5. Establishment of NBEC by the Minister						•	•					
6. Translation of the national biosafety policy, biosafety act, regulations	•	•	•	•	•							
7. Develop and test the operational mechanisms fro biosafety management				•	•	•						
8a) Purchase of laboratory facilities b) Expansion and strengthening of laboratory facilities for RA and RM				•	• •	•						
9. Training courses and workshops as shown in the activities and budget allocation from the GEF			•	•	•	•	•	•	•	•	•	•
10a) Setting up of a BCHM b) Upgrading of web site c) Brochure drafting, editing, printing and dissemination d) Newsletter drafting, editing, printing and dissemination e) Brochures and Newsletter deposition on the web site			•	•	•	•	•	•	•	•	•	•
11. Evaluation and monitoring of the project activities	•	•	•	•	•	•	•	•	•	•	•	•
12. Reporting to the implementing agency (UNEP)		•		•		•		•		•		•

## Public Involvement Plan

The Ministry of Higher Education, Training and Employment Creation (MHETEC) shall be the competent authority. The interim technical advisory body is NABA, the Namibian Biotechnology Alliance. Regulatory input is also the responsibility of the Ministry of Environment and Tourism (MET), Ministry of Agriculture, Water and Rural Development (MAWRD), Ministry of Health and Social Services (MHSS), Ministry of Mines and Energy (MME), Ministry of Trade and Industry (MTI) and Ministry of Labour (ML).

Because border control is a crucial element to restrict the movement of genetically modified organisms across Namibia's borders, the Ministry of Home Affairs (MHA) will have enforcement responsibilities. A priority need is to train border control, police and customs officers to search for and recognise potentially genetically modified material, with mechanisms established to screen suspect material. Labelling regulations on imported material will be central to the success of these inspection and enforcement functions.

Regulatory competence exists in the following areas, although all areas need specific strengthening:

Ministry	Regulatory competence
MAWRD	Agricultural law enforcement (including sanitary and phytosanitary import/export control) , crop and livestock disease control, registration of livestock importation and agricultural products)
MET	Environmental impact assessment and permit review functions
MHSS	Public health impact assessment and food safety review functions
MTI	Industrial practices review and import/export management functions
ML	Occupational safety standards review function
MF	Custom and excise functions
MHA	Border control and forensic science
MHEVTST	Policy integration and institutional coordination functions
MFMR	Marine resources management stock assessment and input to impact assessment processes.

In all cases, there is an urgent need for awareness-building and detailed training exercises, following institutional capacity needs assessment as indicated in the project activities.

Promotion of biosafety in Namibia involves the development of biosafety capacities. Institutions and companies with current biosafety/biotechnology research activities include the National Forensic Science Institute, the MAWRD Central veterinary Laboratory, the Medical Laboratory Services, the Palmdat Namibia, MAWRD Division of Plant Production Research. The Government of Namibia, together with the University of Namibia or Polytechnic of Namibia, shall liaise with heads of regional training programmes to determine a cost-effective strategy for training Namibians in biosafety procedures, biosafety guidelines, risk assessment and risk management. It shall also include awareness modules in fields such as trade, finance, health, agriculture and environmental management.

Besides the mentioned Ministries and institutions, the national biosafety framework in Namibia was and is highly supported by NGOs, in particular The Desert Foundation and the Namibia Nature Foundation who contributed to its development with very highly valuable inputs.



The consumer lobby is represented in the management of NABA and will also be represented in the NBAC. The private sector is also part of the process and has been strongly involved in the development of the national biosafety framework.

