

## MSP PROJECT BRIEF

<b>Project Identifiers</b>	
<p>1. <b>Project name:</b> Support to the Implementation of the National Biosafety Framework of China</p>	<p>2. <b>GEF Implementing Agency:</b> United Nations Environment Programme (UNEP)</p>
<p>3. <b>Country in which the project is being implemented:</b>  China</p>	<p>4. <b>Country eligibility:</b>  China has ratified the CBD on the 5<sup>th</sup> January 1993 and signed the Cartagena Protocol on Biosafety on 8<sup>th</sup> August 2000</p>
<p>5. <b>GEF Focal Area:</b>  Biodiversity/Biosafety</p>	<p>5. <b>Operational programme</b> The project relates to biosafety issues and cross-cuts the Biodiversity Operational Programmes 1,2,3,4, and follows the Initial Strategy adopted by the GEF Council in November 2000.</p>
<p>7. <b>Project linkage to national priorities, action plans and programmes:</b></p> <ul style="list-style-type: none"> <li>• China is a country rich in biodiversity, and China is aware of the need to preserve and enrich that biodiversity. In China's Biodiversity country study, "the release of genetically modified organisms (GMOs) and biosafety" is among the key issues to be considered when assessing the current status of biodiversity in the country and the potential threats to it. Living modified organisms are addressed because of the potential ecological and biological risks and benefits associated with their use and release.</li> <li>• It is recognised that living modified organisms used in China may originate in the country or may be imported for many purposes. The need for regulation of those designed and produced within the country and of those imported is a national priority.</li> <li>• This project follows up to the GEF-funded enabling activity "National Biosafety Framework for China", which was one of the first, largest and cross-sectoral pilot projects in the field of biosafety. It enabled the identification of biotechnology being done in China and the drafting of a regulatory structure that could apply in the country. The pilot project preceded the Cartagena Protocol and provides a base to allow the implementation of the protocol provisions in China.</li> <li>• China successfully completed the above-mentioned project in September 1999, placing high priority on biosafety issues. The Chinese government is fully committed in the implementation of the Cartagena Protocol on Biosafety as evidenced by its active participation to the negotiation phase as well as by the signature of the Protocol in August 8, 2000. According to the stipulations of the Protocol, Contracting Parties are required to strengthen capacity building on legislation, policies, technologies, human resources and information for biosafety.</li> <li>• In China, legislation, technical research and education for biosafety have been initiated at departmental levels. China is the largest developing country and its economic system is currently being transformed from a planned economy to a market economy. The progressive implementation of the modified National Biosafety Framework for China (NBFC) will benefit not only China, but also the rest of the developing countries, as it will provide a model for biosafety on which others can build.</li> <li>• An "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. Such strategy foresees that "in countries that .... have participated in the pilot project, ... GEF undertakes country-based demonstration projects to assist in the implementation of a country's national biosafety framework". The GEF Initial Biosafety Strategy as well the UNEP/GEF biosafety project 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 (ICCP-1), held in Montpellier on 11-15 December 2000. The ICCP stressed the need for capacity building and strengthening of human and institutional resources of developing countries, especially in least developed and Small Island Developing States, and countries with economies in transition.</li> </ul>	
<p>8. <b>GEF national operational focal point and date of country endorsement:</b></p>	

The project was endorsed on the 31/5/2001, with a letter signed by the Operational Focal Point of China, Mr. Jinlin Yang, , Deputy Director, International Financial Institutions Division II, International Department, Ministry of Finance, Sanlihe, Xicheng District, Beijing 100820, China, PHONE: (86 10) 6855-1134/1184 , FAX : (86 10) 6855-1183/1125

**Project Objectives and Activities**

**9. Project rationale and objectives:**

**GOAL: To support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries**

**OBJECTIVE:**

Implementation of the National Biosafety Framework for China. Specific objectives are:

- (A) To provide China with a legal and administrative basis to ensure 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, and meet the obligations foreseen under the Cartagena Protocol.
- (B) Produce and promulgate technical Guidelines and develop techniques to improve the ability to monitor environmental release of LMOs and provide guidance for assessing and managing the related risk
- (C) Develop proper monitoring parameters/indicators and methods to improve the capacity to monitor environmental release of LMOs
- (D) Develop and set up a Biosafety Database system to serve for the purpose of Biosafety Clearing House Mechanism and to facilitate information sharing among decision-makers, managers, scientists and the public
- (E) Organise a series of training courses and workshops to train decision-makers, custom officials, inspectors, scientists and technicians. This will provide information, knowledge, and understanding of relevant techniques and good practice for biosafety.

**10. Project outcomes:**

- (A.1.) Promulgation of the “Biosafety Regulation of the People's Republic of China” according to the Cartagena Protocol and Chinese needs;
- (A.2) Established administrative/management system for biosafety in China. This will take account of the nature of Chinese Government and the devolution of regulatory responsibilities to regional government, and allow for coordination

**Indicators:**

- **Approval** of the "Biosafety Regulation of the People's Republic of China" by the State Council and implementation of the related biosafety management system. This Regulation to now take into account needs that will become important when the Cartagena Protocol comes into force.
- **Draft** laws, regulations and guidance at government/department level on the environmental release and transboundary movement of living modified organisms (LMOs).
- Publication and Application of the "Technical risk assessment and management guidelines".
- Biosafety data information system and Biosafety Clearing House Mechanism established and in-use.
- Publish developed monitoring parameters indicators and methods

**Indicators:**

- Draft of the “Biosafety Regulation of the People’s Republic of China” available.
- Reports on regularly meetings and on-going coordination activities carried out among the different Chinese ministries/agencies involved in biosafety management issues.

<p>to ensure that the Protocol can efficiently be implemented.</p> <p>(B) Technical Guidelines for risk assessment and risk management of living modified animals, living modified plants and living modified microorganisms (including specific working reports and research achievements on transgenic cotton) developed as required under Articles 15 and 16 and Annexes I – III of the Cartagena Protocol.</p> <p>(C) Parameters/indicators and methods to improve the ability to monitor environmental release of LMOs developed.</p> <p>(D) Set up Biosafety Database System and a Clearing House Mechanism in China in order to be able to fully implement the requirements for import and export of living modified organisms subject to the Advance Informed Agreement procedures and the requirements for living modified organisms intended for feed or food use. The database will assist in public participation identified in Article 23 of the Cartagena Protocol</p> <p>(E) Relevant stakeholders and government officials trained on biosafety policy, management, administration and risk assessment/management, 2 workshops organised.</p>	<ul style="list-style-type: none"> <li>➤ Formal approval of "Technical Guidelines for the Risk Assessment and Risk Management of LMOs in China"</li>   <li>➤ Database and Web site established</li>   <li>➤ 4 training courses held and related quality survey carried out. These courses will of necessity include international experts where local expertise is lacking.</li> <li>➤ Minimum 50 participants in total attending the different training activities</li> </ul>
<p><b>11. Planned activities to achieve outcomes:</b></p> <p>(a.1) Undertaking a policy study on the environmental release and transboundary movement of LMOs in China;</p> <p>(a.2) Review and integrate existing regulation on biosafety management (mostly at department level) according to the Cartagena Protocol requirements</p> <p>(a.3) Compilation and submission of the "Biosafety Regulation of the People's Republic of China" according to the Cartagena Protocol and Chinese needs;</p> <p>(a.4) Coordination of the biosafety related activities among different Governing bodies and organisations</p> <p>(a.5) Develop and test the operational mechanisms for biosafety management in China through;</p> <p><b>(TOTAL:USD243 000;GEF:198 000USD)</b></p> <hr style="border-top: 1px dashed black;"/> <p>(b.1) Development of information inventory of living modified organisms (LMOs-animals, plants and microorganisms)</p> <p>(b.2) Methods of identification, estimation,</p>	<p style="text-align: center;"><b>Indicators</b></p> <ul style="list-style-type: none"> <li>➤ Establishment of Project Coordination Committee and Management Office and quarterly reporting of activities</li> <li>➤ Survey of institutes and actors involved in the policy study activity on the environmental and transboundary movement of LMOs</li> <li>➤ Cartagena obligations used as references</li> <li>➤ Final report contains references to other countries biosafety regulation</li> <li>➤ Number of meetings held and related reporting</li> </ul> <ul style="list-style-type: none"> <li>➤ Identification and testing of a core set of LMOs environmental release indicators and related monitoring methods, to be produced on a regular basis</li> </ul>

<sup>1</sup> This pilot case study on transgenic cotton will be developed because 1) transgenic cotton has been approved for commercial release in China and 2) there are many hectares of transgenic cotton planted than of any other transgenic crops in China.

<p>predication and comprehensive benefit analysis for LMOs</p> <p>(b.3) Revision and testing of the Technical Guidelines for Risk Assessment and Risk Management of LMOs</p> <p>(c.1) Development of indicators and monitoring methods for environmental risk assessment of LMOs in order to be able to provide information to importing countries when exporting living modified organisms.</p> <p>(c.2) Pilot development of monitoring parameters/indicators and monitoring methodology in pilot fields for transgenic cotton<sup>1</sup>.</p> <p>(c.3) Strengthening of the established National Key Laboratories on Biosafety through purchase of equipment for the purpose of risk assessment and environmental monitoring.</p>	<p>basis</p> <p>➤ Independent peer review for the review of the guidelines</p>
<p><b>(TOTAL:426 000 USD; GEF: 361 000USD)</b></p>	
<p>(d.1) Develop a biosafety database system on LMOs field trials, use or release, import and export in China with an adequate mechanism for information sharing and security management so as to link to the Biosafety Clearing House and provide the necessary information to the BCH.</p> <p>(d.2) Develop a biosafety website for China</p>	<p>➤ Counting hits on the website</p> <p>➤ Survey of the main information users</p> <p>➤ Networks between government bodies, research institutes and commercial bodies are established</p>
<p><b>(TOTAL:200 000USD;GEF:135 000USD)</b></p>	
<p>(e.1) Organise</p> <p>➤ A 2 weeks training workshop for 8 decision-makers and managers assisted by international experts to learn about policies, legislation, institutional arrangements, operational mechanism and research program for biosafety in other countries;</p> <p>➤ A 1 month training workshop assisted by international experts for scientists to be trained in risk assessment, risk management (including monitoring of LMOs);</p> <p>(e.2) Organize two national workshops with the participation of international experts and the main stakeholders (including representatives of universities, research institutes, NGOs) on biosafety regulation, the interrelation between WTO and biosafety issues, technologies and methods for risk assessment and risk management of LMOs, monitoring of LMOs, the Biosafety Clearing House Mechanism, the impact of the Cartagena Protocol on China's biotechnology industry and eco-environment, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity;</p>	<p>➤ Survey of participants taking part to study-tours, international workshops and training courses</p> <p>➤ A manual produced during the training workshop will be published.</p>

