Lao National Biosafety Frameworks

Prime Minister's Office
Science Technology and Environment Agency

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National Biosafety Frameworks of Lao People's Democratic Republic

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United Nations Environment Programme

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Content

ABBREVIATIONS

ABS	Accesses and Benefit Sharing
AFTA	ASEAN Free Trade Area
ASEAN	Association of South East Asian Nations
BCH	Biosafety Clearing House
BIOTEC	National Center for Genetic Engineering and Biotechnlogy
BSO	Biological Safety Officer
CBD	Convention on Biological Diversity
CHM	Clearing House Mechanism
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic acid
EE	Environment Education
GEF	Global Environment Facility
GMOs	Genetically Modified Organism
HEIs	Higher Education Institutions
HRD	Human Resources Development
IBC	Institutional Biosafety Committee
IT	Information Technology
JICA	Japan International Cooperation Agency
LDCs	Least Developed Countries
LMOs	Living Modified Organism
NA	National Assembly

NBC	National Biosafety Committee
NBF	National Biosafety Framework
NCC	National Coordinating Committee
NEA	National Executing Agency
NGO	Non Government Organization
NPC	National Project Coordinator
NRIES	National Research Institute for Education Science
PCM	Project Cycle Management
PEAP	Public Education Awareness and Participation
PM	Prime Minister
PS	Project Supervisor
STEA	Science Technology and Environment Agency
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nation Environmental Program
USA	United States of America
WTO	World Trade Organization

INTRODUCTION

Lao National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology and contains following components:

Chapter I: The Government Policy on biosafety
Chapter II: The Regulatory regime for biosafety
Chapter III: Administrative systems for biosafety
Chapter IV: Mechanisms for public education awareness and participation
Chapter V: Capacity building Program to implement Cartagena Protocol on Biosafety
Chapter VI: Project Priorities to implement Lao National Biosafety Framework

The **UNEP-GEF project** on the Development of the National Biosafety Framework of ***Lao People's Democratic Republic*** started in ***September 2002*** and ended in ***December 2004.*** The National Executing Agency for the UNEP-GEF project was

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Chapter I:
The Government Policy on Biosafety

1.1 The existing and development policy related to biodiversity and human health

1.1.1. National Socio-Economic Priority Programmes

The eight national socio-economic priority programmes have been devised to channel the Government's development efforts in a focused way towards the 2020 goal. They serve as a major reference for the national planning system, and for defining the national investment priorities. Of these priority programmes, ***achieving permanent food security, preserving the country's natural resources, and developing the national human resource potential***, are given the highest importance.

1. Food production – The programme aims to ensure food security by increasing food and rice production. It promotes more intensive and diversified food production, including increasing the productivity of rice, the expansion of dry and rainy season irrigation in identified priority plains, improved animal husbandry and crop varieties, and more appropriate use of machinery, fertilizers, manure and pesticide.

2. Commercial production – The programme seeks to promote investment in commodities including coffee, fruit and forest products, large livestock and fisheries, to encourage exports including hydropower and mining development, to promote light and small-scale industries and handicrafts, and more varied agricultural production. The programme promotes increased commercial production and the development of processing industries and handicraft enterprises as a means to generate income.

3. Stabilization and reduction of shifting cultivation – The Government wishes to protect forests and the environment by providing sedentary settlements, extension programmes and start-up resources for shifting cultivators.

4. Rural development – The intention in this sector is to bring together rural development efforts in an integrated and focused manner within a clearly defined geographical area. The focal sites development strategy is designed to provide development services in an integrated and locally owned way, from the construction of basic transport infrastructure, education and heath care facilities to skills development, aimed at improving the living standards in rural areas. Other aims are increasing food and commercial production, creating employment opportunities and establishing the conditions for improved living standards in rural areas, thereby reducing rural-urban disparities and rural to urban migration.

5. Infrastructure development – The programme seeks to modernize national and international communications and transport networks, including roads, bridges, airports and river port facilities, and to expand postal and telecommunication services in all regions, transforming Lao PDR from a landlocked to a 'landlinked' sub-regional hub in ASEAN.

6. Improved socio-economic management and foreign economic relations – Goals are to consolidate the national economic management and reinforce conditions for the high economic growth essential for development. On the domestic side, the programme seeks to promote domestic production and develop rural markets. On the international side, it aims to expand international trade and reduce the external trade deficit, by increasing the quality and quantity of export goods, lifting regulations and mechanisms hampering export-orientated production, securing increased foreign investment, promoting transit trade, re-export and duty-free zones, and preparing for AFTA and WTO membership.

7. Human resource development – The programme is designed to build capacity at the individual, institutional and community level in nine sub-programmes: education; labour and social welfare; public health; civil service and public administration; culture and information; Lao Women's Union; youth; Lao Federation of Trade Unions; and the Lao Front for National Construction. The objectives are to link training to the Lao PDR's socio-economic goals, to upgrade knowledge and skills, to build managerial and technical capacities, and to enhance leadership.

8. Services development – The programme aims to generate increased foreign revenue, primarily through the development of the tourism sector. The country is endeavoring to improve tourism infrastructure, to facilitate entry into the Lao PDR by improving procedures, ports-of-entry and transit posts, to develop tourist routes in each region, and to train personnel in the tourism sector.

1.1.2. National Policy on concerning sector related to biodiversity and human health

Regarding to the eight national socio – economic priority programmes in a focused way towards the 2020 goal for sustainable development, the concerned line Ministry had established and developed their own policies related to the biodiversity and human health. The Government of Lao PDR has approved:

1. National Policy on the Science and Technology on November 27, 2003, No. 09 / PM
2. National Biodiversity Strategy to the years 2020 and Action Plan for the years 2006 – 2010 on June 11, 2004, No. 84/ PM
3. National Strategy on Environment Education and Awareness to the years 2020 and Action Plan for the years 2006 – 2010 on June 11, 2004, No. 85 / PM.

4. National Strategy on Environment to the years 2020 and Action Plan for the years 2006 – 2010
   on August 27, 2004, No. 120 / PM.
5. National Policy on the Education, Agriculture and Forestry, Public health, Processing industry and other are in the procedure of Government consideration and development.

1.2 National Policy on Biotechnology and Biosafety

The objective of National Policy on Biotechnology and Biosafety is to promote biotechnology research and development for conservation, sustainable use and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and 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 genetic resources, taking also into account risks to human health, and specifically focusing on transboundary movements.

1.2.1. Policy on Biotechnology Research and Development

1. Biotechnology Research Priorities:

The Government of Lao PDR promotes infrastructure investment and provides material equipment and human research development, necessary for the national socio-economic development by financial support to the research, development and service on science, biotechnology and advance technology and determination of national research themes in sectoral priorities as following:

- Agriculture and forestry biotechnology:
  - Plant and Animal Varieties
  - Identification and Prevention of Plant and Animal Daisies
  - Plant Propagation for Reforestation
  - Soil Resource
- Human health biotechnology:
  - System of Diseases Identification and Diagnosis
  - Pharmaceuticals
  - Human Cloning
- Industrial biotechnology:
  - Agriculture and Forestry Processing Industry
  - Biofuel Industry
  - Environment Protection Industry
- Environmental biotechnology:
  - Protection and Conservation Benefits
  - Biological Indicator of Environment
  - Environment Mitigation and Restoration

2. Genetic Identification and Data base

In accordance with the genetic identification and data base, Competent National Authorities should take necessary principles to:

1. Identify components of genetic resource important for its conservation and sustainable use having regard:
   - Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes.
   - Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of genetic resource, such as indicator species.
   - Described genomes and genes of social, scientific or economic importance.
2. Monitor, through sampling and other techniques, the components of genetic resource identified pursuant to subparagraph (1) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use.
3. Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of genetic resource, and monitor their effects through sampling and other techniques.
4. Summarize and establish data base, by using of system of information technology, derived from identification and monitoring activities pursuant to subparagraphs above.

3. In situ conservation

In situ conservation means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Competent national authorities should take necessary principles as following:

1. Establish a system of protected areas or areas where special measures need to be taken to conserve genetic resource.
2. Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve genetic resource.
3. Regulate or manage biological resources important for the conservation of genetic diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use.

4. Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings.
5. Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas.
6. Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, *inter alia*, through the development and implementation of plans or other management strategies.
7. Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from modern biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of genetic resource, taking also into account the risks to human health.
8. Control or eradicate those alien species which threaten ecosystems, habitats or species.
9. Endeavour to provide the conditions needed for compatibility between present uses and the conservation of genetic resource and the sustainable use of its components.
10. Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations.
11. Where a significant adverse effect on genetic resource must, regulate or manage the relevant processes and categories of activities.

4. Ex situ conservation

Ex situ conservation means the conservation of components of genetic resource outside their natural habitats. Competent national authorities should take necessary principles as following:

1. Adopt measures for the *ex-situ* conservation of components of genetic resource, preferably in the country of origin of such components.
2. Establish and maintain facilities for *ex-situ* conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources.
3. Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions.
4. Regulate and manage collection of genetic resources from natural habitats for *ex-situ* conservation purposes so as not to threaten ecosystems and *in-situ* populations of species, except where special temporary *ex-situ* measures are required under subparagraph above.

5. Accesses and Benefit Sharing to Genetic Resource

Recognizing the sovereign rights over its natural resources, the Government of Lao PDR should determine principles to access to genetic resources and benefit sharing of its uses, as appropriate, by following:

1. shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the conservation of genetic resource, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.
2. The Contracting Party, that provided genetic resources, are counties of origin of such resources and the parties that have acquired the genetic resources.
3. Access, where granted, shall be on mutually agreed terms and subject to the provisions.
4. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
5. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
6. Each Contracting Party shall take legislative, and through the financial mechanism established with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

6. Traditional Knowledge

Subject to the establishment of traditional knowledge principles, the Government of Lao PDR :

1. Respect, preserve and maintain knowledge innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of genetic diversity.
2. Promote their wider application with the approval and innovations of the holders of such knowledge, innovation and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.
3. Protect and encourage customary use of genetic resources in accordance with traditional cultural practices that are compatible with conservation and sustainable use requirement.