## **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 FAO as collaborating agency, 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 National Biosafety Framework
- ANNEX 2** Matrix showing the relation between the project activities, the Cartagena Protocol and the National Biosafety Framework
- ANNEX 3** Provisional list of equipment needed to strengthen laboratories and enable them to perform inspections within the risk assessment and management procedure
- ANNEX 4** UNEP Response to the STAP Technical Review

## ANNEX 1

### SUMMARY OF THE NAMIBIAN BIOSAFETY FRAMEWORK

The National Biosafety Framework of Namibia consists of the following documents:

1. The country study on the status of biotechnology. This was the first task carried after the task force was established, to enable the country to know what Namibia has in terms of biotechnology and biosafety. Needs for Namibia have been set out clearly in this book.
2. The National Technical Guidelines. These guidelines have been written based on the UNEP technical guidelines on biosafety and the EU and modified according to the Namibian environment.
3. The National Policy on the safe use of biotechnology. The National Policy is approved by cabinet in November 1999 and sets out under others the regulatory framework as discussed below.
4. The draft biosafety act: based on the national policy, a draft act is produced to provide for the regulation of the import, export, release into the environment, contained use, handling, use, placing on the market and the placing in transit of living modified organisms (LMO(s)).
5. The draft biosafety regulations. These regulations intend to implement the obligations defined under the draft Biosafety Act for Namibia. The Regulations are justified by §39 of the draft Biosafety Act. They sets out the general administrative procedures regulating the application, review-, decision- and appeal-process for the contained use, intentional release, in- and export as well as transit of LMOs and/or LMO-FFPs for Namibia. For better clarity and transparency, administrative procedures are described separately and cover:
  - a. Scope (authorisation and registration)
  - b. Application (format, information to be submitted, reference to regulation)
  - c. Acknowledgement and notification (time scale and format)
  - d. review and decision procedure (time scale, obligations and responsibilities of authorities, public participation, independent reviews, format and content of decision)
  - e. Advice in advance (on application, registration)
  - f. public notice (information provided to the public, format and content)
  - g. appeal procedure (time scale, requested information, format)
  - h. costs and fees

with respect to the proposed activities involving LMOs.

This Regulation is primarily based and justified by the Biosafety Act for Namibia and refers to particular Regulations for:

- i) Contained Use of LMOs, Regulation-LC
- ii) Trial, General Release and Placing on the Market of LMOs, Regulation-LR
- iii) Placing on the Market of LMO-FFPs, Regulation-LF
- iv) Transit of LMOs or LMO-FFPs under contained conditions, Regulations-LT

## PRINCIPLES

- A. Namibia has sovereign rights over natural (including genetic) resources in its area of jurisdiction, and authority to control activities, which exploit or may have deleterious impacts on such resources. As Party to the CBD and the *United Nations Conference on Environment and Development*, Namibia is explicitly obliged to control biotechnology applications, which may harm its biological diversity and human health.
- B. Namibia shall endeavour to strike an appropriate balance between biotechnology promotion and regulation in the sustainable development pathway of Namibia.
- C. The use, import, export, sale or transit of biotechnology applications, practices and products must conform fully to all existing national legislation.
- D. The formal regulation of biotechnology shall be by a competent authority advised by a technical body independent of both government and industry, whose decision-making process is transparent, takes full account of environmental, public health, socio-economic and socio-cultural concerns, is based on locally applicable scientific and other data, and applies the precautionary approach.
- E. All costs involved in the decision-making process, including running costs and field trials shall be financed by the applicant, unless otherwise agreed by the Government of the Republic of Namibia.
- F. Biotechnology applications based on or inspired by the knowledge, innovations or practices of communities or individuals in Namibia shall be subject to national legislation related to community or individual intellectual property rights, and shall incorporate contractual agreements to share financial or other benefits arising from such applications with these communities or individuals. The State shall facilitate community access to appropriate advice for the purposes of negotiating and concluding such contractual agreements.
- G. Namibia shall endeavour to co-operate with other States, particularly its neighbours, to ensure the safe use of biotechnology within its borders.
- H. Namibia shall not permit the importation or use of biotechnology products and procedures, which do not meet minimum safety standards identified by the competent authority as stated in this policy document. Namibia shall endeavour to implement local field trials of such products or procedures to the extent of its ability, financed by the applicant, where existing data are regarded as inapplicable to local circumstances.
- I. Where scientific risk evaluation of a biotechnology product, application or procedure gives rise to a negative recommendation, this shall not be overruled for reasons of political or economic expediency; but a positive recommendation may be overruled on political or economic grounds.