<p>exchanging update information and discussing new problems occurring in biosafety management or risk assessment. This will build on the expertise gained from the Pilot project and modify that already done to meet with the requirements of the Protocol (estimated participants: 50 with 2 international experts, duration of the workshops: 3 and 7 days respectively)</p> <p>(e.3) Organize 3 training courses for custom officials, managers, and inspectors.</p> <p><b>(TOTAL:397 400USD;GEF:303 400USD)</b></p>							
<p><b>12. Estimated budget (in US\$ or local currency):</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">GEF:</td> <td style="text-align: right;">997 400</td> </tr> <tr> <td>Co-financing:</td> <td style="text-align: right;">269 000 (in-kind by China)</td> </tr> <tr> <td> Total:</td> <td style="text-align: right;"> 1 266 400</td> </tr> </table>		GEF:	997 400	Co-financing:	269 000 (in-kind by China)	 Total:	 1 266 400
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<p><b>13. Information on project proposer</b></p> <p>Department of Nature &amp; Ecology Conservation, SEPA (State Environmental Protection Administration)</p> <p>The State Environmental Protection Administration of China is a ministerial-level authority directly under the State Council responsible for the environmental protection in China. Its main responsibilities are as follows:</p> <ol style="list-style-type: none"> <li>1. To formulate the national policy, laws and administrative regulations for the environmental impact assessment of major economic and technological policies, development planning and key economic development plans and to formulate the national environmental protection plans; to formulate and monitor the implementation of the national plan for pollution control and ecological conservation in key regions and river basins, and to organize the zoning of environmental functions of different regions.</li> <li>2. To formulate and organize the enforcement of the laws and regulations for prevention of vehicle exhausts; to supervise, coordinate and monitor the protection of the marine environment.</li> <li>3. To supervise the activities of exploiting and utilizing the natural resources, which have impacts on ecological environment, the important ecological environmental construction and recovery of ecological damage; to supervise and examine the environmental protection in various types of nature reserves, tourist attractions and forest parks; monitor and examine the biodiversity conservation, the protection of wild animals and plants, the wetland conservation and the prevention and control of desertification and to supervise and to provide suggestions to the State Council concerning whether to approve the establishment of new national nature reserves of various types and manage the national nature reserves.</li> <li>4. To guide and co-ordinate the efforts in dealing with major environmental problems involving different departments, localities, river basins and regions; investigate and deal with major environmental pollution and ecological damage accidents; to co-ordinate the inter-provincial environmental disputes; co-ordinate and organise pollution prevention and control of key river basins at the national level; be responsible for the environmental supervision and management and administrative inspection of the environmental protection; and organize and undertake the examination of the enforcement of environmental laws and regulations at the national level.</li> <li>5. To formulate the national standards for environmental quality and for pollutants emission and discharge and launch them according to the relevant procedure; be responsible for filing of local environmental standards; to examine the content of environmental protection in the master plan of urban growth; to organise the compilation and submission of the national report on the environmental quality and the issuance of the national report on the state of the environment and to release on a regular basis the report of the environment quality of key cities and river basins; and to participate in the development of national program for sustainable development.</li> <li>6. To formulate and organize the implementation of various regulations of environmental management; to examine and approve the report of environmental impact assessment for the development and construction activities as required by the relevant regulation; to supervise the urban and rural ecological</li> </ol>							

environmental conservation and supervise the construction of national ecological demonstration areas and the eco-agriculture.

7. To organize the development of environmental science and technology and important research projects and technical demonstration projects; to manage the national environmental management system and the certification of environmental labels; to establish and organize the implementation of the rule of accreditation for the qualification for environmental market access and to guide and promote the development of environmental industry.
8. To be responsible for the environmental monitoring, statistics and information collection; to formulate the rule, regulation and specification for the environmental monitoring; to organize the construction and management of the national network of environmental monitoring and of environmental information; to organize the monitoring of the environmental quality and the supervisory monitoring of the pollution sources at the national level; to organize, supervise and coordinate the environmental education, publicity and publication and to promote the participation of the public and non-governmental organizations in the environmental protection.
9. To formulate the national principles for addressing the global environmental issues; to manage the international cooperation for the environmental protection; to participate in the coordination of important international environmental activities; to participate in the negotiation of the multilateral environmental agreements; to manage and coordinate as the national focal point the domestic implementation of the multilateral environmental agreements; to manage the international economic cooperation in the environmental field; to coordinate the foreign funded projects for the implementation of multilateral environmental agreements and to deal with the foreign affairs in the environmental field with the mandate of the State Council and be responsible for communication with the international environment-related organizations.
10. To be responsible for the management of nuclear safety, radioactive environment and radioactive wastes, formulating the relevant policy, regulations and standards; to participate in the emergency responses to nuclear accidents and the radioactive environmental accidents. To exercise the overall supervision and management of nuclear facility safety and the emergency response to nuclear accidents and the radioactive environmental accidents; to exercise the overall supervision and management of nuclear facility safety and the pollution prevention and control related to the electromagnetic radiation, the application of nuclear technology and the exploitation and utilization of mineral resources with associated radioactive materials and to exercise the management of nuclear resources with associated radioactive materials and to exercise the management of nuclear materials and to exercise the management of nuclear materials and the safety supervision of nuclear pressure equipment.
11. To be responsible for the institutional staffing and human resources management of SEPA and organize the institutional and administrative management reforms in the national system of environmental protection.
12. To undertake other matters entrusted or mandated by the State Council.

**Contact person at SEPA:**

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

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

30 August 1999

**16. Project Identification number:**

Not yet assigned

**17. Implementing Agency contact person:**

Ahmed Djoghlaf, Executive Coordinator, 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.

The 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.

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 included China, 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 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;
  - 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, 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 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, China successfully completed its project entitled “National Biosafety Framework of China (NBFC)” in 1999. The Pilot Project played an important role in initiating and promoting biosafety management worldwide. This was the first large and cross-sectoral project in the field of biosafety.

In China’s report on the Pilot Project, a number of steps were recommended for further action needed to implement the National Framework that had been developed. China suggested that training workshops and seminars be organized to allow developing countries to train relevant officials and experts and to provide information about the experience gained in other countries. China also suggested to UNEP that

experts with experience of drafting technical guidelines be available to assist in the drafting of each country's guidelines, and that UNEP provide relevant technical materials and biosafety information to assist countries in their endeavour to institute and implement Biosafety Frameworks.

5. The pilot project for China was completed before the Cartagena Protocol on Biosafety<sup>2</sup> 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. Such strategy foresees that:

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

*This type of assistance might best be provided to countries that have already ratified the Protocol, in much the same way that assistance through the financial mechanism of the Convention on Biological Diversity is to be provided to Parties to the Convention. However, in the interest of gaining experience and developing good practices that may promptly and effectively be provided to assist Parties once the Protocol enters into force, it is proposed that the GEF finance a limited number of country-based demonstration projects (maximum of eight countries - two per region for Africa, Asia, Eastern Europe, and Latin America and the Caribbean)."*

The strategy was further supported in the Final Decisions of 21<sup>st</sup> Governing Council of UNEP. The Governing Council

- *congratulated the 18 countries that participated in the United Nations Environment Programme/Global Environment Facility Pilot Enabling Activity Project for their exemplary execution of the national component of the pilot project, and*
  - *invited the Global Environment Facility to provide further financial support to these and other countries for the implementation of national biosafety frameworks (or similar policy administrative, legislative biosafety frameworks) they have developed in preparation for the entry into force of the Cartagena Protocol on Biosafety and for the first phase of the biosafety clearing house;*
6. This project proposal *"Implementation of the National Biosafety Framework"* is a follow-up to the pilot project *"Assistance for Developing a National Biosafety Framework"*. The project therefore addresses the most urgent priorities among those identified in the National Biosafety Framework for China (NBFC), i.e. management, research and capacity building, and ensures that China can meet its obligations under the Cartagena Protocol (China signed the Protocol in August 2000). The Pilot project was completed before the agreement to the Cartagena Protocol and that produced during the project

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<sup>2</sup> *Article 1 of the Cartagena Protocol on Biosafety: "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".*

needs to be modified so as to meet the requirements of the Protocol. This needs to be implemented with the support of UNEP through GEF.

The objectives of the proposed activity are to:

- Ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology, taking also into account risks to human health, and specifically focusing on transboundary movements.
- Formulate relevant laws and regulations, and establish appropriate mechanisms to effectively assess, monitor, control and regulate the transboundary movement, environmental release of living modified organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, to ensure that China can meet its obligations under the Cartagena Protocol to ensure an adequate level of protection.
- Produce and promulgate technical guidelines and develop techniques to improve national ability in risk assessment and risk management in connection with the storage, transportation, environmental release, use and transboundary movement of LMOs.
- Develop further a proper monitoring system and devise methods to improve the ability to monitor environmental release of LMOs so as to allow for the ability to provide the necessary risk assessments for export, and to ensure the safe use of living modified organisms that may have a deleterious impact on biological diversity.
- Develop and set up a biosafety database system and establish a Biosafety Clearing House Mechanism to facilitate information sharing among decision-makers, managers, scientists and the public which will contribute to the Biosafety Clearing House set up through the Cartagena Protocol and allow for full participation in the Clearing House. This participation to allow the Clearing House to be fully utilised as a resource for deciding on the import of living modified organisms and to allow information to be placed on the Clearing House database for use by those accepting exports from China
- Organize a series of training courses and workshops to train decision-makers, customs officials, inspectors, scientists and technicians in the use of risk assessment and risk management. These will provide information, knowledge, and understanding of relevant techniques and good practice for biosafety.

## **Current situation**

1. Since the middle 1980s, China has made great progress in the use of modern biotechnology and achieved a series of breakthroughs in basic and applied studies on transgenic plants, animals and microorganisms. It is estimated that between 1998 and 1999, there were about 45 transgenic plants approved pilot tests, 23 approved environmental releases (field tests) and 22 approved commercial releases of transgenic plants in China. Animals that have been modified in the laboratory include pigs, cows, sheep, chickens and model experimental animals such as rabbits and rats, but no transgenic animals have been approved for environmental release. The acreage of field tests and commercial production of transgenic crops in China is only exceeded by that in the USA, Argentina and Canada. Import and export of living modified organisms will be important to China.
2. It is known that crops imported into China contain some transgenic components, but it is difficult to estimate the volume of LMOs imported. In addition to the development of modern biotechnology products in China, some foreign biotechnology research and development companies have undertaken both transgenic research and field tests. It is recognised that there are large potential benefits in the development and use of modern biotechnology, but transgenic organisms may also pose a potential risk to China's biodiversity, ecosystem and human health. It is therefore important that a full framework be instituted that brings together the many interests within Government that influence biosafety policy.
3. China places high priority in biosafety issues and the Chinese government delegations have attended all rounds of working group meetings and negotiations concerning the Protocol on biosafety. China signed the Cartagena Protocol on Biosafety on August 8, 2000. Legislation, technical research and education for biosafety have been initiated at departmental levels. According to the stipulations of the Protocol, Contracting Parties are required to strengthen capacity building on legislation, policies, technologies, human resources and information for biosafety.
4. China is the largest developing country and its economic system is currently being transformed from a planned economy to a market economy. The progressive implementation of the modified National Biosafety Framework for China (NBFC) will benefit not only China, but also the rest of the developing countries, as it will provide a model for biosafety on which others can build.