4. Support local population to develop and implement remedial action in degraded areas where genetic diversity has been reduced, and
5. Encourage cooperation between governmental authorities and private sector in developing methods for sustainable use of genetic resources.

7. Intellectual Property right

Recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the conservation and sustainable use of genetic resources that do not cause significant damage to the environment and human health.

In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The Government of Lao PDR :

1. Take legislative measure, as appropriate, with the aim that Contracting Parties, which provided genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights.
2. Take legislative measure, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology for the benefit of both governmental institutions and the private sector of developing countries.
3. Cooperate and ensure that national legislation and international law supportive of and do not run counter to its objectives.

1.2.2. Policy on Biosafety regulation

The Government of Lao PDR should make and translate National Policy on biotechnology and biosafety into national framework, law and regulation, technical guidelines, plans and detailed project for the management and monitoring of biotechnology and living modified organism.

1.2.3. Policy on Risk assessment and management on Modern Biotechnology

The Government of Lao PDR should take necessary principles to establish develop and improve competent national authorities, to identify and evaluate the potential adverse effects from the research, development handing and using of living modified organisms on the conservation and sustainable use of genetic resources in the likely potential receiving environment, taking also into account risks to human health.

1. General Principles of Risk Assessment

Competent national authorities should be use the general principles of risk assessment to make the correct decision regarding to living modified organism as following:

1. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
3. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
4. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

2. Risk Management

The basis principle of risk management is to:

1. Establish appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and transboundary movement of living modified organisms.
2. Measure based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of genetic resources, taking also into account risks to human health.
3. Take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:
    - Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of genetic resources, taking also into account risks to human health
    - Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

3. Technical guidelines

The Government of Lao PDR should take necessary principles to establish technical guidelines on risk assessment and management to the research development and using of living modified organism as following:

1. Biosafety Guidelines in Biotechnology and Genetic Engineering for Laboratory work
2. Biosafety Guidelines in Biotechnology and Genetic Engineering for field work and planned release.
3. Biosafety Guidelines on Risk Assessment and Management to Living Modified food.

1.2.4. Policy on Notifications, Movement and Management of Modern Biotechnology Product.

1. Notification of modern Biotechnology Product

- **Advance Informed Agreement Procedure**

The advance informed agreement procedure shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of Lao PDR, which does not refer to living modified organisms intended for direct use as food or feed, or for processing.

The advance informed agreement procedure includes:

- Notification
- Acknowledgement of receipt of notification
- Decision procedure
- Review of Decisions
- Simplified Procedures

- **Procedure Intended for Direct use as Food or Feed, or for Processing**

The procedure Intended for Direct use as Food or Feed, or for Processing includes:

- It makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House.
- This information shall contain, at a minimum, the information specified in formation required for direct use as food or feed, or for processing and shall provide a copy of the information, in writing, to the national focal point of each Party to Cartagena protocol on Biosafety, which this provision shall not apply to decisions regarding field trials.
- The competent national authorities take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework.

2. Movements of Modern Biotechnology Product

- **Transit and Contained use**

Competent national authorities must take necessary and appropriate legal, administrative and other measures to regulate the transport of living modified organism and make available to the Biosafety Clearing House. The provision of this law with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit through its territory.

The contained use means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment

Lao PDR has the right to subject all living modified organism to risk assessment prior to decisions on import and to set standard for contained use with in its jurisdiction, the provision of this law with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organism destined for contained use.

- **Unintentional Trans Boundary Movements and Emergency Measures**

Lao PDR shall take appropriate measures to notify affected or potentially affected States through the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of genetic resources, taking also into account risks to human health in such States.

Any notification arising from mentioned above, should include:

- Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism.
- Information on the circumstances and estimated date of the release and on the use of the living modified organism in the environment.
- Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures.
- Any other relevant information.
- A point of contact for further information.

In order to minimize any significant adverse effects on the conservation and sustainable use of genetic resources, taking also into account risks to human health, under whose jurisdiction the release of the living modified organism referred to mentioned above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

- **Illegal Trans Boundary Movements**

Lao PDR shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures and such movements shall be deemed illegal transboundary movements.

In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

Competent national authorities must make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

3. Management of Modern Biotechnology Product

- **Handling Packaging and Transport**

Competent national authorities must take necessary measure to require that living modified organism and its processing products that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety, taking into consideration relevant imitational rules and standards, in order to avoid adverse effects on the conservation and sustainable use of genetic resources, taking also into account risks to human health.

- **Product Identification**

The competent national authorities shall take measures to require that documentation accompanying:

1. Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they " contain " living modified organisms or its product are not intended for intentional introduction into the environment, as well as a contact point for further information. Competent Authority may take additional measures to identify requirement, including specification of their identity and any unique identification, taking into consideration relevant international rules and standards.
2. Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned.
3. Living modified organisms that are intended for intentional introduction into the environment of the Lao PDR, clearly identifies them as living modified organisms; specifies the identity and relevant traits and characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of the exporter.

- **Socio-economic Considerations**

Lao PDR, in reaching a decision on import living modified organism under domestic measures, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological

diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Competent national authorities are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

- **Transfer of Technology**

The transfer of technology on the biotechnology and genetic engineering issues must be insure 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 genetic resources, taking also into account risks to human health, and specifically focusing on transboundary movements.

Competent national authorities must, as far as possible and as appropriate, adopt economically and socially sound measures that as incentives for the transfer of technology on the biotechnology and living modified organisms in the following matters:

- Food and Drug processing.
- Fermentation for production of food additives, pharmaceuticals, enzymes, etc.
- Commercial propagation of seeds, plantlet, flowers, etc.
- Progeny from approved parents.
- Life of permit and approval.
- Application for multiple uses.
- Personnel care and management.
- Emergency measures for food and feed aid, accidents, etc.

1.2.5. Policy on Public Awareness, Education, Participation and Human Resource Development

1. Public Education, Awareness and Participation

In accordance with the Public Education, Awareness and Participation, the competent national authorities should take necessary principles to:

1. 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 genetic resources, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies.

2. Ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with Cartagena Protocol on Biosafety that may be imported.
3. Consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with respective laws and regulations,
4. Inform its public about the means of public access to the Biosafety Clearing-House.

2. Human Resources Development

In accordance with human resource development, the competent national authorities should take necessary principles to:

1. Establish and maintain human resources development programmes for scientific and biotechnological education and training in measures for the identification, conservation and sustainable use of genetic resources and its components and provide support for such education and training for the specific needs of concerning sectors.
2. Promote and encourage science biotechnology and genetic engineering research and development which contribute to the conservation and sustainable use of genetic resources and its component.
3. Include and provide biotechnology and biosafety topics in the educational programmes as appropriate, from elementary school to university level.
4. Adopt economically and socially sound measures that act as incentive for the scientists in concerning sectors.

3. Roster Expert

Competent national authorities should take necessary principles as appropriate, to survey and identify national roster experts and provide support to:

1. Provide scientific and technical assessment of the state of genetic resource and its component.
2. Prepare scientific and technical assessment of measure taken its accordance with the provisions of the biosafety law.
3. Identify innovative, efficient and state-of-the-art biotechnologies and know-how relating to the conservation and sustainable use of genetic resources and advise on the ways and means of promoting development and transferring such technologies.
4. Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of genetic resources.
5. Respond to scientific, technical, technological and methodological questions.

1.2.6. Policy on Cooperation, Coordination and Information.

1. Scientific and Technical Cooperation

In accordance with the scientific and technical cooperation, the competent national authorities should take necessary principles, as appropriate to:

1. Promote international scientific and technical cooperation in the field of conservation and sustainable use of genetic resources, where necessary, through the appropriate international and national institutions.
2. Promote international scientific and technical cooperation with other Contracting Party, in particular developing countries, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.
3. Determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.
4. Encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in accordance with national legislation and policies.
5. Promote cooperation in the training of personnel and exchange of experts.
6. Promote the establishment of joint research programmes and joint adventures for the development of technologies relevant the conservation and sustainable use of genetic resources and the fair and equitable sharing of the benefits arising out of its utilizations, subject to mutual agreement.

2. National Coordination

The Government of Lao PDR shall establish National Research Institute of Science and Technology, being the national coordinating institution at central level, for the research, development and management on biotechnology, genetic engineering, biosafety and advanced technology.

The competent national authorities should facilitate and provide national coordinating mechanism to implement national policies on biotechnology and biosafety, which concerning sectors should take part of their responsibilities related to the authority and functions and should take necessary principles to establish, develop and strengthen academia of science in concerning sectors, being as advisory committee on science biotechnology and advanced technology to their authorities.

3. Exchange of Research Information

Competent national authorities should establish research network to exchange information on results of scientific, technical and socio–economic research, training and surveying programmes, specialized knowledge, indigenous and traditional knowledge and access to transfer of technology, from all publicly available sources, relevant to the conservation and sustainable use of genetic resources and its components. It shall also, where feasible, include repatriation of information.

Information and communication technology shall provide support and facilitate the exchange of information of all contracting parties related to research network.

4. Biosafety Clearing House

A Biosafety Clearing-House is established as part of the international clearing-house mechanism with the following responsibilities:

1. Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.
2. Assist competent national authorities to implement the Cartagena Protocol on Biosafety , taking into account the special needs of Lao PDR and countries that are centres of origin and centres of genetic diversity.

The Biosafety Clearing House shall serve as a means though above mentioned responsibilities, shall provide access to information made available by the member parties of Catagena protocol on biosafety and shall also provide access to the international biosafety information exchange mechanism.