Pending the outcome of global and regional assessments of the severe potential socio-economic, ethical, and environmental risks posed by “Genetic Use Restriction Technologies” (GURTs), Namibia shall enforce a five-year, renewable moratorium on the import, export, sale, or use of genetic material, such as seeds, altered by these technologies, including the so-called “Terminator Technology” and related processes. Such moratorium shall take immediate effect on the acceptance of this policy by Cabinet. A publicly transparent annual review of this moratorium shall be conducted by the Namibian Biosafety Advisory Council

The policy offers guidance for sustainable development by providing for mechanisms to ensure the safe use of biotechnology so as to strengthen the economy and enhance human livelihoods without prejudice to public health, environmental health, national sovereignty, human dignity or fundamental human rights.

## **Biotechnology and biosafety objectives**

The two main goals of Namibia's national policy on biotechnology and its safe use (hereafter *biosafety*) are:

- to guide the judicious use of modern biotechnology in Namibia for sustainable development, in ways which do not in any way jeopardise human or environmental health, including Namibia's biodiversity and genetic resources;
- to ensure effective control of transboundary movements of genetically modified organisms or products thereof resulting from modern biotechnology, through the exchange of information and a scientifically based, transparent system of advance informed agreement.

## **POLICY FRAMEWORK**

### **Scope**

The policy covers all GMOs and their products. This coverage includes all living organisms, germ-plasma, and all elements of genetic material used in genetic manipulation.

The national policy covers in detail:

- a) laboratory and field applications of biotechnology within Namibia, whether currently known to science or those developed in the future;
- b) the fields of agriculture, human and veterinary medicine, food / beverage production, industry, environmental management, bioremediation of mining, industrial and domestic wastes, and other fields of current or future application;
- c) the regulatory process, including notification, information transfer and review, risk assessment including socio-economic impact and ethical considerations, monitoring and enforcement measures pertaining to import or export of the products of biotechnology, or laboratory or field use of biotechnology in Namibia, including handling, disposal, containment, control, monitoring and release;
- d) the biotechnology research and development process, including academic, agricultural, industrial and other research;
- e) occupational safety at workplaces where biotechnology procedures are used or products handled;
- f) labelling of genetically modified organisms in foodstuffs and feeds sold in or imported to or through Namibia;
- g) any other measures to ensure public health or environmental safety with respect to the use of biotechnology in Namibia or its neighbouring territories or waters.

### **Implementation strategy**

- The policy attempts to strike a balance between protection and promotion. This can happen only with a clear, balanced and supportive policy, biosafety act, and a better-informed public.
- The policy outlines a national institutional framework for regulatory, administrative, research and development activities in the field of biotechnology.

## **Institutional framework**

This strategy necessitates a sound institutional framework, with urgent attention to the increased regulatory and enforcement capacity.

### **Regulatory and administrative structures**

Regulatory and administrative processes include notification, information transfer and review, risk assessment, approval or refusal, risk management, including monitoring and enforcement measures pertaining to laboratory use, research and development activities, or field release procedures including handling, containment, monitoring, agreed disposal or destruction procedures, and contingency plans for spillage or accidental release. In order to trace GMOs at the point of import, sectoral legislation related to import control may require appropriate amendment and enforcement.

Risk assessment is primarily the responsibility of agencies tasked with environmental protection, public health, occupational health, and food safety.