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

The proposed GEF project has been designed as a key activity in a range of those that are addressing biosafety issues. This intervention is in fact assuring that the biosafety framework worked out during the Pilot Project phase becomes fully operational, playing an important role in launching biosafety management in China with a potential for replication world- wide.

Implementation of the project will therefore lead to the following outcomes that constitutes the basic legal and technical framework needed for making the biosafety management operational:

- Finalise and submit to the State Council the "Biosafety Regulation of the People's Republic of China" that will provide a legal basis to enable the safe use of LMOs in China and effective implementation of Cartagena Protocol.
- Management mechanisms for biosafety will be established to effectively protect the environment and

human health from risks that may result from research, development and use of LMOs.

- Promulgation of “Technical Guidelines for the Risk Assessment and Risk Management of LMOs in China” in accordance with Articles 15 and 16 and Annexes I – III of the Protocol.
  - Promulgation of “Indicators and Methods for the Monitoring of Environmental Release of LMOs in China”
  - A Biosafety Database system and a Biosafety Clearing House Mechanism will be established in China in order to meet China’s obligations under the Cartagena Protocol and to promote information exchange and sharing among departments in China, and between China and the rest of the world.
  - Through a series of training courses and workshops, the knowledge and practice for biosafety shall be greatly improved for the decision-makers, customs officials, inspectors and scientists that will be needed to fully implement the framework.
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## **Activities**

### **1. The Establishment of legislative system and an operational mechanism for biosafety management in China**

#### **1.1 The establishment of the operational mechanisms for biosafety management in China**

China is rich in genetic diversity, but information and responsibility for protecting this diversity and ensuring the safe use of biotechnology is spread amongst many Government Departments, research institutions and universities. Many institutions undertaking research and development of biotechnology belong to different ministries or agencies. Many ministries and agencies are also involved in biosafety management. An operational mechanism is needed to co-ordinate the actions of ministries, institutions, and research bodies involved in the biosafety assessment, monitoring and management activities. In this respect, an investigation, analysis and assessment of the mechanisms in use for biosafety management in China will be carried out. Such an investigation will aim at identifying current factors and gaps in terms of procedures, human resources, techniques, and the actors involved. A model for effective and integrated biosafety management that meets the requirements of the Cartagena Protocol and provides an adequate involvement of the main actors at both consultative and decisional level will be therefore structured and presented. Similar mechanisms will be also set up at local government's level and mechanisms to ensure that the Protocol is properly implemented at National and regional level will be explored.

#### **1.2 Policy study on the environmental release and transboundary movement of LMOs**

A large-scale investigation will be initiated to provide basic information of environmental release and transboundary movement of LMOs in China. The benefits and potential risk will be analysed. The impact of the Cartagena Protocol on Biosafety on China’s environment will also be assessed. The impact of the entry to WTO on China’s biosafety management and related requirements will be analysed. Policies concerning the environmental release and transboundary movement of LMOs, based on the guidelines for a National Biosafety Framework developed in China under the Pilot Project and shaped according to requirements of the Cartagena Protocol, will be put forward to the State Council.

### **1.3 The “Biosafety Regulation of the People’s Republic of China”**

At present, several regulations in connection with biosafety management have been issued at departmental level in China and they play an important role, but an Integrated Biosafety Regulatory structure at national level is lacking. In addition, the measures have been focused on the development, testing and the environmental release of some genetically transferred organisms, but there is a lack of measures addressing the export, transportation, commercialisation, storage, use and in particular a shortage of management rules such as release licensing, AIA for transboundary movement, impacts assessment, etc. Therefore, it is essential to formulate legislation both at national and local level in accordance with the Cartagena Protocol on Biosafety and Chinese needs. The most urgent need is to compile and promulgate the “Biosafety Regulation of the People’s Republic of China” at the level of the State Council. It will cover the following areas:

- Basic principles for biosafety management;
- Institutional arrangement and mechanism for biosafety management;
- “Advance Informed Agreement” in the transboundary movement of LMOs;
- Management in the import and export of LMOs:
- Packaging and identification of LMOs:
- Environmental monitoring of LMOs:
- Risk management associated with the transport, release, production and use of LMOs;
- Enforcement.

## **2. Technical Guidelines for Risk Assessment and Risk Management of LMOs**

Technical guidelines for risk assessment and risk management of LMOs is essential to assess and manage the potential risk resulting from the release, production, use and transboundary movement of LMOs. They are needed to implement the “Biosafety Regulation of the People’s Republic of China”. The guidelines can provide guidance on the determination of risk associated with LMOs, and enable evaluation and minimisation of risk. Guidelines will cover the following aspects:

- a. Objective and scope of risk assessment;
- b. Principles and procedures of risk assessment;
- c. Classification and determination of risk levels and types where appropriate;
- d. Information requirements for risk assessment of various LMOs;
- e. Analytical methods for risk/benefit analysis;
- f. Risk management for laboratory research, environmental release and transboundary movement of LMOs so as to ensure compliance with the Protocol.

According to different categories of LMOs, guidelines will include the following:

### **2.1 Guidelines for risk assessment and risk management of living modified animals**

- The development of an information inventory of environmental risk of living modified animals;
- The development of indicators and monitoring methods for environmental risk assessment of living modified animals;
- Methods of identification, estimation, prediction and comprehensive benefit analysis for risk due to living modified animals:

- The development of technical measures and methods for risk management of environmental releases of living modified animals.

## **2.2 Guidelines for risk assessment and risk management of living modified plants: a pilot model on transgenic cotton**

This activity is needed to provide the necessary information and understanding where products are to be exported from China, or where it is intended to import a product to be grown and where there is a need to perform a full risk assessment and ensure adequate risk management. In order to learn from this training work, a crop already grown in China will serve as a model for structuring the necessary integrated risk assessment and management procedures. This activity will therefore consist of two components:

a) *A general component covering:*

- The development of an information inventory of environmental risk for living modified plants;
- The development of indicators and monitoring methods for environmental risk assessment of living modified plants;
- Methods of identification, estimation, prediction and comprehensive benefit analysis for risk due to living modified plants;
- The development of technical measures and methods for risk management of environmental releases of living modified plants.

b) *a Pilot Environmental Monitoring Component on Transgenic Cotton*

Transgenic cotton has been approved for commercial release in China and there are more hectares of transgenic cotton planted than of any other transgenic crop. The environmental monitoring of transgenic cotton could be used as a model for pest-resistant transgenic crops. The monitoring indicators and methods developed in China for cotton could then be applied to other transgenic crops. Research institutes, universities and companies will be encouraged to begin research through meetings of 10 participants, that will be organised to consider:

- Indicators and methods for the environmental monitoring of transgenic cotton;
- The design of environmental monitoring of transgenic cotton;
- Impact on other organisms and plants of pest-resistant cotton;
- Escape of transgenic pest-resistant cotton from receiving environment;
- Evolution of tolerance of target pests to transgenic pest-resistant cotton;
- Potential effects of transgenic cotton on non-target organisms.

## **2.3 Guidelines for risk assessment and risk management of living modified micro-organisms**

- The development of an information inventory of environmental risk for living modified micro-organisms;
- The development of indicators and monitoring methods for environmental risk assessment of living modified micro-organisms;
- Methods of identification, estimation, prediction and comprehensive benefit analysis for risk due to living modified microorganisms;
- The development of technical measures and methods for risk management of environmental releases of

living modified microorganisms.

## **2.4 Strengthening of national facilities for risk assessment and environmental monitoring.**

China has established National Key Laboratories on Biosafety, such as the National Key Laboratory on Biosafety at Nanjing Institute of Environmental Sciences under the SEPA and National Key Laboratories at related ministries. These laboratories are main technical supporting units for biosafety in China, and have been undertaking field environmental supervision and monitoring, and the study of risk assessment and experiments of LMOs. The tasks of the National Key Laboratories on Biosafety are the following:

- 1) Establishing norms for the risk assessment of LMOs;
- 2) Undertaking field monitoring of LMOs;
- 3) Developing test methods of indicators for and guidelines of risk assessment and risk management of LMOs;
- 4) Undertaking risk assessment of LMOs;
- 5) Promoting information exchange and international cooperation on biosafety;
- 6) Providing training on biosafety.

In order to implement the obligations occurring under the Protocol for the purpose of LMO risk assessment, environmental monitoring and safety inspections, it is necessary to strengthen mentioned National Key Laboratories on Biosafety with a series of advanced equipment. The set of needed equipment is presented in Annex 3.

## **3. The Establishment of a Biosafety Database System and a Biosafety Clearing House Mechanism in China**

Decision-making in biosafety management depends upon accurate and sufficient information. However, biosafety database to be linked to the biodiversity and information sharing mechanisms are not available in China. The biosafety data needed for assessing and managing risk are scattered in different ministries that are inaccessible to the public and are difficult to retrieve. Hence, it is necessary to organize, integrate, and develop existing information and make it accessible to decision-makers, managers, the public and scientists. A complete database providing basic information is essential in order to implement Article 23. The database needs to take into account policy and provide a mechanism for information sharing so as to ensure the safe management of LMOs. The Database and the Clearing House must be set up to so that:

- There is a unique identifier for living modified organisms that can be the same in all countries
- It provides details of approvals for field trials of LMOs within China, including a summary of the risk assessment;
- It provides details of approvals of LMOs within China, including a summary of the risk assessment;
- It provides information about imported or exported LMOs;

A website which provides the policies, laws, planning, priority and measures for biosafety management in China, mechanisms for searching the database for LMOs, and links to the main biosafety Web sites in the world and in the country will be set up. The biosafety clearing house will be accessible from the web.

#### 4. Workshops and training courses

Many of those who will have to be decision-makers, managers, customs officials and the public in China are short of knowledge and experience of biosafety management. Although expert in their fields, the use of their expertise to ensure safety needs training and confidence-building. They need to be trained to understand how to assess the benefits and potential risks of LMOs, and the principles to both determine the risks and the methods that may be used, where appropriate to minimise the identified risk to either human health or to the environment. Article 23 of the Cartagena Protocol requires member countries to ensure public participation in the decision making process. In particular, countries are expected to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

A professional team will be needed to carry out risk assessments. This team must be set up, and provided with the tools to allow them to ensure the safe use, import or export of any LMOs. Although China is advanced in the application of modern biotechnology, little attention has hitherto been given to biosafety and risk management. It is, therefore, imperative to hold a series of training activities in order to improve human resource capacity for biosafety. The main activities that are needed include:

- **Two workshops for 50 people with 2 international consultants per workshop (3 days and 7 days workshop respectively)** aiming at identifying the likely impact of Cartagena Protocol on China's eco-environment; the WTO and biosafety, biosafety regulation, technologies and methods for risk assessment and risk management of LMOs, monitoring of LMOs, biosafety Clearing House Mechanism, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity; exchanging update information and discussing new problems occurring in biosafety management or risk assessment. Best practices and lessons learnt will be discussed and disseminated. The workshops will involve experts, the civil society, including NGOs, private sector and the scientific community. The activities will require proven expertise in these disciplines, and there is, therefore a need to involve a small number of external experts to provide the vital training and support.
- **Training for appropriate personnel assisted by international experts:**
  - A two-weeks training for 8 decision-makers and managers to learn about the policies, legislation, institutional arrangements, operational mechanism and research program for biosafety;
  - A one-month training for scientists in risk assessment and monitoring of LMOs.
- **A three-days training course for 50 customs officials and managers** introducing general information, laws, regulations, policies, guidelines and practice of domestic and foreign biosafety management; introducing the procedures for the application and approval of LMOs.
- **Two seven-days training course for 30 inspectors:** Provision of information on the Laws, regulations and procedures of biosafety management at home and abroad; introducing basic theories and methods for risk assessment and risk management as well as monitoring technologies; visiting typical biosafety pilot sites of transgenic organisms.