1.2.7. Policy on Biosafety Fund

The government of Lao PDR supports the establishment of a Biosafety fund to support activities in the field of research, development, protection, and restoration of the safe transfer, handing 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 tranboundary movements.

- The Biosafety fund shall be funded from the following sources:

1. Government budget;
2. Development projects and related activities;
3. Contributions from international and local agencies;
4. Contributions from the private sector and individuals;
5. Interest and profit accruing from the fund.

- The Biosafety fund shall be used for the following activities:

1. Scientific biotechnological and genetic engineering research and development project;
2. Management, follow monitoring and risk assessment of the transfer handing and use of living modified organisms resulting from modern biotechnology
3. Mitigation of adverse effects from living modified organisms
4. The promotion of biosafety education, training and awareness building.
5. Supporting campaigns for conservation and sustainable uses of genetic resource.
6. Management of the fund.

1.2.8. Policy on Inspection, Redress, Awards and Sanctions

The biosafety inspection means the supervision of all activities related to the research, development, service, management and using of biotechnology and living modified organism in accordance with legislation for ensuring risk protection, that may have adverse effects on the conservation and sustainable use of biological diversity and human health.

When performing their task to inspect biosafety, the inspectors have to strictly with legislation; there are three types of inspection:

1. Regular inspection is the inspection at certain intervals in accordance with plans.
2. Inspection after notification is inspection in addition to existing plans, after it is found necessary and after advance notice is given to the inspected party.
3. Emergency inspection is inspection without prior warning to the inspected parties.

The competent national authorities must take necessary measures to establish regulation on the liability and redress for damage resulting from the research, development, service, management and using of biotechnology and living modified organism, and must be analyze and take due account of the ongoing processes in international law.

Persons or organizations which have remarkable accomplishments in biotechnology research development and use for the socio-economic development and environment protection shall be awarded or receive other forms of recognition and Persons or organizations which have violated law and related legislation on Biosafety shall be subject to the following sanctions: re-education, warning, fines, civil sanction, and criminal charges, according to the severity of their case.

1.2.9. Policy on Management and Monitoring Organization

The management and monitoring organization system on biotechnology and biosafety includes:

1. Management and Monitoring Organization at central level :
   - Science Technology and Environment Agency
   - National Biosafety Committee
   - Management and Monitoring Unit at the Ministerial level
   - Technical Assistance team
2. Management and Monitoring Organization at local levels:
   - Management and Monitoring Unit at the Provincial, Municipal, City and Special Zone Level
   - Management and Monitoring Unit at the District and Prefecture Level

1.3. The status of Lao PDR with respect to ratification of the Convention on Biological Diversity and Access to Cartagena Protocol

The convention on Biological Diversity (CBD) was opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992. It entered in force on 29 December 1993 and currently has 188 Parties. The Government of Lao PDR has acceded to the convention on Biological Diversity on September 20, 1996.

The Objective of CBD, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

In January 29, 2000, the conference of parties CBD adopted the Cartagena Protocol on Biosafety (CPB) in accordance with article 28 of the CBD. It was opened for signature in Nairobi on May 15, 2000. The Cartagena Protocol on Biosafety entered in force on September 11, 2003 and currently has 110 Parties. The Government of Lao PDR has acceded to the CPB on November 01, 2004.

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of CPB 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.

Chapter II:
The Regulatory regime for biosafety

The Objective of Regulatory regime for biosafety is to establish and develop legislative frameworks on the safe of research, development and use of biotechnology and its product that may have adverse effects on the environment and human health though law, President's Decrees, Prime Minister's Decrees, Minister's Decrees, Guidelines and Manuals.

2.1. The existing regulatory regime for biodiversity and human health

The different types of regulatory instruments of Lao PDR at the various levels might be categorized as follows:

Level 1: includes Laws that approved by Lao National Assembly

Level 2: includes President's Decrees that approved by Lao Government and Permanent Secretarial Committee of National Assembly.

Level 3: includes Prime Minister's Decrees that approved by Lao Government.

Level 4: includes Minister's Decrees that approved by Concerning Ministries.

Level 5: includes Guidelines and manuals as non – legally binding instruments that approved by concerning Committees, Department or Institutions.

Lao National Assembly has approved concerning Laws to regulate National Socio – economic development and the existing Laws related to biodiversity and human health are as follow:

1. Constitution Lao PDR, No. 25/ NA, Date 06 May 2003
2. National Assembly Law, No. 01/ NA, Date 06 May 2003
3. Law on Government of the Lao PDR, No. 02/ NA, Date 06 May 2003
4. Environmental Protection Law, No. 02/99/ NA, Date 03 April 1999
5. Water and Water Resources Law, No. 02/96/ NA, Date 11 October 1996
6. Land Law, No. 04/ NA, Date 21 October 2003
7. Agriculture Law, No. 01/98/ NA, Date 10 October 1998
8. Forestry Law, No. 01/96/ NA, Date 11 October 1996
9. Education Law, No. 03/ NA, Date 08 April 2000
10. Medicine and Medical Law, No. 01/ NA, Date 08 April 2000
11. Law on Hygiene, Prevention and Health Promotion, No. 01/ NA, Date 10 April 2001
12. Processing Industry Law, No. 01/99/ NA, Date 03 April 1999
13. Road Transport Law, No. 03/97/ NA, Date 12 April 1997
14. Law on the Promotion and Management of Foreign Investment , No. 01/94/ NA, Date 14 March 1994

15. Promotion of Domestic Investment Law, No. 03/95/ NA, Date 14 October 1995
16. Business Law, No. 03/94/ NA, Date 18 July 1994
17. Penal Code Law, No. 03/ NA, Date 10 April 2001
18. Custom Law, No. 04/94/ NA, Date 18 July 1994
19. Secured Transaction Law, No. 07/94/ NA, Date 14 October 1994
20. Contract Law, No. 02/90/ NA, Date 27 July 1990
21. Tort Law, No. 08/90/ NA, Date 29 November 1990
22. Food Law No. 04/ NA, Date 15 May 2004
23. Woman protection Law No. 08/ NA, Date 22 October 2004

Regarding to the mentioned existing laws there are no specific items on biosafety issues or items. It's need to establish Biosafety Law to fulfill them and regulate biotechnology research, development and uses.

2.2. The draft of Biosafety Law

The draft of Biosafety Law will be approved by Lao Government Meeting in the beginning of year 2005 and considered by Lao National Assembly in the end of year 2005. The several changes of technical items might happen as necessary that will be developed and detailed by the framework of regulations to implement Biosafety Law.

The draft of Lao Biosafety Law includes 11 chapters as following:

2.2.1. General Provisions:

A. ***Objective:*** to regulate biotechnology and living modified organism, that may have adverse effects on the conservation and sustainable use of genetic resources at adequate level by insurance the safety of living organism and taking also into account risks to human health, socio - economic development and environment protection.

B. ***Scope of the regulation:***

- Biotechnology Research and Development
- Risk Assessment and Management on Modern Biotechnology
- Notifications Movements and Management of Modern Biotechnology Product
- Public Education, Awareness and Participation and Human Resource Development
- Cooperation, Coordination and Information
- Biosafety Fund Management
- Awards and Sanctions
- Management and Monitoring Organization
- Inspection and Redress

C. Use of terms:

- "**Biotechnology**" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- "**Living organism**" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.
- "**Living modified organism**" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- "**Modern biotechnology**" means the application of:
  a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
  b. Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
- "**Genetic resource**" means any material of plant, animal, microorganism and other origin of actual or potential value, that contain functional units of heredity.
- "**Gene**" means the data information of living organism that translates from DNA to specific structure of proteins.
- "**DNA**" means Deoxyribonucleic acid, the molecule that carries the genetic information for most organisms; consists of four bases and a sugar phosphate backbone.
- "**Protein**" means the molecule that carries the genetic information for most organisms; consists of amino acid.
- "**Sustainable use**" means the use of components of genetic resource in a way and at a rate that does not lead to the long-term decline of genetic resource, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

D. Scope of Use: to implement in all concerning sector that included:

- Biotechnology activities
- Living Modified Organism and its product

E. International Items: to promote the international collaboration and cooperation on the implementation of biotechnology and Living Modified Organism's requirements that Lao Government has acceded to the Cartagena Protocol on Biosafety.

2.2.2. Biotechnology Research and Development

A. Biotechnology Research

- **Research Priorities** :to promote modern biotechnology research and development for the conservation, sustainable use of genetic resources and environment protection by determination of national research themes:
  - Genetic resource biotechnology
  - Agriculture and forestry biotechnology
  - Human health biotechnology
  - Industrial biotechnology
  - Environmental biotechnology.
- **Research Investment:** to promote infrastructure investment and provide material equipments and human research development.
- **Traditional Knowledge:** to promote and protect the traditional knowledge.
- **Intellectual Property right:** to promote and protect the transfer of technology and its benefits by Intellectual Property right Law

B. Genetic Resource Biotechnology

- **Genetic Identification and Data base:** to identify and establish data base of genetic resources by using of system of information technology, that derived from identification and monitoring activities.
- **In situ conservation:** to conserve the ecosystems and natural habitats, and maintain and recover of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
- **Ex situ conservation:** to conserve the components of genetic resource outside their natural habitats.
- **Accesses and Benefit Sharing to Genetic Resource:** to promote and facilitate the accesses to genetic resources and share its benefit.

C. Agriculture and Forestry Biotechnology

- **Plant and Animal Varieties:** to focus on the development and production of new varieties of food crops and industrial plant and new varieties of animals with high productivity and nutrient components, suitability to environment situation and disease resistance.
- **Identification and Prevention of Plant and Animal Daisies:** to develop the effective systems of identification and prevention of plant and animal diseases.