Although the Ministry of Higher Education, Training and Employment Creation (MHETEC) shall be the competent authority, regulatory input is also the responsibility of the Ministry of Environment and Tourism (MET), Ministry of Agriculture, Water and Rural Development (MAWRD), Ministry of Health and Social Services (MHSS), Ministry of Mines and Energy (MME), Ministry of Trade and Industry (MTI) and Ministry of Labour (ML).

Because border control is a crucial element to restrict the movement of genetically modified organisms across Namibia's borders, the Ministry of Home Affairs (MHA) will have enforcement responsibilities.

A priority need is to train border control, police and customs officers to search for and recognise potentially genetically modified material, with mechanisms established to screen suspect material. Labelling regulations on imported material will be central to the success of these inspection and enforcement functions.

There is an urgent need for awareness-building and detailed training exercises, following institutional capacity needs assessment, as indicated in the project activities.

### **Interim structures**

The Ministry of Higher Education, Training and Employment Creation shall act as the competent authority, with the elected Management Committee of the Namibian Biotechnology Alliance (NABA) as the *interim* technical review and advisory body. Applications to import or use biotechnology products or procedures shall be processed by NABA, which shall consult international and/or local experts as required to reach sound decisions on the desirability and risks of all applications. This process shall be conducted on a fast track or full review basis.

### **Permanent structures**

The National Biosafety Advisory Council (NBAC) will be established after the biosafety act is approved by Parliament. The NBAC shall be an independent, transparent technical advisory body, with the MHETEC as government competent authority.

The NBAC shall receive and process applications on a fast-track or full review basis and convey the recommendations and supporting materials to the NBEC, which shall be responsible for all such decisions. A small National Biosafety Inspectorate (NBI) unit will be established to carry out inspection activities.

**Interim application and review procedures**

Applicant submits proposal\* to Registrar, NABA Management Committee



Registrar screens completeness and adequacy of proposal:

*fast-track*

or

*full-review*



Review by one specialist advisor and

body



a: No likely impacts on neighbouring countries: review by 3 specialist advisors  
 b: Likely impacts on neighbouring countries: Review by 3 specialist advisors,

request any objections from neighbouring national advisory



NABA Management Committee meets to consider referees' reports  
 Forwards recommendation to Director of interim competent authority  
 Minister of interim competent authority issues formal decision to applicant



*approval*

or

*refusal*



initiation of proposal and only) self-monitoring



Appeal may be lodged (new supporting material) for re-review  
 Revised proposal may be submitted at any time (new design/techniques

***Permanent application and review procedures***

The following four classes are thus recommended:

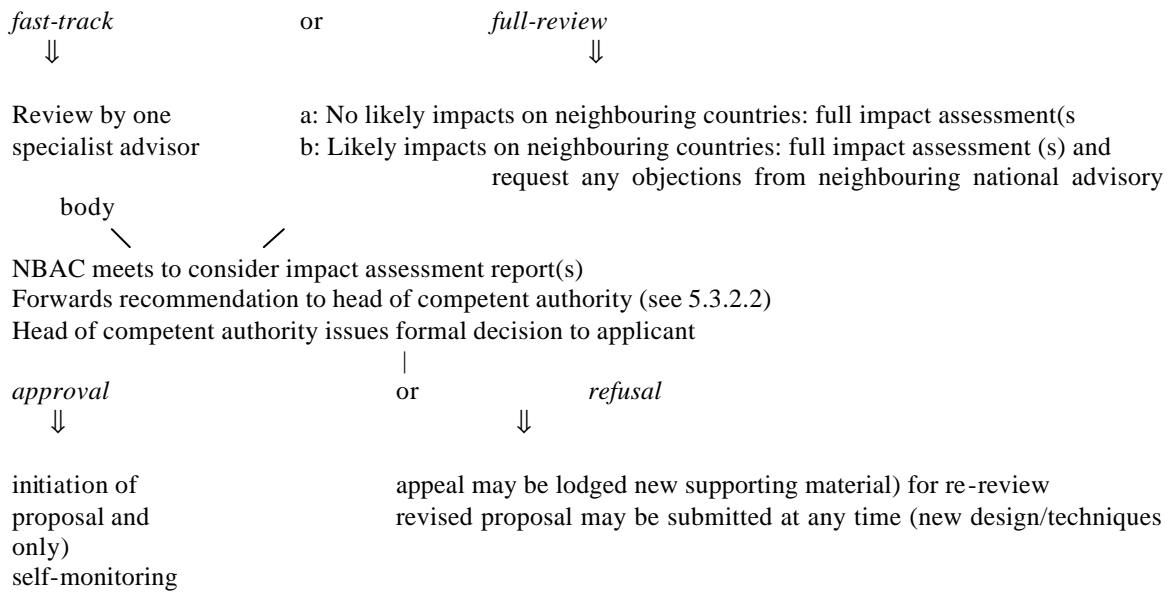
- CLASS 1 Activities of no or negligible risk - for which level 1 containment is enough to protect human and environmental health.
- CLASS 2 Activities of low risk - for which level 2 containment is enough to protect human and environmental health.
- CLASS 3 Activities of moderate risk - for which level 3 containment is enough to protect human and environmental health.
- CLASS 4 Activities of high risk - for which level 4 containment is enough to protect human and environmental health.