## **Sustainability analysis and risk assessment**

Once completed, the project will be self-sustainable. By the time the project will be finalised, in fact, the biosafety management structure developed will be translated into a legislative framework that, once officially approved, will be binding.

The risks associated with the implementation and successful outcome of this project can be described in four general categories: rapid expansion of the LMOs market; legislation updating; core project regulatory activities updating; capacity building; knowledge and information.

In fact, China is about to join the WTO and this represents a key issue to consider. Given the growing expansion of the LMOs market and the strong potentialities that it offers in economic terms for China as well as for many other countries, it will be extremely important to guarantee that the legal framework keeps on reflecting the market reality. This legal framework will need a constant review based on the new coming scientific evidence associated to the risk of any new LMOs being used/commercialised in and outside the country. Accordingly, the indicators and monitoring methods selected and adopted for the risk assessment and management as well as the in-use Technical Guidelines developed in order to provide guidance in the implementation of the "Biosafety Regulation of the People's Republic of China" would have to be continuously updated. Research activities relating to LMOs release, use, commercialisation will be extremely important and China is providing an adequate support in this respect. To date estimates speak about a 3.000.000USD being under disbursement for research activities.

Finally, there is a common lack of basic information on LMOs release and use. This information is needed to set regulatory frameworks and to determine risk management strategies. This project has been designed to address this risk by using data assessment tools, to set up an information system, manage and use existing scientific knowledge effectively, and to focus on training and information sharing activities. A capacity -building component is specifically foreseen within the project. It is addressed to all those involved in the biosafety-related activities, i.e. decision-makers, customs-officials, inspectors and scientists. It is strongly believed that it will guarantee a solid basis for setting up a good biosafety management. However, it will need as well further development and updating through further training activities, workshops and national/international meetings. It is no doubt that the implementation of the National Biosafety Framework for China will have a wider effect at global level than that one strictly limited to the country itself: China will be a major counterpart for any forthcoming activity on biosafety and this guarantees its involvement in all the major activities carried out in the sector worldwide.

## **Stakeholder involvement and social assessment**

The project is addressing policy-makers, government departments and all the institutions (including research centres and universities) involved in the biosafety management system in China. Their involvement insure a high level acceptance of the legislation "Biosafety Regulation of the People's Republic of China" due to be approved by the State Council during the development of the project. At present, in fact, China has issued several regulations at departmental level, but they do not address import and export of LMOs and an Integrated Biosafety Regulatory structure at national level is still lacking. Customs-officials, inspectors, managers and scientists, who are to be involved in

- 1) the provision of general information, laws, regulations, policies, guidelines and practice of domestic and foreign biosafety management;
  - 2) introducing the procedures for the application and approval of LMOs,
- are going to be important stakeholders as well. Their pro-active participation to all the capacity building activities foreseen in the project and their direct involvement in different phases of the biosafety management system (inspection, custom clearance, application of the existing regulations, etc.) will guarantee the needed support for the Biosafety Framework to be effectively implemented.

The access of the general public to biosafety related information and ongoing activities is also considered a key issue: besides mass media, a user -friendly website will be set up and connected to the Clearing House Mechanism.

## INCREMENTAL COST ASSESSMENT

- According to the "Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety" approved by the GEF Council in November 2000, it is foreseen that GEF will undertake country-based demonstration projects to assist in the implementation of a country's national biosafety framework. China is in need to carry out such an activity now, profiting from the political momentum that makes of biosafety one of the highest priority in the country. China has placed high attention to the biosafety sector over the last decade and an estimate of the past activities and related investments in the sector include:
  1. Training activities for an amount of around USD900,000;
  2. Workshops and meetings for around USD1,000,000;
  3. Activities aiming at building up a biosafety regulatory system for around USD700,000;
  4. Data collection and development of a database for an estimated amount of around USD800,000;
  5. Research projects are estimated at around 3,000,000, of which 1,800,000 devoted to risk assessment and monitoring.
- As already stated, this project follows up to the previous GEF-funded enabling activity "Development of a National Biosafety Framework" carried out over the past two years in eighteen pilot countries. China, being one of these pilot countries, has performed extremely well and has actively contributed in terms of efforts, time spent and results achieved to promote biosafety issues management at national level. China's in-kind contributions to mentioned project have amounted to around USD300,000.
- 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 (B)	Alternative (A)	Increment (A-B)
<i>The Establishment of legislation system and operational mechanism of biosafety management in China</i>	China has got sector specific regulations in place but no national one. A LMOs Regulation has been drafted. The involvement of many ministries and sections of government makes the biosafety management system quite difficult.	A national "Biosafety Regulation of the People's Republic of China" meeting the requirements of the Cartagena Protocol finalised and submitted	To support the correct implementation of the Cartagena Protocol, a revision of the draft regulation to include the requirements of the Protocol as well as the co-ordination of the biosafety activities among different Governing bodies and organisations involved is needed.
<i>Risk Assessment Management of LMOs: Technical Guidelines and Strengthening of national facilities</i>	Mechanisms for risk assessment, risk management, are in the very early stages of development and need to be defined. SEPA, other central government departments and the National Science Foundation support with small projects the development of guidelines for LMOs risk assessment and	Technical Guidelines as well as indicators and monitoring methods for environmental risk assessment management and monitoring will be finalised and published. Pilot development of monitoring parameters/indicators and monitoring methodology in fields for transgenic cotton <sup>3</sup>	Risk assessment and management is improved once guidelines, indicators, monitoring methodologies have been defined as well as laboratories properly equipped. A pilot use of the selected monitoring indicators and monitoring methodology in fields for transgenic cotton <sup>4</sup> is

<sup>3</sup> This pilot case study on transgenic cotton will be developed because 1) transgenic cotton has been approved for commercial release in China and 2) there are many hectares of transgenic cotton planted than of any other transgenic crops in China.

	management, which are still in first draft.China has established National Key Laboratories on Biosafety, such as the National Key Laboratory on Biosafety at Nanjing Institute of Environmental Sciences under the SEPA and National Key Laboratories at related ministries, which still lack some of the equipment needed for the purpose of LMO risk assessment, environmental monitoring and safety inspections as requested by the Cartagena Protocol.	carried out. National Key Laboratories on Biosafety will be strengthened with the equipment needed for the purpose of LMO risk assessment and environmental monitoring.	extremely important for assuring their effective applicability.
<i>The Establishment of a Biosafety Database system to serve for the purpose of the Biosafety Clearing House Mechanism</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, collection of the related information, the opening of a user-friendly web site are the basic activities needed to make the Central BCHM as structured in the Protocol operational
<i>Training courses and workshops for decision-makers, customs-officials, inspectors and scientists</i>	Lack of adequate knowledge among those involved in the management of bio safety activities of the Cartagena Protocol	Capacity strengthened through specific training courses and workshops organised for decision-makers, scientists, technical and other relevant target groups	Strengthened national capacity to ensure the correct fulfillment of the commitments coming from the Cartagena Protocol

As shown in the table below, the cost of the increment is of **USD 1,266,400** of which **USD997,400** is being requested from the GEF; the remaining **USD269,000** is provided as in-kind contribution by China.

*Table 1 - Incremental Cost Table (US\$)*

<b>Project components</b>	<b>Baseline</b>	<b>Alternative</b>	<b>Increment</b>	<b>Cost to GEF (Global Benefit)</b>	<b>Co-financing (in-kind contributions from China)</b>
<i>The Establishment of legislation system and operational mechanism of biosafety management in China</i>	900,000	1,143,000	243,000	<b>198,000</b>	<b>45,000</b>
<i>Risk Assessment Management of LMOs: Technical Guidelines and Strengthening of national facilities</i>	800,000	1,226,000	426,000	<b>361,000</b>	<b>65,000</b>
<i>The Establishment of a Biosafety Database system and a Clearing House Mechanism in China</i>	100,000	300,000	200,000	<b>135,000</b>	<b>65,000</b>
<i>Training courses, workshops and study tour for decision-makers,</i>	---	397,400	397,400	<b>303,400</b>	<b>94,000</b>

<sup>4</sup> This pilot case study on transgenic cotton will be developed because 1) transgenic cotton has been approved for commercial release in China and 2) there are many hectares of transgenic cotton planted than of any other transgenic crops in China.

<i>customs-officials, inspectors and scientists</i>					
<b>Total</b>	1,800,000	3,066,400	1,266,400	<b>997,400</b>	<b>269,000</b>

The implementation of a National Biosafety Framework for China will not only be of relevance for the region in which it will be applied, but also to other regions of the world. The legal framework will provide guidance for the LMOs use and the model set up can become a reference for all nations as they seek to adopt a biosafety framework in their own country.

## PROJECT BUDGET

### BUDGET

<b>The Establishment of legislation system and operational mechanism of biosafety management in China</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind BY China</b>	<b>Total</b>
<b>The establishment of the operational mechanisms for biosafety management in China</b>						
Pre-preparation of project documents	28000			28000		28000
The establishment of the Project Coordination Committee	5000			5000		5000
The establishment of project management office	10000			10000	10000	20000
The Coordination and management of the project	15000	10000	15000	40000	10000	50000
<b>Policy study on the environmental release and transboundary movement of LMOs</b>						
Investigation on the environmental release of LMOs in China	15000			15000		15000
Investigation on the release of LMOs in China	15000			15000		15000
Investigation on the transboundary movement of LMOs in China	10000			10000		10000
Analysis of data obtained during the investigation	10000			10000	10000	20000
Impact of the Cartagena Protocol on China's environment	10000			10000		10000
Impact of the entry of WTO on biosafety management in China and related requirements	10000			10000		10000
Policies of the environmental release and transboundary movement of LMOs	10000			10000		10000
<b>The Biosafety Regulation of the People's Republic of China</b>						
Coordination of legal needs of ministries relating to biosafety management	10000			10000	10000	50000
Compilation of the draft regulation	15000			15000		15000
Discussion and revision of the regulation and submission to the State Council		2000	8000	10000	5000	15000
<b>Subtotal</b>	<b>163000</b>	<b>12000</b>	<b>23000</b>	<b>198000</b>	<b>45000</b>	<b>243000</b>