- **Plant Propagation for Reforestation:** to produce sufficient plantlets for reforestation by plant tissue culture.
- **Soil Resource:** to develop and improve the quality of soil resources by using of biotechnology principles and bio fertilizer.

D. Human Health Biotechnology

- **System of Diseases Identification and Diagnosis:** to support and facilitate the research on biomedical science sector, in accordance with the specific areas and tropical disease, and develop the system of diseases identification and diagnosis.
- **Pharmaceuticals:** to promote the using of traditional medicine and support the modern biotechnology medicine.
- **Human Cloning:** to support only the research, development and capacity building need for the therapeutic human cloning, but don't support for the reproductive human cloning to make a full living copy of a sentient human being that is generally considered ethical unacceptable.

E. Industrial Biotechnology

- **Agriculture and Forestry Processing Industry:** to insure the good quality standard of product and sustainable use of agriculture and forestry products.
- **Biofuel Industry:** to promote biofuel from agriculture and forestry processing and waste.
- **Environment Protection Industry:** to respect the environment protection and decrease waste that may have adverse effect to human health.

F. Environmental Biotechnology

- **Protection and Conservation Benefits:** to promote sustainable development of genetic resources and its component by using appropriate biotechnology for its identification, monitoring and in situ and ex situ conservation, and contribute to the National Biodiversity Strategies and Action Plans.
- **Biological Indicator of Environment:** to support and facilitate the research and development on biological indicator of environment which is used to control any change in the environment.
- **Environment Mitigation and Restoration:** to support and facilitate the research and development on environment mitigation and restoration.

2.2.3. Risk Assessment and Management on Modern Biotechnology

A. Risk Assessment on Modern Biotechnology

- **Procedure of Risk Assessment:** to identify and evaluate the potential adverse effects from the research, development handing and using of living modified organisms
- **General Principles of Risk Assessment:** to make the correct decision regarding to living modified organism
- **Process of Risk Assessment:** to give the information about specific subjects, which may be identified and requested during the assessment process,
- **Items to be considered of Risk Assessment:** to take into account the relevant science and technology details.

B. Risk Management on Modern Biotechnology

- **Risk Management:** to establish appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and transboundary movement of living modified organisms.
- **Technical guidelines:** to establish technical guidelines on risk assessment and management to the research development and using of living modified organism as following:
  - Biosafety Guidelines in Biotechnology and Genetic Engineering for Laboratory work
  - Biosafety Guidelines in Biotechnology and Genetic Engineering for field work and planned release.
  - Biosafety Guidelines on Risk Assessment and Management to Living Modified food.

2.2.4. Notifications Movements and Management of Modern Biotechnology Product

A. Notification of Modern Biotechnology Product

- **Advance Informed Agreement Procedure:** to apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment.
- **Notification:** to notify or require the exporter to ensure notification to the competent national authorities prior to the intentional transboundary movement of a living modified organism.

B. Movements of Modern Biotechnology Product

- **Transit and Contained use:** to regulate the transport of living modified organism and make available to the Biosafety Clearing House. and to set standard for contained use.
- **Unintentional Trans Boundary Movements and Emergency Measures**: to notify affected or potentially affected States through the Biosafety Clearing-House
- **Illegal Transboundary Movements**: to adopt appropriate domestic measures aimed at preventing and penalizing transboundary movements of living modified organisms.

C. Management of Modern Biotechnology Product

- **Handling Packaging and Transport:** to require the intentional transboundary movement of living modified organism and its processing products are handled, packaged and transported under conditions of safety, taking into consideration relevant imitational rules and standards.
- **Product Identification:** to clearly identify that contain living modified organisms and its product and specify some requirements for the safe handling, storage, transport and use.
- **Socio-economic Considerations:** to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.
- **Transfer of Technology:** to insure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology.

2.2.5. Public Education, Awareness and Participation and Human Resource Development

- **Public Education, Awareness and Participation:** to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms, consult the public in the decision-making process and inform its public about the means of public access to the Biosafety Clearing-House.
- **Human Resources Development:** to establish, promote and maintain human resources development programmes for scientific and biotechnological education and training.
- **Roster Expert:** to survey and identify national roster experts

2.2.6. Cooperation, Coordination and Information

A. *Cooperation and Coordination*

- **Scientific and Technical Cooperation:** to promote international scientific and technical cooperation in the field of conservation and and sustainable use of genetic resources.
- **National Coordination:** to establish National Research Institute of Science and Technology, being the national coordinating institution at central level, for the research, development and management on biotechnology, genetic engineering, biosafety and advanced technology.
- **Academia of Science:** to establish, develop and strengthen academia of science in concerning sectors, being as advisory committee on science biotechnology and advanced technology to their authorities.

B. Information

- **Exchange of Research Information:** to establish research network to exchange information on results of scientific, technical and socio–economic research, training and surveying programmes.
- **Biosafety Clearing House:** to establish as part of the international clearing-house mechanism to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.
- **Information Sharing:** to make available to the Biosafety Clearing-House any information required.
- **Confidential Information:** to identify and protect information submitted under the procedures of advance informed agreement procedure that is to be treated as confidential, with the justification shall be given in such cases upon request.

2.2.7. Biosafety Fund Management

- **Establishment of Funds:** to support activities in the field of research, development, protection, and restoration of the safe transfer, handing and use of living modified organisms resulting from modern biotechnology.
- **Source of Funds:**
  - Government budget;
  - Development projects and related activities;
  - Contributions from international and local agencies;
  - Contributions from the private sector and individuals;
  - Interest and profit accruing from the fund.

2.2.8. Inspection and Redress

- **Biosafety Inspection:** to inspect all activities related to the research, development, service, management and using of biotechnology and living modified organism.
- **Types of Inspection:**
  - Regular inspection is the inspection at certain intervals in accordance with plans.
  - Inspection after notification is inspection in addition to existing plans, after it is found necessary and after advance notice is given to the inspected party.
  - Emergency inspection is inspection without prior warning to the inspected parties.
- **Liability and Redress:** to establish regulation on the liability and redress for damage resulting from the research, development, service, management and using of biotechnology and living modified organism.

2.2.9. Management and Monitoring Organization

- **Management and Monitoring Organization at central level** :
  - Science Technology and Environment Agency
  - Management and Monitoring Unit at the Ministerial level
- **Management and Monitoring Organization at local levels**:
  - Management and Monitoring Unit at the Provincial, Municipal, City and Special Zone Level
  - Management and Monitoring Unit at the District and Prefecture Level

2.2.10. Awards and Sanctions

- **Awards:** to be awarded persons or organizations which have remarkable accomplishments in biotechnology research development and use for the socio-economic development and environment protection.
- **Sanctions:** to be sanction persons or organizations which have violated Biosafety legislation by following: re-education, warning, fines, civil sanction, and criminal charges, according to the severity of their case.
-

2.2.11. Final Provisions

- **Implementation:** to implement Biosafety law by the Government of Lao People's Democratic Republic.
- **Entry into Force:** to be entering into force after 90 days, that the promulgation enforcement decree is signed by the President of the Lao People's Democratic Republic and any regulation, provisions conflicting with this Law shall be abrogated.

2.3. Framework of regulations to implement Biosafety Law

1. Framework of Prime Minister's Decree to implement Biosafety Law
2. Framework of Minister's Decree to implement Biosafety Law
3. Framework of Guidelines and Manuals to implement Biosafety Law

Chapter III:
Administrative systems for biosafety

The objective of Administrative systems for biosafety is to establish and develop Competent National Authorities and the procedures of handing application, risk assessment, decision making, monitoring, inspections and enforcement.

3.1. The existing system for Risk assessment and Management on Biodiversity and Human health

The concerning Ministries have established and developed procedure for handing application, risk assessment and management on biodiversity and human health, but biosafety issue is not included.

The Science Technology and Environment Agency have approved Regulation on Environment Assessment in Lao PDR by Minister's Decree No. 1770 / STEA, October 3, 2000 with following objective: to establish uniform environmental assessment requirements and procedures for including environmental protection in all development project in Lao PDR and to lay the general foundation for line Ministries responsible for planning and implementing development projects to fulfill their obligations in issuing sector specific Environmental Assessment Regulations.

Ministry of Agriculture and Forestry and Ministry of Health have established Minister's Decrees on agriculture, forestry, food and drug issues.

3.2. Competent National Authorities on Biosafety

3.2.1. Scientific National Authorities on Biosafety

1. **National Biosafety Committee (NBC)**

The organization structure of National biosafety committee includes: Chair by the Minister to Prime Minister's Office and President of the Science Technology and Environment Agency, Permanent secretariat by National Focal Point to Cartagena Protocol on biosafety, and Members by manager officers at the fifth or sixth level, which proposal and appointed by concerning ministries and sectors.

- **Authorities and Functions of NBC**

A. Ensure that ambient conditions surrounding genetic manipulation work reflect and adhere to the specifications of national guidelines for the safety of personnel, the community and the environment exposed to the risks borne by the study.

B. Cooperate with the Customs Department and with other relevant state authorities overseeing the import of live organisms to formulate guidelines for the identification, inspection and regulation of transgenic species, exotic and otherwise.

C. Review the aspects of research methodologies in genetic engineering.

D. Identify, characterize and assess the hazards associated with innovative genetic manipulation techniques or research for which the risks are as yet uncertain.

E. Warn the authorities and individuals who are involved with, or who may be afflicted by genetic manipulation experiments, of potential hazards throughout the conduct of work.

F. Recommend, instruct and lend specialist technical expertise to various research institutions and regulatory agencies in setting up appropriate experimental conditions for work with specific regulated material.

G. Facilitate all levels of supervision of genetic manipulation work by establishing and assisting other regulatory bodies in establishing pertinent codes, disciplines and guidelines for the appraisal of biohazards and the management of biosafeguards.