In all cases, uncertainty should lead to the use of the most stringent protective measures until sufficient evidence, by agreement of the NBAC, justifies the application of less stringent measures.

Applicant submits proposal to Registrar of the NBAC (three deadlines per year for receipt of proposals shall be set).



NBAC Registrar informs competent authority of receipt and screens proposal: Classifies proposal into Class 1 (fast-track) or higher (full review):



**Research and development structures**

Promotion of the safe use of biotechnology in Namibia involves the strengthening of research, development and biosafety capacities.

The Government of Namibia, together with the University of Namibia or Polytechnic of Namibia, should liaise with heads of regional training programmes to determine a cost-effective strategy for training Namibians in biotechnology procedures, biosafety guidelines, risk assessment and risk management. It shall also include awareness modules for non-specialist undergraduates in fields such as trade, finance, health, agriculture and environmental management.

**Risk assessment and containment of laboratory and field uses**

- *Laboratory use* of biotechnology can be in any field, e.g. agriculture, the beverage industry, and mining, veterinary research.
- *Field releases* are currently most likely in agriculture or waste management
- Fundamental steps in risk assessment, below, shall be followed for all biotechnology activities:

The process is set out in the national policy.



## ANNEX 2

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

Reference Activities	National Biosafety Framework	Provisions, Obligations and Objectives Cartagena Protocol on Biosafety
9 A, legal and administrative basis	Competent authority, ICCP identified as per National policy and Draft Biosafety Act	Article 2.1 (General Obligations) “...take necessary and appropriate legal, administrative and other measures to implement the obligations under this Protocol.” Article 16.1 (Risk management) “...establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified...”
9 B, ability to screen, identify and monitor LMOs	As part of the NBF, the technical guidelines approved and biosafety regulations drafted	Article 16.5 (a) (Risk management) “Identifying living modified organisms or specific traits...” Article 18.3 (Handling, transport, packaging and identification) “The Conference of Parties...shall consider the need for and modalities of developing standards with regard to identification...” Article 25.1 (Illegal transboundary movements) “Each Party shall adopt appropriate domestic measures aimed at preventing...transboundary movement of LMOs carried out in contravention of its domestic measures...” <sup>1</sup>
9 C, Strengthen capacity building	The need for strengthening capacity is stressed in the National Policy, under <i>Regulatory and Administrative</i> structures and <i>Research and Development</i>	Article 22.1 (Capacity-building) “The parties shall co-operate in the development...of human resources and institutional capacities in biosafety....” <sup>2</sup>
9 D, information sharing and public awareness	It is explicitly mentioned under the administrative procedures, point d, Review and Decision procedures, where public participation is covered	Article 20.1 (a) (Information sharing and the Biosafety Clearing-House) “Facilitate the exchange of scientific, technical, environmental and legal informations...” Article 23.1 (a) (Public awareness and participation) “The parties shall (a) Promote and facilitate public awareness, education and participation....” <sup>3</sup>
10 A, Biosafety Act and Regulations	NBF includes a Biosafety Act, currently with the government drafters, biosafety regulation	Article 2.1 (General Obligations) “...take necessary and appropriate legal, administrative and other measures to