<b>Technical Guidelines for Risk Assessment and Risk Management of LMOs</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind by China</b>	<b>Total</b>
<b>Guideline for risk assessment and risk management of living modified animals</b>						
Development of information inventory of environmental risk of living modified animals	2000	2000	1000	5000		5000
Development of indicators and its monitoring methods for environmental risk assessment of living modified animals	6000	6000	3000	15000		15000
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified animals	6000	6000	3000	15000		15000
Development of technical measures and methods for risk management of environmental releases of living modified animals	2000	4000	4000	10000		10000
<b>Guideline for risk assessment and risk management of living modified plants</b>						
Development of information inventory of environmental risk of living modified plants	2000	2000	1000	5000		5000
Development of indicators and its monitoring methods for environmental risk assessment of living modified plants	6000	6000	3000	15000		15000
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified plants	6000	6000	3000	15000		15000
Development of technical measures and methods for risk management of environmental releases of living modified plants	2000	4000	4000	10000		10000
<b>Guideline for risk assessment and risk management of living modified microorganisms</b>						
Development of information inventory of environmental risk of living modified microorganisms	2000	2000	1000	5000		5000
Development of indicators and its monitoring methods for environmental risk assessment of living modified microorganisms	6000	6000	3000	15000		15000
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified microorganisms	6000	6000	3000	15000		15000
Development of technical measures and methods for risk management of environmental releases of living modified microorganism	2000	4000	4000	10000		10000
<b>Revision and Publication of Technical Guidelines</b>						
Hold meeting to discuss and revise the proposed technical guidelines (20 people)			16000	16000	10000	26000
Publication of technical guidelines			10000	10000		10000
Translation of technical guidelines into English			8000	8000		8000
<b>Subtotal</b>	<b>48000</b>	<b>54000</b>	<b>67000</b>	<b>169000</b>	<b>10000</b>	<b>179000</b>

<b>Environmental Monitoring of Transgenic Cotton</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind by China</b>	<b>Total</b>
<b>The establishment of monitoring parameters/ indicators for transgenic cotton</b>						
Literature retrieval of monitoring indicators for transgenic plants, including morphological, physiological, biochemical, genetic and ecological indicators	5000			5000		5000
Design of monitoring indicators for transgenic cotton	5000			5000		5000
Meeting to discuss the proposed indicators (10 people)	8000			8000	5000	13000
<b>The establishment of monitoring methodology for transgenic cotton</b>						
Analysis of monitoring methods for transgenic plants	5000			5000		5000
Design of monitoring methods for transgenic cotton	5000			5000		5000
Meeting to discuss the proposed monitoring methods (10 people)	8000			8000	5000	13000
<b>Monitoring of transgenic cotton in pilot fields</b>						
Overall design for monitoring of transgenic cotton in pilot fields	10000			10000		10000
Purchase and install monitoring equipment	100000			100000	20000	120000
Monitoring of transgenic cotton	4000	8000	8000	20000	20000	40000
Data analysis		5000	5000	10000		10000
Submission and publication of working reports and research achievements			6000	6000	5000	11000
Translation of reports and achievements into English			10000	10000		10000
<b>Subtotal</b>	<b>150000</b>	<b>13000</b>	<b>29000</b>	<b>192000</b>	<b>55000</b>	<b>247000</b>

<b>The Establishment of Biosafety Database System and Clearing House Mechanism in China</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind by China</b>	<b>Total</b>
<b>Policies and mechanism for information sharing and information security management of LMOs</b>						
Policies and mechanism for information sharing of LMOs	5000			5000	10000	15000
Policies and mechanism for information security management of LMOs	5000			5000	10000	15000
The establishment of unique identifier for transgenic organisms	10000			10000	5000	15000
<b>Development of databases of LMOs in China</b>						
Environmental release database of LMOs	4000	10000		14000		14000
Commercial release database of LMOs	4000	10000		14000		14000
Database of import and export of LMOs	4000	8000		12000		12000
<b>The development of biosafety website of China</b>						
Collection of materials and information of policies, laws, planning and measures of biosafety management in China	10000			10000		10000
Purchase of web servers and computers	40000			40000	30000	70000
Design of biosafety website of China	4000	6000		10000		10000
Management of biosafety website of China	4000	6000	5000	15000	10000	25000
<b>Subtotal</b>	<b>90000</b>	<b>40000</b>	<b>5000</b>	<b>135000</b>	<b>65000</b>	<b>200000</b>

<b>Training courses and workshops for decision-makers, customs officials, inspectors and scientists</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind by China</b>	<b>Total</b>
<b>Training</b>						
Training 8 decision-makers and officials,	47000			47000	10000	57000
Training on risk assessment and monitoring of LMOs	27000			27000	40000	67000
<b>Workshops</b>						
Workshop to initiate the project	51200			51200	10000	61200
Workshop to discuss the achievements of the project, best practices and lessons learnt			51200	51200	10000	61200
<b>Training courses</b>						
Training course for customs officials and managers		45000		45000	10000	55000
Training course for inspectors		41000		41000	7000	48000
Training course for inspectors			41000	41000	7000	48000
<b>Subtotal</b>	125200	86000	92200	303400	94000	397400

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total GEF</b>	<b>In-kind by China</b>	<b>Total</b>
<b>TOTAL</b>	576,200	205,000	216,200	997,400	269,000	1,266,400



Technical Guidelines for Risk Assessment and Risk Management of LMOs	Year 1	Year 2	Year 3
<b>Guideline for risk assessment and risk management of living modified animals</b>			
Development of information inventory of environmental risk of living modified animals			
Development of indicators and its monitoring methods for environmental risk assessment of living modified animals			
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified animals			
Development of technical measures and methods for risk management of environmental releases of living modified animals			
<b>Guideline for risk assessment and risk management of living modified plants</b>			
Development of information inventory of environmental risk of living modified plants			
Development of indicators and its monitoring methods for environmental risk assessment of living modified plants			
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified plants			
Development of technical measures and methods for risk management of environmental releases of living modified plants			
<b>Guideline for risk assessment and risk management of living modified microorganisms</b>			
Development of information inventory of environmental risk of living modified microorganisms			
Development of indicators and its monitoring methods for environmental risk assessment of living modified microorganisms			
Methods of identification, estimation, predication and comprehensive benefit analysis for risk of living modified microorganisms			
Development of technical measures and methods for risk management of environmental releases of living modified microorganism			
<b>Revision and Publication of Technical Guidelines</b>			
Hold meeting to discuss and revise the proposed technical guidelines (20 people)			
Publication of technical guidelines			
Translation of technical guidelines into English			



<b>The Establishment of Biosafety Database System and Clearing House Mechanism in China</b>	Year 1						Year 2						Year 3						
<b>Policies and mechanism for information sharing and information security management of LMOs</b>																			
Policies and mechanism for information sharing of LMOs																			
Policies and mechanism for information security management of LMOs																			
The establishment of unique identifier for transgenic organisms																			
<b>Development of databases of LMOs in China</b>																			
Environmental release database of LMOs																			
Commercial release database of LMOs																			
Database of import and export of LMOs																			
<b>The development of biosafety website of China</b>																			
Collection of materials and information of policies, laws, planning and measures of biosafety management in China																			
Purchase of web servers and computers																			
Design of biosafety website of China																			
Management of biosafety website of China																			



## **PUBLIC INVOLVEMENT PLAN**

### **Stakeholder identification**

Primary national stakeholders of the project are government bodies, including the national counterparts (in particular SEPA, the State Environmental Protection Administration) and the ministries involved in the biosafety management system. The successful implementation of this project will require these stakeholders to work closely with other organisations, institutions, and agencies in order to implement from one side the framework developed and from the other side to proceed with research and updating on new LMOs release and monitoring methodologies. This collaboration will be particularly important in activities associated with the development of information systems, priority setting, awareness raising and policy development, methodology testing .

Benefiting of the results of the pilot project, the current proposal has been developed over a year period and involved consultations and meeting with government Ministries and State Agencies.

### **Information dissemination and consultation**

Specific project components are dedicated to communications, information and dissemination. International workshops, training and research activities will be accompanied and supported by information materials, web updating (a specific biosafety website for China will be set up as part of the project component "The Establishment of a Biosafety Database System and Clearing House Mechanism in China") and feedback to the public on actions and advances in research and follow-up of this initiative.

### **Social and participation issues**

The primary direct stakeholder of the project are the government policy makers while the main beneficiary will be the global community itself. Wide public involvement will be facilitated by the establishment of the web page, which will provide information on the project activities but also invite for comments and feedback.

It is worth mentioning that the Chinese Government has actively taken part to the GEF-funded Pilot Project "Developing of a National Biosafety Framework" and has expressed strong interest in following it up with an implementation phase. The proposed project will assist in setting up a legal mechanism that will guarantee to the country autonomy in biosafety related issues management and will represent an important reference for all developing countries.

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

## **LIST OF ANNEXES**

- ANNEX 1** Summary of the 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**

### **China: Summary of the National Biosafety Framework**

#### **The development and adoption of China's NBF**

Under the auspices of UNEP through GEF, the project of National Biosafety Framework of China was led by the State Environmental Protection Administration (SEPA) and involved many relevant departments during 1998 and 1999. To ensure the smooth implementation of the project, an Interdepartment Coordinating Group was established based on the consultation with relevant departments. This group was composed of the officers-in-charge from different departments, and acted as the steering committee for this project. Its main responsibilities were to coordinate the work by different departments in undertaking project activities and deal with the problems arising in the process of project implementation. SEPA is the leading department of this steering committee and its members include the Ministry of Agriculture (MOA), Ministry of Education, Ministry of Science and Technology (MOST), Ministry of Foreign Trade and Economic Cooperation (MOFTEC), State Forestry Administration, Chinese Academy of Sciences (CAS) and the State Drug Administration. A project office was established in Department of Nature and Ecology Conservation, SEPA, which deals with the routine work relating to the project implementation. A panel was also established composed of more than 30 experts from different disciplines and sectors, such as biotechnology, botany, zoology, microbiology, agriculture, forestry, aqua-culturing, environment, foreign trade, medicine, law and economics. The task of this panel was to implement the project, including the survey and data collection, analysis of current situation, drafting sectoral survey reports and the final report for this Framework.

One working meeting on this project was organized on August 11, 1998. The members of the project coordinating group and relevant experts participated in this meeting. This meeting discussed about and decided on the TOR and work plan. An international workshop and two national workshops on biosafety were held to exchange the practice and experience of biosafety management home and abroad, and to discuss the draft of NBF. Representatives from related departments, provinces, local governments, local communities and NGOs participated in these meetings and provided their suggestions and comments. These experiences, suggestions and comments played an important role in the formation, revision and finalization of NBF.

The meeting of the National Coordinating Group for Implementation of CBD of China, which is lead by SEPA and composed of 20 departments under the State Council, was convened on Sept. 28, 1999 for examination of the draft of NBF. NBF was adopted at this meeting. It was agreed that NBF would play an important role in guiding the policy, institutional arrangement and measures in the field of biosafety management. The Ministry of Foreign Affairs, China, finally approved the National Biosafety Framework.

The principles and frameworks of policies, regulations, guidelines, management and capacity building on biosafety are disseminated across the country. NBF has been adopted by many departments and is implemented progressively in China.