H. Coordinate efforts to inform and educate the public on biosafety issues and on proposed national policies. Forge ties with foreign biosafety committees and relevant agencies overseas to ensure that genetic manipulation practices in Lao address international biosafety concerns and observe universal codes of conduct.

In addition to the authorities and functions listed, the NBC recognizes that no single authority can foresee all conceivable developments in the domain of genetic engineering and biotechnology and reserves the right to consult with the STEA, the various biosafety committees, state authorities and concerned individuals in amending national biosafety policies and pertinent legislation, to suit the existing needs of this discipline.

- **Responsibilities of NBC to Laboratory Research**

To ensure that laboratory genetic manipulation work conforms to the regulations circumscribed within these Guidelines, the NBC must address the following charges:

A. Provide advice and assistance to the IBC on the consideration of Category 3 work and, if necessary, on the consideration of other work bearing various levels of risk.

B. Suggest practical alternatives, if any, to high-risk laboratory procedures.

C. Prepare and provide to IBCs, the various notification and assessment forms, biosafety guidelines, related documents and assorted signs for facilities.

D. Alert the various institutions and offices, of state or private, engaged in genetic manipulation work, to new developments in biosafety so as not to expose laboratory personnel, the community or the environment to undue risks.

E. Coordinate efforts between pertinent state agencies and private organizations to maintain safety levels in genetic manipulation facilities and to prepare for bio- logical emergencies.

F. Certify higher-level laboratories, plant glasshouses and animal houses pending inspection. Upon request by the institution, and at the earliest convenience, the NBC will inspect a facility and either issue certification, or recommend additional precautions, if elements of the facility are determined to be inadequate to support the types of risk/hazard accompanying work requiring such strict physical containment.

G. Inspect higher-level laboratories and containment facilities on a regular basis. The NBC reserves the right to inspect laboratories and facilities of containment level C2, PH2, C2A, equivalent or higher, at any time subsequent to certification, without prior notice.

H. Inspect systems, equipment and instruments governing ambient biosafety levels in genetic manipulation laboratories.

I. Protect and restrict access to information of commercial significance, not in the public domain, that researchers have provided in project proposals but wish nonetheless to keep private. On the written proposals submitted, researchers will mark such information, Commercial-In-Confidence.

2. Institutional Biosafety Committee (IBC)

Institutions and organizations, state or private, engaged, or with the intent to engage, in the purchase, construction, propagation or field release of genetically modified organisms or components must each arrange for the establishment of an Institutional Biosafety Committee (IBC) to serve as the administrative board on matters of biosafety and on compliance with Biosafety Guidelines.

- **Powers and Functions of IBC**

A. Assist researchers in undertaking risk assessment, organizing training programs and generally, in harmonizing experimental conditions with national guidelines.

B. Determine additional biosafeguards and draft supplementary operating procedures for work supported by the institution, in line with and addressing the specific risks and concerns uncovered.

C. Evaluate the qualifications of researchers involved in biotechnological projects and assess whether each retains a thorough understanding of good microbiological practices necessary for the supervision of students, assistants and junior personnel.

D. Monitor all regulated work under progress within the institution and counsel the proponents on issues of biosafety and on compliance with national guidelines on a regular basis, or as requested. The IBC should set apart time for researchers and for laboratory and field personnel to approach the committee with questions, disputes or concerns.

E. Where appropriate, bridge the gap between the NBC and the research teams, and serve as a throughway for the flow of information, ideas and opinions between the two parties.

- Maintain and update a directory of all personnel engaged in activities at every biosafety level, and instruct new personnel on the correct laboratory and/or field practices, emergency procedures and equipment operations at the relevant level.
- Attend to the health of laboratory and field personnel regularly or as necessary, considering test results from baseline serum samples and medical records.

- **Responsibilities for Laboratory Research of IBC**

To ensure that laboratory genetic manipulation work within the institution conforms to the regulations circumscribed within these Guidelines, the IBC must address the following charges:

A. Assess all project proposals referred to the committee, and on the basis of the information provided and the risks forecast, determine under which category of work the proposals fall and whether to endorse the work proposed.

B. Maintain records of approved project proposals for laboratory genetic manipulation work (including notifications for project exemption) and the committee s assessments thereof.

C. Forward copies of all project proposals submitted for IBC notification, and the committee s assessments thereof, to the NBC for records and information or for review and recommendation in the case of proposals for Category 3 work.

D. Undertake risk assessment, in cooperation with the research teams as necessary, to determine the appropriate containment and biosafety conditions, operating procedures and emergency safeguards for Category 2 and 3 genetic manipulation work, and for the housing, storage or movement of regulated material.

E. Prepare, in conjunction with the research teams, specific contingency plans after undertaking risk assessments and reviewing project proposals.

F. Suggest practical alternatives, if any, to high risk laboratory procedures.

G. With particular emphasis on Category 3 work, enforce NBC and committee recommendations, and ensure that NBC and committee comments have been acknowledged and promptly addressed.

H. Inspect and certify, before use in genetic manipulation work, C1 level laboratories, conventional animal houses, PH1 plant glasshouses, and quarantine and medical facilities for infected animals. (The NBC will be responsible for certification of higher level laboratories and containment facilities.)

- Monitor and assay the containment features of, and the working conditions within all laboratories, plant glasshouses and animal houses supporting the institution s work, to ensure that the various facilities are maintained at the standards and requirements.

3. Biological Safety Officer (BSO)

Institutions and organizations involved in genetic manipulation work should appoint a Biological Safety Officer to the IBC. Alternatively, institutions affiliated with an IBC yet without the services of a BSO may opt to transfer the responsibility of securing a biosafety officer over to the committee. For larger institutions contracting the services of multiple BSOs, the NBC requires that one representative shall be designated and shall serve as the NBC contact or relations officer. BSOs on leave of absence must arrange for competent replacement to take up the forsaken responsibilities.

To meet the objectives of Biosafety Guidelines, BSOs should have considerable experience with pertinent biosafety issues and emergency counter-measures. The BSOs are expected to have undergone rigorous training on biosafeguards in order to participate in the training and instruction of personnel, to review (in conjunction with the IBC, and on a regular basis) operating procedures and biosafety records, and to assay the integrity of containment facilities and safety equipment/utilities.

The BSO and the Chairperson of the IBC shall assume direct advisory positions to the head of the institution on all matters pertaining to risk and biosafety, the health of personnel, contingencies at work and infractions of national guidelines. As with the IBC, the BSO shall set a part time for researchers and for laboratory and field personnel to approach the officer with questions, disputes and concerns.

4. Project Supervisor (PS)

The project supervisor or head researcher should possess requisite thorough understanding of the codes, regulations and laws applicable to genetic engineering and biotechnological work and exhibit an appreciation for the biosafety concerns that underlie the need for such provisions.

As the officer-in-charge, much of the responsibilities of the project supervisor rests in the initial stages of originating proposals and obtaining IBC approval, where necessary. For laboratory genetic manipulation work, the project supervisor should assess the nature of the research and determine whether the work proposed falls within the scope of these Guidelines. Uncertainty and doubt

should be addressed by submitting a detailed proposal of the experimental conditions to the IBC for endorsement or clearance before any work is carried out. If work is indeed regulated under these Guidelines, the project supervisor must submit a completed project proposal form (including requests for exempt status) to the supervising IBC for consideration and recommendation, and inform the committee of any notable intents (e.g. plans to import regulated material). Laboratory work may begin after authorization from the IBC. As directed by the IBC, the project supervisor may be required, from time to time, to provide additional details of the research for the various evaluation and monitoring activities of the committee.

The project supervisor should sincerely enforce the provisions and adhere to the intent of these Guidelines through the duration of research work, with special emphasis on the following charges:

A. Submit new project proposals to the IBC for consideration and recommendation before adopting radical operating procedures or substantially changing any parameter of the work (especially approaches to physical and biological containment) which may introduce novel risks, delimit new biosafety levels or warrant change of classification.

B. Establish and maintain working conditions appropriate to the level of biosafety as approved and advised by the IBC--and, in the case of Category 3 work, in accord with the recommendations of the NBC.

C. Ensure that students, junior personnel, co-investigators and other persons entering controlled areas realize the nature and degrees of the risks involved and have been properly instructed on applicable codes of conduct.

D. Cooperate closely with the IBC and BSO in carrying out various tests and safety audits, for instance, inspections of containment facilities and personnel examinations.

E. Report all personnel developments, including extended absenteeism, replacements and unusual illnesses, to the IBC.

F. Relay to the IBC, details of all contingencies and the emergency procedures instigated to deal with such incidents.

3.2.2. Management and Monitoring National Authorities on Biosafety

1. Science Technology and Environment Agency

The Science Technology and Environment Agency, being the management and monitoring organization on biotechnology and biosafety at the central level, has the following authorities and functions:

1. To act as a Secretary to the Government of Lao PDR in making and translating biotechnology and biosafety policies into national framework, law and regulation, technical guidelines, plans and detailed project for the management and monitoring of biotechnology and living modified organism.
2. To implement management and monitoring activities, and to report the situation of the biotechnology and biosafety of the country regularly to the Government.
3. To act as the coordination centre between the concerned sectors and local administrations for managing and monitoring any biotechnology and biosafety activities.
4. To conduct research and identify methods to protect and mitigate the biosafety problems by using appropriate advanced science and technology.
5. To instruct the development projects and activities to prepare reports of the risk assessment and management to research development and using of living modified organism.
6. To monitor and control the implementation of the national framework, law and regulations, technical guidelines, plans and detailed project to the biotechnology and living modified organism.
7. To issue or revokes licenses of any organization engaging in biotechnology and genetic engineering related services.
8. To cooperate with authorized concerned sectors in giving orders to adjust, suspend, remove or close down any activities that cause adverse impacts to human health, genetic resources and environment.
9. To receive and response petitions from the population and other sector regarding to the biosafety issues.
10. To organize the meeting and seminars on the biotechnology and biosafety issues.
11. To train and upgrade the skills of the scientific and biotechnology staff, and to educate and raise biosafety awareness for all strata of the population in the country, in close cooperation with the sectoral agencies and local administrations.
12. To disseminate, collect and evaluate system of biotechnology and biosafety information for use as inputs in the national socio - economic planning process.
13. To promote international relations and cooperation related to biotechnology and biosafety issues.