<sup>1</sup> The Government of Namibia realises the necessity to establish surveillance schemes beyond simple documentation of history of descent or identity preservation systems.

<sup>2</sup> This applies to all operational measures defined in the Protocol, especially in the field of risk assessment and risk management. The Government of Namibia also realises the urgent need to develop national capacities in this area.

<sup>3</sup> The Government of Namibia considers the need for incorporating the public and affected Parties in the decision process.

	under consultative process	implement the obligations under this Protocol.” Covering the assessment and decision procedure, defined in Articles 8-13 and 15-19 and implementing the obligations formulated in Articles 21, 23, 25, 26 and 27
10 B, laboratory facilities for risk assessment and management	NBF calls for improving inspection ability in the country. A National Biosafety Inspectorate will be established as requested by the National policy and currently included in the Draft Biosafety Act	Article 16 (Risk management) Considering the need for reliable standards and certified procedures and laboratories for identifying LMOs and assessing potential risks as well as analysing the efficiency of risk management measures and strategies.
10 D, information exchange/system and public awareness	NBF calls for using all possible mechanisms to communicate biosafety information to the general public, specific provision "Public participation" are drafted under the Biosafety Act	Article 20.1 (a) (Information sharing and the Biosafety Clearing-House) “Facilitate the exchange of scientific, technical, environmental and legal information...” Article 23.1 (a) (Public awareness and participation) Article 26 (Socio-economic considerations) <sup>4</sup>

<sup>4</sup> The Government of Namibia considers public information and education a prerequisite for public participation and the ability to formulate of social and economic concerns and expectations.

### ANNEX 3

#### PROVISIONAL LIST OF LABORATORY EQUIPMENT

1 lockable refrigerator  
1 lockable deep-freezer  
1 multi-block PCR-machine  
2 sets of automatic pipets (one PCR)  
1 PC (lab documentation/data-processing)  
2 protein gels  
1 IEF-gel  
1 Western-/semiwet-blot system  
1 DNA-sequencing-gel  
1 hybridisation oven  
3 power supplies  
1 shaker  
1 waterbath  
1 fluorimeter  
1 double-distille/pure water filter system  
1 autoclave  
1 vacuum pump  
1 gel-blotter (southern)  
1 gel-dryer  
1 dish-washer  
2 vortex  
2 magnetic stirrer  
1 pH meter  
1 set of basic and small equipment

## 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 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>
<b>Kenya</b> <ul style="list-style-type: none"><li>• <i>Capacity building should also be addressed to inspectors, for example by organizing training workshop and developing inspection manuals.</i></li></ul>	<ul style="list-style-type: none"><li>• 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</li></ul>

<p><b>Poland</b></p> <ul style="list-style-type: none"> <li>• <i>One important element that is missing, is the development of implementing regulations.</i></li> <li>• <i>The proposed training activities are very fragmented and it is recommended to merge some of the training activities.</i></li> <li>• <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></li> </ul>	<ol style="list-style-type: none"> <li>1) The EU covers the regulatory component and therefore Poland didn't ask for any further financing from GEF.</li> <li>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.</li> </ol>
<p><b>Uganda</b></p> <ul style="list-style-type: none"> <li>• It is recommended to include training activities on topics such as “other international obligations”.</li> </ul>	<ul style="list-style-type: none"> <li>• Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.</li> </ul>