#### **I. Policy Framework of National Biosafety Management**

### *1.Objectives for national biosafety management*

The overall objective for national biosafety management is to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected in a maximum way while promoting the research, development and commercialization of modern biotechnology and regulating the transboundary movement of the products resulting from modern biotechnology through formulation of relevant policies, regulations and technical guidelines and establishment of management bodies and supervisory mechanism.

### *2 Main principles for national biosafety management*

These principles include: (1) the principle of encouraging research and development combined with the precautionary approach which means that the development of modern biotechnology and the trade of modern biotechnology products will be promoted taking into full consideration the protection of biodiversity, human health and environmental security; (2) the principle of prevention as priority which means that all the phases of modern biotechnology development will be strictly managed and all the potential risks reduced in the initial stage; (3) the principle of coordination and cooperation between departments which means that the communications and coordination between different departments and disciplines will be strengthened; (4) the principle of adopting science-based management which means that the risk assessment and management will be based on full scientific evidence; (5) the principle of public participation which means that the public will be important players of biosafety management and supervision; and (6) the principle of promoting actively the international negotiations concerning a Biosafety Protocol and other related international activities.

### *3 Targets and methods of biosafety management at the national level*

The targets of biosafety management are the living modified organisms and their products resulting from biotechnology through introducing the restructured DNA into the organic bodies by physical, chemical and biological means or applying the technique of using the restructured DNA in the receiving organism. The methods of biosafety management include (a) dividing into several phases the activities of modern biotechnology, such as lab research, pilot testing, environmental release, commercialization, transportation, use and waste disposal and classifying LMOs by four risk levels according to their potential risks and adopting differentiated risk management practice according to different levels; (b) biosafety management on a case-by-case basis and adoption of different measures according to the differences in the receiving organisms, genetic operation, proposed applications and the conditions of receiving environment and the approval of the work for the next phase based on the safety assessment results of the previous phase.

### *4. Policy for development and marketing of products resulting from modern biotechnology*

The overall guiding principle for the development and marketing of LMOs and their products is to promote the research, development, production, sales and use of the products resulting from modern biotechnology and the introduction of foreign products from modern biotechnology on the basis of protecting biodiversity, human health and ecology, taking into consideration the situation of China and its international obligations. The specific policy for the development and marketing of the products resulting from modern biotechnology include: (1) encouraging and supporting those products without risks; (2) taking precautionary approach to those products with low risks; (3) limiting those products with intermediate risks; (4) banning those products with high risks; and (5) requiring

special packaging and labeling for the transportation and sales of the products according to the different risk levels and the needs for risk management.

#### *5. EMS for the release of products resulting from modern biotechnology*

The environment management system (EMS) will be gradually established for the research, development, environmental release and commercialization of LMOs and their products. EMS includes mainly: (1) requiring advanced informed agreement for the transboundary movement of LMOs; (2) establishing the rule of liability and redress for the accidents caused by LMOs; (3) requiring a report of environmental impact assessment for the environmental release of LMOs; (4) establishing the environmental monitoring and supervisory system and the emergency response system for the environmental release of LMOs; and (5) the public participation in the management of biosafety.

### **? . Regulatory Framework of Biosafety Management in China**

#### *1. Assessment of existing regulations governing biosafety*

In the past few years, some departments under the State Council have formulated and promulgated some administrative regulations. They include the Regulation Concerning Safety of Genetic Engineering, which was promulgated by the former State Commission on Science and Technology (1993), the Regulation Concerning Safety of Agricultural Genetic Engineering issued by the Ministry of Agriculture (1996), the Provisional Regulation Concerning Management of Anthropological Genetic Resources which was jointly issued by the Ministry of Science and Technology and the Ministry of Health in 1998, and the Regulation Concerning Approval of New Biological Pharmaceuticals issued by the State Drug Administration in 1999. Some experience has been collected in enforcing these regulations. However, compared with those developed countries in the West, the biosafety legislation in China is relatively late and there is much room to be improved for biosafety management in China. For example, a regulatory system is needed at the national level in terms of legal construction, and a set of effective management rules are also short in terms of management and supervision. In addition, the capacity building for biosafety management at the national level should be strengthened.

#### *2. Regulatory system for biosafety*

The national regulatory system of biosafety will be composed of different levels of legislation, namely national law, regulations and administrative regulations. They mainly include a law of biosafety ratified by the National People's Congress or a regulation concerning biosafety issued by the State Council, the administrative regulations issued by the relevant departments under the State Council specially for biosafety and some departmental and local procedural and management rules which are drafted to enforce the national law and regulation.

#### *3. Main content of national regulation concerning biosafety*

In the above regulatory system, what is most urgently needed currently is a national law or regulation governing biosafety as an overarching regulation for biosafety management at the national level. The main content of the proposed law will include: (1) a management procedure according to which one national competent authority for biosafety management will unify the management and supervision and the sectional departments manage their assigned responsibility; (2) a clear requirement that the activities of all phases ranging from the research, pilot

testing, environmental release, commercialization, application to transboundary movement shall go through safety assessment and providing the content and procedure of risk assessment; (3) providing that the developers of biotechnology and its products must report to the relevant authorities by following relevant procedures of reporting according to different phases of activities and approval by different levels of authorities according to their different risk levels: (4) providing the specifications and requirements for risk management and requiring that different risk management measures will be adopted for different phases of activities.

#### *4. Principles for formulating departmental specialized regulation concerning biosafety*

Based on the national law or regulation concerning biosafety, the relevant authorities under the State Council will promulgate specialized regulations for biosafety management. While formulating such a regulation, the following principles should be followed.

- (1) Principle of differentiated management. Different regulations for biosafety management will be formulated for the sectors of agriculture, pharmaceutical and food, which are categorized according to the sectional application of modern biotechnology and the direction of modern biotechnology development.
- (2) Principle of reflecting sectional characteristics. Different systems of biosafety assessment will be established for different sectors according to different activities of modern biotechnology and proper safety control measures adopted according to different categories of LMOs and their products and different safety levels.
- (3) Principle of making enforcement easy. The regulation will be drafted in the way it will be enforced easily and effectively by drawing upon the experience, research and experiment data and effective control measures adopted in other countries and taking into consideration the real situation and sectoral characteristics of China.

#### *5. Market management system of genetically modified products*

The market management of genetically modified products calls for a system where the national competent authority of biosafety will take a leading role and relevant sectional departments exercise their own responsibilities. For example, the Ministry of Science and Technology is responsible for the policy for development of products resulting from modern biotechnology. The State Economic and Trade Commission and the State Administration of Industry and Commerce are responsible for market management. The Ministry of Foreign Trade and Economic Cooperation is responsible for the import and export of products and foreign investment in this field. The State Customs Administration is responsible for the quarantine of the products of modern biotechnology. The Ministry of Public Security is responsible for cracking down those illegal behaviors. The Ministry of Agriculture, the Ministry of Health, the State Drug Administration and the State Forestry Administration will be responsible for the production, safety supervision and management of the products within their own responsibilities. The State Environmental Protection Administration is responsible for the coordination among departments and the safety management of the whole process ranging from environmental release, commercialization, transportation, sales to transboundary movement of genetically modified products.

#### *6. Procedures and main content of environmental impact assessment of the release of LMOs*

The main steps for conducting the environmental impact assessment of the release of LMOs are (1) to analyze the

data and survey on the site; (2) to define the terms of reference for the assessment; (3) to conduct the assessment of sources and status quo and analysis of environmental impacts; (4) to undertake the analysis of economic benefits and losses and projection of environmental impacts; (5) to compile the report or form of environmental impacts and propose the measures for control of environmental impacts; (6) to submit the report or form of EIA to the competent authority for approval. The content of assessment includes mainly the analysis of the types and characteristics of LMOs, the assessment of the status quo or the receiving organism, projection of environmental impacts, risk assessment of the damages likely to be caused by some uncertain and unanticipated accidents and environmental protection measures adopted to minimize the damages.

## **? . Framework of Technical Guidelines for Risk Assessment and Management of LMOs**

### *1. Contents of risk assessment*

- (1) The risk assessment of the release of LMOs includes the purpose and scale of release, the receiving environment, ways of release, monitoring methods and control measures. The safety levels of the release will be determined based on comprehensive assessment of these factors.
- (2) The risk assessment of the commercialization includes the safety determination of the facilities for cultivation, fermentation, separation and purification according to the safety of LMOs and their physical barriers and determination of the risk of commercialization accordingly.
- (3) The risk assessment of sales and application of products includes the safety assessment based on the biological, pharmaceutical and toxicological examination of safety and determination of their possible impacts on biodiversity, human health and ecology.

The risk assessment of the genetically modified pharmaceuticals include mainly the biological types of pathogens, the process of development and production, quality standard, method and procedure and ways and methods to apply them to human bodies. Specifically the risk assessment covers different types of pathogens, the research and development and production of genetically modified pharmaceuticals, the quality standard, method and procedure and ways and means to apply them to human bodies.

### *2. Classification and determination of risk levels*

The current risk classification for LMOs and their production is mainly based on the determination of the risk levels of the receiving organism and the selection of the types of genetic operation. Among others, the risk level is determined based on the four following levels:

Level 1: the receiving organism which has seldom yielded negative impacts on biodiversity, human health and ecology or is slightly likely to be evolved into harmful organism or almost impossible to exist in the natural environment, judging from its history;

Level 2: the receiving organism which has low risks on biodiversity, human health and ecology but whose risks can be avoided if proper measures are to be taken;

Level 3: the receiving organism which has intermediate level risks on biodiversity, human health and ecology but

whose risks can be basically avoided through adoption of risk management measures;

Level 4: the receiving organism which has high risks on biodiversity, human health and ecology but whose risks cannot be avoided for the time being even if some proper risk management measures are taken.

### *3. Control measures of risk management*

#### (1) General control measures for risk management

The control measures of risk management of LMOs and their products are divided into the physical, chemical and biological control measures if classified by the nature of control measures. Different kinds of risk management measures will be adopted towards different risk levels and in different phases of activity or various control measures combined in the process of development of LMOs and their products. For example, the physical control measures in the lab research include the four-level prevention facilities, the four-level lab design and four-level operation rules. The control measures for the pilot testing and environmental release include the general biological barriers (level ? ), the physical, chemical and biological control measures (levels ? and ? ) and emergency response in case of accidents.

#### (2) Risk management of genetically modified pharmaceuticals

The risk management of genetically modified pharmaceuticals must follow the management rules formulated by the State Drug Administration. For example, the experimental conditions for safety testing of genetic reformation must meet the specifications provided in the rules governing the quality of pre-clinical pharmaceuticals. The production of genetically reformed pharmaceuticals must completely comply with the regulations concerning the quality of pharmaceuticals and can start only the relevant certificates issued. The clinical testing of these pharmaceuticals at stages ? ,? ,? and ? must be approved by the State Drug Administration. The treatment using such a pharmaceutical must strictly follow the quality control standard for the treatment using human genetic cells and genetically modified pharmaceuticals.

### *4. Monitoring of the environmental release of LMOs*

The monitoring of LMOs includes the existence, reproduction and distribution of LMOs in the environment, the potentiality of excessive population growth; the risk of escape of transferred genes, the risk of generation of new viruses from the anti-virus LMOs and the invasion of LMOs.