14. To perform other rights and duties related to the biotechnology and biosafety which are assigned by the Government, or as stipulated in the regulations and laws.

2. Management and Monitoring Unit at the Ministerial Level

If a Ministry is required to establish its management and monitoring organization on biotechnology and biosafety unit, it has to cooperate with the Science Technology and Environment Agency.

The Ministerial management and monitoring units have the following authorities and function for conducting its sectoral activities:

1. To make and implement plans and regulations on biotechnology and biosafety concerning its sector based on the general plans and regulation issued by the Science Technology and Environment Agency.
2. To conduct research and identify methods to protect and mitigate the biosafty problems concerning its sector by using appropriate advanced science and biotechnology.
3. To instruct the development projects and activities in its sector to prepare reports of the risk assessment and management to research development and using of living modified organism.
4. To monitor and control the implementation of the biosafety regulations and law.
5. To recommend the authorized authority to issue orders to adjust, suspend, remove or close down any activities in its sector that cause adverse impacts to human health, genetic resources and environment.
6. To report, participate in discussions and exchange experiences on biotechnology with the Science Technology and Environment Agency the local authorities and other concerned parties for mitigating biosafety impacts.
7. To train and upgrade the skills of the scientific and biotechnological staff, and to educate and raise biosafety awareness for all parties in its sectors.
8. To disseminate, summarize and analyze biosafety information.
9. To promote informational relations and cooperation related to biotechnology and biosafety in its sector.
10. To perform other authorities and functions related to biosafty with are assigned by the Ministry or as stipulated in regulations and laws.

3. Management and Monitoring Unit at the Provincial, Municipal, City and Special Zone Level

Provinces, municipality, city and special zone shall establish their own management and monitoring on biotechnology and biosafety units in cooperation with the Science Technology and Environment Agency.

The management and monitoring units at the provincial, municipal, city and special zone level have the following rights and duties to conduct activities in their areas:

1. To make and implement plans and regulations on biotechnology and biosafety at the Provincial, Municipal, City and Special Zone Level, in accordance with the general plans and regulation.
2. To conduct research and identify methods to protect and mitigate the biosafty problems concerning in their respective area by using appropriate advanced science and biotechnology.
3. To monitor and control the implementation of the law, decrees, regulation and rules on biosafety.
4. To receive and study the petitions from the population and other parties regarding to biosafety issues and submits to the central level for their consideration and responsibility.
5. To recommend the authorized authority to issue orders to adjust, suspend, remove or close down any activities in its sector that cause adverse impacts to human health, genetic resources and environment.
6. To report, participate in discussions and exchange experiences on biotechnology with the Science Technology and Environment Agency the local authorities and other concerned parties for mitigating biosafety impacts.
7. To train and upgrade the skills of the scientific and biotechnological staff, and to educate and raise the public awareness on biosafety issues.
8. To disseminate, summarize and analyze biosafety information.
9. To perform other authorities and functions related to biosafty with are assigned by the Governor, Major and the special zone chief or as stipulated in regulations and laws.

4. Management and Monitoring Unit at the District and Prefecture Level

District and prefecture shall establish own management and monitoring units on biotechnology and biosafety in cooperation with management and monitoring units at the provincial, municipal, city and special zone level in which they are located.

The district and prefecture management and monitoring units have the following rights and duties to conduct activities in their areas:

1. To make and implement plans and regulations on biotechnology and biosafety at the district and prefecture level, based on the provincial, municipal and special zone's plans in which they are located.
2. To conduct research and identify methods to protect and mitigate the biosafty problems concerning in their district and prefecture by using appropriate advanced science and biotechnology.
3. To monitor and control the implementation of the law, decrees, regulation and rules on biosafety.
4. To receive and study the petitions from the population and other parties regarding to biosafety issues and submits to the central level for their consideration and responsibility.
5. To recommend the authorized authority to issue orders to adjust, suspend, remove or close down any activities in its sector that cause adverse impacts to human health, genetic resources and environment.
6. To report, participate in discussions and exchange experiences on biotechnology with the provincial, municipal and special zone's management and monitoring units, the local authorities and district sectors for mitigating biosafety impacts.
7. To train and upgrade the skills of the scientific and biotechnological staff, and to educate and raise the people's and other parties in their district awareness on biosafety issues.
8. To disseminate, summarize and analyze biosafety information.
9. To perform other authorities and functions related to biosafty with are assigned by the district chiefs, and the management and monitoring units of the Provinces, municipality, city and special zone or as stipulated in regulations and laws.

3.3. The Administration systems for Handing Application and Decision making on Biosafety

3.3.1. Categories of Genetic Manipulation work

- **Category 1 Work**

Granted that the risks conveyed by Category 1 work appear minimal, exempted work must nonetheless be undertaken in strict compliance with standard practices for conventional microbiological laboratories. Experiments involving pathogenic organisms should conform to suitable containment and precautionary measures including personnel training and instruction. Laboratory staff should be familiar with all pathogenic organisms under study and aware of the appropriate safety procedures required.

- **Category 2 Work**

Category 2 work poses low levels of risk towards laboratory personnel, the community or the environment and necessitates, at the very least, containment level C1. Situations involving whole plants and animals should normally be conducted under PH1 plant glasshouses or C1A animal houses. Certain types of work, however, may call for further security precautions or higher levels of physical containment (e.g. special containment conditions in some animal houses designed for transgenic species) because the DNA concerned, or segments and fragments thereof, may conceal hazards or cause diseases. Such work will be negotiated on a case-by-case basis. Regulations and criteria for the procedures, facility design and containment features at the various biosafety levels.

- **Category 3 Work**

Category 3 distinction is placed on work which poses a substantial level of risk to laboratory personnel, the community or the environment, gene-therapy work, and work for which the character and degree of the risks are as yet uncertain. With such an array under the umbrella of Category 3, appropriate containment levels are far from rigid and may vary considerably depending on the inherent nature of the experiment and on risk assessment results C1 levels may be adequate for some types of work whereas other situations may demand higher levels and experienced adept personnel.

3.3.2. Framework of the Various Notification Forms for Laboratory work

Project proposal and supplementary information forms may be obtained from the NBC
Secretariat at the following address:

Science Technology and Environment Agency
Research Institute of Science
P.O.Box: 10782, Vientiane, Lao PDR
Tel/Fax: (856-21) 262002
E-mail: science@laotel.com , laobch@stea.gov.la

Either the Project Proposal Form for Assessment of Laboratory Genetic Manipulation Work or the Project Proposal Form for Request of Exempt Status (along with all attachments and supplements) will serve as the principal source of reference for the IBC and the NBC in the initial consideration and approval of research work regulated under these Guidelines. On the basis of information provided in, and of risks/concerns that may be inferred from these proposals, the IBC shall classify research work and determine additional biosafety measures to be adopted/implemented as necessary, including facility up grades and procedural amendments. Proposals intended for Category 3 work shall also be reviewed by the NBC, and whatever details provided will constitute the framework for NBC assessment and recommendations. Recognizing that IBC and NBC activities, in these initial stages of genetic manipulation practice, depend on the written forms submitted, researchers should be thorough yet concise, and clear as to their intentions, so that the committees may readily and fully understand the nature of proposed work. All important details should be included and as many additional sheets/pages may be attached as necessary to accommodate. Notable and exceptional intents should be stressed, ideally in the title or under the objectives.

Particular care must be observed regarding phrasing-approval will be restricted to the specific experimental procedures and biological system components identified so descriptions should be broad enough (though never vague) for the purposes of the research.

Project Proposal Form for Request of Exempt Status

1. Name and Institutional Address of Project Supervisor
2. Names of other Supervisors, Co-Investigators or Program/Section Leaders
   - Indicate Institutional addresses where different from (1).
3. Affiliations
   - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
4. Project Title
5. Project Objectives

6. Methodology and Protocol
   - Provide thorough yet concise descriptions of the main experimental procedures.
   - Include timetable of activities.
7. Reasons why Project Merits Exempt Status
   - Account with reference to standard Category 1 work.
8. Signature (of Project Supervisor) and Date

Project Proposal Form for Assessment of Laboratory Genetic Manipulation Work

Section A - Authorities and Outlook

1. Name and Institutional Address of Project Supervisor submitting proposal
2. Names of other Supervisors, Co-Investigators or Program/Section Leaders
   - Indicate institutional addresses where different from (1).
3. Affiliations
   - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
4. Project Title
5. Project Objectives

Section B - Materials and Methods

6. Methodology and Protocol
   - Provide thorough yet concise descriptions of the main experimental procedures.
   - Include a timetable of activities.
   - Describe any special precautions/safeguards to be adopted.
7. Details of the Biological System

7.1 Account of the Origin (biological source) of donor DNA
7.2 Characteristics of the donor DNA
7.3 Description of the Host Organisms or Tissues
7.4 Description of the Vectors or Methods for transfer of donor DNA into the Host
7.5 Characteristics of the Host/Vector System(s), as applicable (for each, describe)
   - Predicted Stability of Introduced Genetic Traits.
   - Identification Characteristics or Markers.
   - Hazard and Biological Containment.
   [ ] NBC Authorized [ ] Not Authorized

7.6 Ecological Context (Auto-Ecology) (for each host/vector system, assess)
- Viability in Open Environments.
- Natural Crossing Possibilities to Related Species.