The monitoring of LMOs' impacts on environment and biodiversity includes the potential impacts on ecosystems, target and non-target organisms, the risk of resistance of pests against the transferred genes and the disease-causing nature of LMOs in human bodies and other organisms.

## **? . Capacity Building for Biosafety Management at the National Level**

### *1. Priority areas of biosafety*

(1) genetically modified plants, including the genetically modified crops resistant to diseases, pests and reversion, the genetically modified agricultural crops with better quality and the genetically modified timber resistant to

diseases, pests and reversion. The relevant varieties cover cotton, rice, potato, tomato, maize, tobacco, sweet pepper and tree. The traits include resistance to pests, viruses, disease, herbicide, and better quality.

- (2) genetically modified animals, including the genetically modified sheep, cattle, chicken and worms for producing medical proteins and GM pigs for transplantation of organs and GM mouse for pharmaceutical selection, assessment modeling or studies on the mechanics of diseases.
- (3) GM aquatic organisms, including GM marine and fresh water aquatic animals, such as GM fish, shrimp, shell, plankton, with focus on biosafety issues arising from marine aquaculture.
- (4) GM microorganisms, including those with special characteristics for genetic engineering, agricultural use and used for environmental treatment, metallurgical production, oil drilling through genetic engineering and those used widely as food and feed stock additives, antibiotic and for food and industrial fermentation.

## *2. Priority actions for biosafety management at the national level*

- (1) To improve the regulatory system of biosafety management. The proposed actions include (a) formulation of a national regulation governing biosafety; (b) improvement of sectional regulation concerning biosafety; (c) establishment of the system of EIA for LMOs; (d) establishment of the system of rules for biosafety management;
- (2) To establish the technical system for risk assessment and management of LMOs, which includes mainly the method and technical system for analyzing the potential risks of LMOs, the indicator system of risk assessment and the rules for classifying the risk levels, the technical guidelines for risk assessment, the technical specifications, procedures and guidelines for risk management and the indicator system and the procedures for the environmental monitoring of LMOs, etc.;
- (3) To establish the institutional system of biosafety management which includes the three-level bodies, namely, the interdepartmental coordinating body, the competent authority and the sectoral operating body and the scientific and technical advisory bodies and the technical supporting bodies:
- (4) To establish the biosafety information system which mainly includes a series of data banks for biosafety, the clearing-house mechanism for international exchange of information and the interdepartmental mechanism of information exchange and the electronic networking for public information;
- (5) To strengthen the scientific researches on biosafety management and incorporate the biosafety studies into the national and sectoral plans for science and technology which will provide scientific evidence and basis for biosafety management;
- (6) To establish the system of biosafety monitoring which mainly includes the operational mechanism of networking of biosafety monitoring, the risk monitoring tools and processing techniques, the environmental monitoring facilities for LMOs and the specialized team for biosafety monitoring;
- (7) To undertake publicity and education which will be focused on the development of biosafety films and videos, publication of books on biosafety, holding lectures, workshops and shows on biosafety and training of

undergraduate and postgraduate students in the field of biosafety;

- (8) To undertake international cooperation in the field of biosafety which mainly includes strengthening cooperation with UNEP and other multilateral agencies, actively participating in international affairs related to biosafety, strengthening bilateral cooperation so as to learn more experience from other countries and work on more cooperative projects.

3. *The institutional framework for biosafety management at the national level*

- (1) The national institutional system for biosafety management which consists of three levels of bodies. The first level is the national coordinating committee for biosafety or its associated panels. This is a non-permanent body for interdepartmental coordination and decision making. The second level is the national competent authority and its operational body for biosafety. The government authority empowered by the State Council with such a responsibility will exercise the unified functions for biosafety management. The third level is the sectoral department related to biosafety exercising the sectoral management of biosafety.
- (2) The national coordinating body and its associated panels are led by SEPA and the members of this committee will be MOST, MOA, MOFTEC, Ministry of Health, Ministry of Education, Chinese Academy of Sciences, State Drug Administration and State Forestry Administration. The panels will be composed of the experts from different disciplines.
- (3) The national competent authority will be SEPA, which was empowered by the State Council to be the authority responsible for biosafety in 1998. Its operational body includes the national focal point for biosafety, the clearing-house for biosafety information, a body for risk assessment accreditation and a body for risk monitoring and supervision.
- (4) The sectoral authority and their panel assessment bodies. The sectoral departments will establish their own bodies for biosafety management and some panel committees according to their sectoral characteristics such as those on agriculture, forestry, medicine, food and so on.

## China

### **Biosafety Organization Framework**

The objective of the national biosafety system is to ensure an adequate level of protection in the field of the transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity and human health by:

- Establishing a policy framework and improving the legislative system for the safety management of environmental release, use and transboundary movement of LMOs and their products;
- Establishing the management mechanism to enable the safe environmental release, use and transboundary movement of LMOs and their products;
- Establishing a technical system for risk assessment and risk management to monitor environmental release, use and transboundary movement of LMOs and providing guidance for assessing and managing the related risk;
- Developing a biosafety information system and website;
- Training personnel and promoting public awareness;
- Strengthening international cooperation.

#### *Coordinating body*

As the safe environmental release, use and transboundary movement of LMOs and their products involves several sectors, the National Biosafety Management Coordinating Committee should be established, which is led by State Environmental Protection Administration (SEPA) and composed of Ministry of Science and Technology (MOST), Ministry of Agriculture (MOA), Ministry of Foreign Trade and Economic Cooperation (MOFTEC), Ministry of Health, Ministry of Education, Chinese Academy of Sciences, State Drug Administration, State Forestry Administration, Ministry of Construction which is in charge of urban afforestation and gardening, State Administration of Industry and Commerce responsible for managing commodity market, General Customs Administration which takes care of import and export, State Oceanic Administration in charge of marine resources. Besides, its members also may include State Intellectual Property Office and State Administration of Radio, Film and TV, etc. This is the highest authority on coordination and decision making for biosafety issues at national level.

#### *National Advisory Committee on Biosafety*

This committee is a scientific and technological consulting body affiliated to the National Biosafety Management Coordinating Committee, consisting of senior experts of various disciplines and fields, such as biotechnology, biology, ecology, agriculture, forestry, pharmacology, food hygiene, environmental protection, foreign trade, law, economics and ethics, etc. The task of this advisory committee is to follow the trend of and promptly provide the information of biotechnology and biosafety, provide consultation for the National Biosafety Management Coordinating Committee, examine the strategies, policies, plans, laws, regulations, standards, guidelines on biosafety, prepare recommendations for risk assessment to human health and environment, examine transboundary movement of LMOs and their products, and to complete other tasks entrusted by the National Biosafety Management Coordinating Committee.

#### *National Competent Authority*

Biosafety is an important part of the implementation of the CBD. SEPA is the leading agency for implementation of the CBD. SEPA is empowered the national competent authority on biosafety issues by the State Council in 1998. The tasks of SEPA include: implementing the Protocol, formulating and supervising the implementation of biosafety policies, laws, regulations, standards, and guidelines, accepting, evaluating and approving applications of environmental release, use and transboundary movement of LMOs, organizing personnel training, enhancing public awareness, and developing international cooperation. The National Biosafety Management Office will be established in SEPA to act as the secretariat of the National Biosafety Management Coordinating Committee and the National Advisory Committee on Biosafety, and to conduct routine work of national biosafety management. Its operational body includes the national focal point for ICCP

and the biosafety clearing house.

#### *Sectoral Biosafety Responsible Organizations and Expert Review Bodies*

The specialized operating body should be set up to manage biosafety issues in the administrative departments relating to biosafety. These departments include MOST, MOA, MOFTEC, Ministry of Health, Ministry of Education, Chinese Academy of Sciences, State Drug Administration, State Forestry Administration, Ministry of Construction, General Customs Administration, and State Oceanic Administration. The tasks of sectoral biosafety responsible organizations include: managing biosafety issues in its own department under the coordination of the National Biosafety Management Coordinating Committee, implementing national strategies, policies, and tasks on biosafety, drawing up departmental strategies, action plans, guidelines, and rules, reviewing environmental release, use and transboundary movement of LMOs within their responsibilities, training personnel, and strengthening capacity building of the department.

Based on specific biosafety issues, sectoral expert review committees need to be set up, such as committees on LMOs in agriculture, forestry, medicine, food, etc. The tasks of sectoral expert review committees include drawing up sectoral biosafety standards, guidelines, rules, and regulations, reviewing the risk grade of LMOs, examining the safety of release, use and transboundary movement of LMOs, offering risk management measures, and providing consultation and services for departmental biosafety management.

#### *Legislative system*

China has issued several regulations at departmental level, but they do not address import and export of LMOs and an integrated biosafety regulatory structure at national level is still lacking. A large-scale investigation will be initiated to provide basic information of environmental release, use and transboundary movement of LMOs and their products in China. The benefits and potential risk will be analysed. The impact of the Cartagena Protocol on Biosafety on China's biotechnology industry and eco-environment will be assessed. The impact of the entry to WTO on China's biosafety management and related requirements will be analysed. Strategies and policies concerning the environmental release, use and transboundary movement of LMOs will be put forward. The China Biosafety Regulation will be drafted, and it will be submitted to and promulgated by the State Council. Departmental regulations on biosafety will also be drafted and promulgated. Specific rules and management methods, such as rules on environmental impact assessment, evaluation and approval, labeling, permit, import and export, packaging, transportation, and waste disposal, will be promulgated and implemented.

#### *Risk assessment and risk management*

Guidelines for risk assessment and risk management of living modified animals, plants and microorganisms will be drafted and used as guidance for application, appraisal, approval, monitoring of environmental release, use and transboundary movement of LMOs.

Application for the environmental release, use and transboundary movement of LOMs and their products should be sent to applicant's administrative department which will carry out preliminary assessment of the application and prepare recommendation for approval of the application for SEPA. Each application must contain the assessment of risk to environment and suggested procedures of risk management. All costs connected with risk assessment are the obligation of the applicant.

The National Advisory Committee on Biosafety will prepare and suggest a list of experts for evaluation and review of applications submitted through relevant departments. This list should consist of the best experts available in each field and should also include, if possible, experts with different views on the release, use and transboundary movement of LMOs. In addition, the advisory committee would have the possibility to ask for additional experts, outside this list for evaluation of specifically difficult applications. The National Biosafety Management Office will prepare an appraisal report according to the evaluation of experts for SEPA. SEPA takes the decision and publishes it in an official journal.

National institutions will be entrusted to monitor the adverse impact of environmental release, use and

transboundary movement of LMOs on biodiversity, the environment and human health.

*Information management*

Biosafety data needed for assessing and managing risk are scattered in different ministries that are inaccessible to the public and are difficult to retrieve. Information and data distributed in different departments, institutions and regions will be organized, integrated, and developed into a database system that will be accessible to decision-makers, managers, the public and scientists. The database needs to take into account policy and provide a mechanism for information sharing so as to ensure the safe management of LMOs. The database provides details of approvals for release and use of LMOs within China, including a summary of the risk assessment, and provides information about imported or exported LMOs.

A website will be established which provides the policies, laws, planning, priority and measures for biosafety management in China, provides mechanism for searching the data of LMOs and their products, and links to the main biosafety websites in the world and China.

*Training and public awareness*

Decision-makers, managers, customs officials and the public in China are short of knowledge and experience of biosafety management. They need to be trained to understand the benefits and potential risks of LMOs, and the principles to both determine the risks and the methods that may be used, where appropriate to minimise the identified risk to either human health or to the environment. Representatives from relevant departments, institutions, local governments, local communities, and NGOs will be invited to participate in training courses and workshops to enhance their capacity and awareness.

## ANNEX 2

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

Proposed activities		Provision in China's NBF	Provision in the Protocol
A	Establish the legislation system, administrative mechanism and management system for biosafety in China	Priority actions to formulate national biosafety regulation, improve sectoral biosafety management rules, set up an EIA system, set up biosafety management system are identified in Section 4.2 of the NBF, and are listed as priority projects in Annex III of the NBF.	<i>Article 2, paragraph 1</i> : take the necessary and appropriate legal, administrative and other measures to implement obligations under the Protocol; <i>Article 2, paragraph 2</i> : ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biodiversity, taking also into account risks to human health; <i>Article 2, paragraph 4</i> : take action that is more protective than called for in the Protocol;
a.1	Develop and test the administrative mechanisms for biosafety related activities among different Governing bodies and organisations	Interdepartmental coordinating body, the national competent authority and sectoral biosafety responsible organizations should be established and put into sound operation, as stipulated in Section 4.2.3 of the NBF.	<i>Article 6, paragraph 1</i> : right of any party of transit to regulate the transport of LMOs through its territory and to communicate any decision regarding transit to the Biosafety Clearing House; <i>Article 7</i> : application of the advanced informed agreement procedure; <i>Article 8</i> : Party of export to notify competent national authority of Party of import prior to the intentional transboundary movement of a LMO;
a.2	Undertake a policy study on the handling, environmental release, use and transboundary movement of LMOs in China;	The importance and framework of policies of national biosafety management was clarified in Chapter I of the NBF. These are listed as Priority Project 1 in Annex III of the NBF.	<i>Article 9</i> : Party of import to acknowledge receipt of notification and of whether it will proceed according to its domestic regulatory framework or the decision procedure under the Protocol;
a.3	Review and integrate existing regulation on biosafety management (mostly at department level), compilation and submission of the "Biosafety Regulation of the People's Republic of China" and departmental regulations and rules on the handling, environmental release, use and transboundary movement of LMOs according to the Cartagena Protocol and Chinese needs;	The integrated national biosafety regulation, sectoral biosafety regulations and rules should be established and implemented, as stipulated in Section 4.2.1 of the NBF. These are listed as Priority Project 1 in Annex III of the NBF.	<i>Article 10</i> : take decision on import in accordance with risk assessment provisions of the Protocol and inform the notifier whether the intentional transboundary movement may proceed; <i>Article 12</i> : review of a decision regarding an intentional transboundary movement in light of new and relevant scientific or technical information or a change in circumstances that may influence the outcome of the risk assessment; <i>Article 16, paragraph 1</i> : establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol;
a.4	Design and implement biosafety management system of environmental impact assessment, evaluation and approval, labeling, permit, import and export, packaging, transportation, and waste disposal.	The biosafety management system should be established and implemented, as stipulated in Section 4.2.1 of the NBF. It is listed as Priority Project 1 in Annex III of the NBF.	<i>Article 19</i> : designation of one national focal point and competent national authorities; <i>Article 25</i> : preventing and, if appropriate, penalizing transboundary movements carried out in contravention of domestic measures to implement the Protocol;

B	Promulgate technical guidelines for risk assessment and risk management of living modified animals, living modified plants and living modified microorganisms, including specific environmental monitoring system on transgenic cotton	Priority actions to draw up technical system for risk assessment and risk management of LMOs, and to establish biosafety monitoring system are identified in Section 4.2.2 and 4.2.6 of the NBF, respectively. These are listed as Priority Project 2 and Priority Project 8 in Annex III of the NBF, respectively.	<i>Article 2, paragraph 1:</i> above <i>Article 10:</i> above <i>Article 12:</i> above <i>Article 15 and Annex III:</i> undertake risk assessments pursuant to the Protocol in a scientifically sound manner, taking into account recognized risk assessment techniques and in accordance with the steps outlined in Annex III; <i>Article 16, paragraph 2 and 3:</i> risk management including to impose measures to the extent necessary to prevent adverse effects of a LMO, and to take appropriate measures to prevent unintentional transboundary movements of LMOs; <i>Article 16, paragraph 4:</i> endeavor to ensure that any LMO whether imported or locally developed, has undergone an appropriate period of observation before it is put to its intended use; <i>Article 17:</i> notify affected or potentially affected States of an unintentional transboundary movement of a LMO and consult such States to determine appropriate responses, including emergency measures; <i>Article 18, paragraph 1:</i> take necessary measures to require that LMOs that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards;
b.1	Develop information inventory of living modified organisms (LMOs-animals, plants and microorganisms)	One of the components of Priority Project 2 in Annex III of the NBF.	
b.2	Develop indicators and monitoring methods for environmental risk assessment of LMOs	One of the components of Priority Project 2 in Annex III of the NBF.	
b.3	Develop methods of identification, estimation, prediction and comprehensive impact analysis for LMOs	One of the components of Priority Project 2 in Annex III of the NBF.	
b.4	The development of technical measures and methods for risk management of contained use, environmental release, use, handling, and transboundary movement of LMOs	One of the components of Priority Project 2 in Annex III of the NBF.	
b.5	Revise and test the Technical Guidelines for Risk Assessment and Risk Management of LMOs	One of the components of Priority Project 2 in Annex III of the NBF.	
b.6	Pilot development of monitoring parameters/indicators and monitoring methodology in pilot fields for transgenic cotton	One of the components of Priority Project 8 in Annex III of the NBF.	

C	Set up a biosafety database system and a Clearing House in China	Priority actions to set up national biosafety information system to collect, sort out, coordinate and exchange information of different sectors, departments and provinces, are identified in Section 4.2.4 of the NBF. These are listed as Priority Project 13 in Annex III of the NBF.	<p><i>Article 2, paragraph 1:</i> above</p> <p><i>Article 6, paragraph 1:</i> above</p> <p><i>Article 11, paragraph 1:</i> inform the Parties through the Biosafety ClearingHouse of a final decision regarding domestic use, including placing on the market of LMOs;</p> <p><i>Article 14, paragraph 2:</i> Parties shall inform each other, through the Biosafety ClearingHouse, of any bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol;</p> <p><i>Article 14, paragraph 4:</i> any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety ClearingHouse of its decision;</p> <p><i>Article 19, paragraph 3:</i> each Party should notify the Secretariat of the names, addresses and responsibilities of its focal point and its competent national authorities through the Biosafety ClearingHouse.</p> <p><i>Article 20:</i> make available to the Biosafety Clearing-House information, including summaries of risk assessments or environmental reviews and decisions regarding importation or release of LMOs;</p> <p><i>Article 21:</i> protect confidential information received under the Protocol;</p> <p><i>Article 23, paragraph 1:</i> the Parties shall: (a) promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs; (b) endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with this Protocol that may be imported.</p> <p><i>Article 23, paragraph 3:</i> each Party shall endeavor to inform its public about the means of public access to the Biosafety ClearingHouse.</p>
c.1	Develop a biosafety database system on LMOs handling, environmental release, use and transboundary movement in China with an adequate mechanism for information sharing and security management	One of the components of Priority Project 13 in Annex III of the NBF.	
c.2	Develop a biosafety website for China	One of the components of Priority Project 13 in Annex III of the NBF.	

D	Workshops, training courses, and study tour for decision-makers, customs officials, inspectors, scientists and the public	Priority actions to strengthen publicity, education and international cooperation on biosafety are identified in Section 4.2.6 and 4.2.8, respectively. These are listed as Priority Project 11, Priority Project 12, Priority Project 14 in Annex III of the NBF, respectively.	<i>Article 2, paragraph 1 above</i> <i>Article 22, paragraph 1:</i> The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, for the purpose of the effective implementation of this Protocol. <i>Article 22, paragraph 2:</i> the needs of developing country Parties, for financial resources and access to and transfer of technology and know-how, shall be taken fully into account for capacity building in biosafety. Cooperation in capacity building shall, subject to the different situation, capabilities and requirements of each Party.
d.1	Two International workshops with the participation of the main stakeholders (including representatives of universities, research institutes, NGOs) on biosafety regulation, the interrelation between WTO and biosafety issues, technologies and methods for risk assessment and risk management of LMOs, monitoring of LMOs, biosafety Clearing House, the impact of the Cartagena Protocol on China's eco-environment, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, exchanging update information and discussing new problems occurring in biosafety management or risk assessment	One of the components of Priority Project 11, Priority Project 12 and Priority Project 14 in Annex III of the NBF.	<i>Article 23, paragraph 1:</i> above. <i>Article 23, paragraph 2:</i> the Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public.
d.2	Study tour for 8 decision-makers and managers to developed countries to learn about policies, legislation, institutional arrangements, operational mechanism and research program for biosafety in other countries and 3 months overseas training for two scientists to be trained in risk assessment and monitoring of LMOs	One of the components of Priority Project 14 in Annex III of the NBF.	
d.3	A three-days training course for decision-makers, custom officials, managers on introducing general information, laws, regulations, policies, guidelines and practice of domestic and foreign biosafety management, introducing the procedures for the application and approval of LMOs, and two seven-days training courses for inspectors on information on the laws, regulations and procedures of biosafety management at home and abroad, introducing basic theories and methods for risk assessment and risk management as well as monitoring technologies	One of the components of Priority Project 11 and Priority Project 12 in Annex III of the NBF	

### ANNEX 3

#### Provisional list of priority equipment needed for strengthening Biosafety Laboratories.

Equipment	Type	Number of Equipment
Freezer minus 80?		1
UV visible spectrophotometer		1
Thermal cycler	4*96	1
Table centrifuge		1
Gel imaging system		1
Incubator		2
Refrigerator		2
Pure water machine		1
Electronic balance		1
PH meter		1
Air conditioner		3
Computer		2
Other accessories and consumable materials		

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## ANNEX 4

### UNEP Response to the STAP Technical Review

The STAP Technical Review provided that "the implementation of these 8 projects needs to be coordinated 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.

<b>Issue</b>	<b>Response</b>
<b>Kenya</b> <ul style="list-style-type: none"><li>• <i>Capacity building should also be addressed to</i></li></ul>	<ul style="list-style-type: none"><li>• Capacity building for inspectors in training</li></ul>

<p><i>inspectors, for example by organising training workshop and developing inspection manuals.</i></p>	<p>workshop is now explicitly mentioned in the project proposal. It will be further addressed during the implementation of the project</p>
<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>• <i>It is recommended to include training activities on topics such as "other international obligations".</i></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>