8. History of Prior Work with Components of the Biological System
9. Intended Classification
   [ ] Category 2 [ ] Category 3
10. Laboratories and Facilities where Work will be Conducted (for each, indicate)
    - Complete Address.
    - Work to be Conducted.
    - Certified Physical Containment (Biosafety) Level.
    [ ] C1 [ ] C2 [ ] C3 [ ] C1A [ ] C2A [ ] PH1
    [ ] PH2 [ ] PH3
    [ ] Other (please specify)
    - Special Containment/Safety Features.
    - Approval (Contract) for Use.
11. Intended Date of Commencement; Expected Date of Completion

Section C - Personnel Involved with Research Work Pro posed

12. Details of Personnel
    - Name, Qualifications and Experience.
    - Responsibilities and Duties.
    - Medical History.
13. Signature (of Project Supervisor) and Date

Instructions for Completion of the Project Proposal Form for Assessment of Laboratory Genetic Manipulation Work

The project supervisor must submit two typed, completed project proposal forms to the supervising IBC (one of which shall be forwarded to the NBC for information) and should retain a copy for records and reference. For work supported by two or more institutions, all IBCs of authority must be notified.

Project proposal forms must be signed and dated by the project supervisor to be deceived by the IBC and the NBC. For research work employing multiple project supervisors or head researchers, the name and professional address of the supervisor repairing and submitting the proposal should be indicated under heading (1). Said individual shall sign and date both proposals before submission to the IBC of authority.

As many additional sheets/pages may be attached as necessary. Incomplete proposals will delay IBC endorsement as further information is sought.

Names and Addresses

Names, institutional addresses and addresses of institutions, laboratories, containment facilities and biosafety committees should be given in full. Ideally, telephone numbers, facsimile, e-mail accounts etc. should be provided along with postal addresses. Foreign establishments must indicate both contacts in Lao PDR and abroad. Intentions to relocate must be promptly referred to the IBC so contact/links can be assured at all times.

Project Title and Objectives

Notable and exceptional intents should be indicated in the title or under the objectives.

Short and long term objectives should be state separately if the research work proposed is likely to continue for several years. Distinguishing immediate from remote aims, together with providing a timetable of activities (under the Methodology and Protocol section), will permit the IBC to assess the proposal in sequence. As such, where the entire proposal does not merit endorsement (or where endorsement of later stages depends on the results of early work), the IBC may approve particular initial stages rather than having to reject the proposal as a whole allowing preliminary work to begin as the proposal is revised (or as results are compiled). Researchers should clearly indicate which parameters of the work require primary endorsement.

Ideally, the objectives should communicate, to some considerable extent, a service to the welfare of the community or the environment, local or global. Justify hazardous or high-risk work by relating why the ends cannot be attained through conventional or alternative practices that offer less risk.

Methodology and Protocol

Only a concise but thorough description of the main experimental procedures is required. A timetable of activities should be included to allow the IBC liberty in assessing the proposal in sequence. Detail any special precautions/safeguards to be adopted, with references to the specific risks and concerns identified in initial risk assessments.

Materials

For work with multiple donors DNA, hosts and/or vectors, indicate when and how each shall be used. As with providing a time table of activities and distinguishing short and long term aims, clarifying these points will allow the IBC to assess the project in stages or modules.

Some details of the relevant history of prior work with components of the biological system should be provided under heading (8), including track records of safety and biological containment. Indicate whether the DNA, hosts and vectors concerned are commonly or rarely subjected in regulated work. Above all, identify any problem DNA, host or vector with a history of unsafe use (e.g.

often realizing the hazards determined in initial risk assessments). If related host/vector systems have been field tested or released, a summary of the results/analysis would be appropriate.

Donor DNA

The origin of all donors DNA should be specified--scientific name and strain of the biological source(s), whether procured or constructed by the research team, and if procured, who made it. Researchers must account for how donor DNA was or will be constructed / cloned and should make clear as to whether several genes or species are involved. Some details of the biological source(s) are appropriate, for instance, whether a local or exotic strain and patterns of local distribution, particularly if imported.

All important characteristics of donor DNA should be listed. Uncharacterized donor DNA should be so indicated otherwise, the IBC shall expect a review of the known functions of target genes through to the known functions of the proteins encoded.

Host Organisms or Tissues

The scientific name and strain of all host organisms and biological sources of host tissues need to be specified. In addition, regarding host tissues, researchers should briefly account for how the tissue cultures were or will be prepared / grown. For work using as hosts, genetically modified or constructed organisms, also include a review of the genetic manipulation work involved.

List all substantial hazards conveyed by host organisms or tissues, particularly, regarding pathogenicity and infectivity. Other details of the hosts may be appropriate, for instance, geographic distribution and biologically active compounds secreted.

Vectors

Work with biological vectors requires a concise description of the known vector properties (e.g. host range) in addition to nomenclature or identification. As with host organisms/tissues, list all substantial hazards borne, particularly, regarding pathogenicity and infectivity. For vectors which are genetically modified or constructed (e.g. retroviral vectors), provide some details of the construct and methodology involved. A genetic map would also be appropriate.
In the case of electroporation, and other electrical or mechanical methods for transfer of donor DNA into hosts, only a brief statement is expected.

Host/Vector System(s)

Researchers should elaborate, somewhat, on the predicted stability of introduced genetic traits (including, the localization and copy number of target genes, introduced gene expression, frequency of reversion to wild type characteristics) and the form of heredity of the target phenotype(s). Where

applicable, also assess the likely stability of plasmids, phages, viruses, etc. in host organisms/tissues.

Identification characteristics or markers should be detailed for IBC and NBC references. A concise but thorough risk assessment for the host/vector system(s) proposed is required. Specify whether the level of biological containment provided classifies each system as 'NBC Authorized' or 'Not Authorized'.

Auto-Ecology

Under 'Ecological Context', substantiate the level of biological containment provided by each host/vector system involved. Researchers need to briefly assess the viability of host/vector systems in the open environment (particularly, the natural tendency for invading wild populations, and for developing into pests or weeds) and indicate any factors (including genetic modifications) which might limit growth, reproduction and survival. Additionally, the IBC shall expect a review of the natural crossing possibilities to, or possibilities for ex change of genetic material with related species/natural variants. Any details of the evolutionary potential should be presented under this heading.

Laboratories and Facilities

Clarify which phases of the work will be conducted in each of the laboratories and facilities identified, specify the certified containment level and describe any special containment/safety features offered. Researchers must indicate whether permission has already been obtained for use, and if so, indicate the period of time awarded and attach written confirmation.

Details of Personnel

Attach a CV for each personnel involved in the proposed work, covering personal qualifications (e.g. education, training, professional history) and relevant research experience. Ideally, the general responsibilities of each individual should also be noted, so that the IBC may assess, on a case-by-case basis, whether personnel are adequately prepared and capable to handle the duties assigned. It is essential that brief medical histories of all personnel at risk be included.

Commercial-in-Confidence

Researchers who wish to restrict access to information of commercial significance (e.g. trade secrets or confidential business reports) provided to the IBC and NBC in projects proposals should mark relevant material or portions "Commercial-in-Confidence".

Supplementary Information Form for Laboratory Genetic Manipulation Work on Whole Plants

Attach a copy to both project proposals to be submitted for IBC notification. Attach as many additional sheets/pages as necessary.

Section A - Supplementary Information

1. Name and Institutional Address of Project Supervisor submitting proposal
2. Affiliations
   - indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
3. Project Title
4. Further Details of the Biological System

4.1 Are the experimental plants noxious weeds?
[ ] Yes [ ] No
If yes, elaborate on the ecological context:
- Reproductive Cycle and Evolutionary Potential.
- Dispersal, Proliferation and Persistence in Open Environments.
- Factors which might limit growth, reproduction and survival .
- Natural Crossing Possibilities (to wild populations).
- Noxious Characteristics.

4.2 Are the experimental plants closely related to, or conspecific with wild material which are noxious weeds?
[ ] Yes [ ] No
If yes, indicate which species/strains/natural variants; and elaborate on the ecological context of each:
- Reproductive Cycle and Evolutionary Potential.
- Dispersal, Proliferation and Persistence in Natural Habitats.
- Factors which might limit growth, reproduction and survival.
- Natural Crossing Possibilities (particularly to experimental plants).
- Noxious Characteristics.

4.3 Are the micro-organisms involved harmful to humans, plants or animals?
[ ] Yes [ ] No
If yes, elaborate on the harmful agent (e.g. pathogenic or infectious determinant? toxic substance?) and the known or likely modes of transmission. Indicate any potential to cause epidemics.

5. Further Details of the Methodology

5.1 Substrate for use in cultivation? [ ] Soil
[ ] Soil Substitute (specify)
Describe the sterilization procedures.
(Complete only if genetically manipulated plants are to be grown)

5.2 Plans for Cultivation of Genetically Manipulated Plants

- Developmental Stage(s) Targeted and Intentions to Breed .
- Arrangements for containment of plants and plant materials (spores, seeds, pollen, vegetative materials).
- Arrangements for disposal of plants and plant materials; wastes and by products which may contain viable plant materials.

6. Provide details of equipment and facilities for use in cultivation.
7. Additional information relevant to the assessment of this work.
8. Signature (of Project Supervisor) and Date

Section B - IBC Assessment

9. Assess, on a separate sheet(s) of paper, the supplementary information provided for the proposed work, and attach to the completed IBC Form for Assessment of a Proposal to carry out Laboratory Genetic Manipulation Work
10. Signature (of IBC Chairperson) and Date

Supplementary Information Form for the Engineering of Transgenic Animals

(Considerations in the Design of Transgenic Animal Houses and in the Choice of Animal Containment Levels*)

Attach a copy to both project proposals to be submitted for IBC notification

Attach as many additional sheets/pages as necessary.

* Animal containment levels: CIA, C2A, equivalent or higher

Section A - Supplementary Information

1. Name and Institutional Address of Project Supervisor submitting proposal

2. Affiliations

- Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.

3. Project Title

4. Further Details of the Experimental Animals

4.1 Nomenclature

- lass, scientific name and strain.
- Indicate whether a local or an exotic species.

4.2 Number of Experimental Animals

(schedule of the approx. no. of animals to be handled each session, or at any one time)

4.3 Developmental Stages Targeted

(stages in life cycle involved, for example, "embryo only" or "through reproductive age")

5. Further Details of the Genetic Manipulation

5.1 Does genetic manipulation involve

[ ] germline or [ ] somatic cells?

5.2 Characteristics of donor DNA

- Origin and construct (with references to biological source(s) and to proposal(s) covering preparation of the DNA).
- Characterization and history of prior use in genetic manipulation (with references to published work).
- Physiological traits intended to be conferred (e. g. production of alien, biologically active compounds, heightened resistance, altered appearance and productivity).

5.3 Method for Introduction of donor DNA

[ ] electrical (specify) [ ] mechanical (specify)

[ ] biological vector if a biological vector is involved, describe:

- Construct and characterization (with references to published work and to proposal(s) covering preparation of the vector).
- History of prior use in genetic manipulation and recommended containment level.

5.4 Heredity of Introduced Traits

- Reproductive capacity of experimental animals
- ssessed heritability of transgene(s).
- xpected form of heredity of target phenotype(s).

(Complete this section only if other animals will be housed in the same facilities, but for other work)

6. Concurrent Use of Transgenic Animal Houses

6.1 Number and Composition of the Other Animals (number of animals of different species/strains)

6.2 Basic Nature of the Other Work (use of the other animals, for example, in infectious disease work or in separate genetic manipulation work)

6.3 Arrangements to keep transgenic animals separate from the other experimental animals (physical and temporal provisions)

6.4 Arrangements to identify and to account for individual animals

7. End Use, Care and Disposal

7.1 Intentions to breed, if animals will be reared to full maturity (plans/scheme for projected crosses)

7.2 End Use/Application of transgenic animals (only a brief description is necessary)

7.3 Arrangements for the care or disposal of transgenic animals at the conclusion of work

8. Additional information relevant to the assessment of this work.

9. Signature (of Project Supervisor) and Date

Section B - IBC Assessment

10. Assess, on a separate sheet(s) of paper, the supplementary information provided for the proposed work, and attach to the completed IBC Form for Assessment of a Proposal to carry out Laboratory Genetic Manipulation Work.

11. Signature (of IBC Chairperson) and Date

3.3.3. Framework of the IBC Assessment Form for Laboratory work

The IBC Form for Assessment of a Proposal to carry out Laboratory Genetic Manipulation Work serves, above all, to guide the Institutional Biosafety Committees in the consideration and evaluation of project proposals. These forms are meant to provide a framework for IBCs in assessing the experimental parameters of proposed research leading up to the decision on whether to endorse the work at hand and culminating in the preparation of amendments and provisions to be adopted as necessary. The IBCs must be clear in their evaluation of each component of the experimental system identified in the assessment form. Additionally, the committees should be thoughtful and thorough in drafting the various amendments and provisions to ensure an acceptable standard of biosafety for laboratory work under consideration. Regarding proposals for Category 3 work, special attention should be paid to determine which issues require NBC advice. Completed IBC assessments shall be submitted to the NBC, together with corresponding project proposals, and the efforts of the committee will in turn, guide the NBC in reviewing the work proposed, as required.

Institutional Biosafety Committee Form for Assessment of a Proposal to carry out Laboratory Genetic Manipulation Work

Section A - IBC Assessment of Project Proposal

1. Name and Institutional Address of Project Supervisor who submitted the proposal

2. Affiliations

- Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.

3. Project Title

4. Experimental Parameters

- Indicate whether approved, not approved or inconclusive (insufficient information provided); and
- Include a concise explanation for IBCs position on each of the following.

4.1 Project Objective and Methodology

4.2 Biological System

4.3 Physical Containment (Biosafety) Facilities
4.4 Details of Personnel
- Experience and Expertise
- Training and Instruction
- Health
- Other (please specify)

5. Classification of Proposed Work
- Intended (as indicated by the Project Supervisor on the Project Proposal Form for Laboratory Genetic Manipulation Work).
[ ] Category 2 [ ] Category 3
- As Assessed by the IBC
[ ] Category 2 [ ] Category 3

6. Physical Containment (Biosafety) Level
(for each laboratory and facility where work will be conducted, indicate)
- At Hand (as certified by the IBC or NBC).
[ ] C1 [ ] C2 [ ] C3 [ ] C1A [ ] C2A [ ] PH1
[ ] PH2 [ ] PH3 [ ] Other (please specify)
- Required by the IBC (for the purposes of the work to be conducted).
[ ] C1 [ ] C2 [ ] C3 [ ] C1A [ ] C2A [ ] PH1
[ ] PH2 [ ] PH3 [ ] Other (please specify)

7. The project proposal form attached has been reviewed by the IBC and as assessed above, the committee [ ] endorses / [ ] does not endorse the research work proposed.

Section B - IBC Recommendations

(Complete this segment only if Project Proposal does not receive IBC endorsement)

8. The following conditions and amendments must be adopted for the research work proposed to receive future endorsement from the IBC. (Complete this segment only if Project Proposal receives IBC endorsement)

9. The following special provisions must be adopted and implemented in conjunction with the Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work, during the conduct of research work.

Section C - IBC Requests to the National Biosafety Committee

(Complete this section only if Project Proposal is intended for Category 3 work)

10. The project proposal form attached has been reviewed by the IBC and as assessed above, the committee requires and requests specific NBC advice regarding the following.

11. Signature (of IBC Chairperson) and Date

Instructions for Completion of the IBC Form for Assessment of a Proposal to carry out Laboratory Genetic Manipulation Work

The IBC must submit a typed, completed assessment form to the NBC, attached to the corresponding project proposal, and should retain a copy for records and reference. Assessment forms must be signed and dated by the IBC Chairperson. A clear and concise explanation is required for the IBCs position on each of the experimental parameters identified in the assessment form. The NBC shall expect some justification on IBC decisions to approve or not to approve the various components of the experimental system proposed. Where inconclusive, the IBC must indicate what information is lacking. As appropriate, references should be made to the relevant sections of the NBC Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work. Details of personnel need to be checked by the IBC but the relevant attachments should not be forwarded to the NBC.

Some Specific Provisions

Proposals for work awarded exempt status under Category 1

IBC assessments and corresponding project proposals need not be forwarded to the NBC for information.

Proposals for work assessed as Category 2

The IBCs may authorize or commission research work immediately, upon endorsement of the project proposals, but must in form the proponents of any additional conditions to be adopted or guide lines to be observed, beforehand. IBC assessments should be attached to the top sheet of the corresponding project proposals and submitted to the NBC soon afterwards.

Proposals for work assessed as Category 3

IBC assessments should be attached to the top sheet of the corresponding project proposals and submitted to the NBC at the earliest possible. The IBCs may not authorize or commission research work (even if the committees initially endorse the proposals) until complete reassessment of project proposals following receipt of NBC ad vice and recommendations.

3.3.4. Framework of the Project Proposal Form for field work

Project proposal forms may be obtained from the NBC Secretariat at the following contact (postal address):

Science Technology and Environment Agency
Research Institute of Science
P.O.Box: 10782, Vientiane, Lao PDR
Tel/Fax: (856-21) 262002
E-mail: science@laotel.com , laobch@stea.gov.la

The Project Proposal Form for Assessment of Genetic Manipulation Field Work (along with all attachments and supplements) will serve as the principal source of reference for the IBC and the NBC in the initial consideration and approbation of research work regulated under biosafety Guidelines. On the basis of information provided in, and of risks/concerns that may be inferred from these proposals, the IBC shall classify research work and determine additional biosafety measures to be adopted / implemented as necessary, including site relocation and procedural amendments. Proposals shall also be reviewed by the NBC, and whatever details provided will constitute the framework for NBC assessment and recommendations. The NBC shall assume direct responsibility for endorsing project proposals.

Recognizing that IBC and NBC activities, in these initial stages of genetic manipulation practice depend on the written forms submitted, researchers should be thorough yet concise and clear as to their intentions, so that the committees may readily and fully understand the nature of proposed work. All important details should be included and as many additional sheets/pages may be attached as necessary. Notable and exceptional intent should be stressed, ideally in the title or under the objectives. Particular care must be observed regarding phrasing-approval will be restricted to the specific experimental procedures and biological system components identified so descriptions should be broad enough (though never vague) for the purposes of the research.

Project Proposal Form for Assessment of Genetic Manipulation Field Work

Section A - Authorities and Outlook

1. Name and Institutional Address of Project Supervisor submitting proposal
2. Names of other Supervisors, Co-Investigators or Program/Section Leaders
   - Indicate institutional addresses where different from (1).
3. Affiliations
   - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
4. Project Title
5. Project Objectives
6. Anticipated Future Release and/or End Use

Section B - Materials and Methods

7. Site of Field Work
- Specify the location of trial and how plots are to be arranged on site.
- Provide details of the physical environment and ecology.
- Identify the facilities available on site.
- Give reasons for the choice of location.

8. Scale of Field Work
- Indicate the approximate number of organisms involved and the size of test plots.

9. Methodology and Protocol
- Provide thorough yet concise descriptions of the main experimental procedures.
- Indicate the developmental stages involved, and identify the control, test and challenge groups.
- Include a timetable of activities.

10. Precautions and Safeguards (please describe in full)
- Measures for containment of test plots and experimental organisms
- Arrangements for the disposal of experimental organisms, and for the clean up of organic residues, at the completion of work
- Contingency plans

11. Results from Laboratory Tests of the Biological System

11.1 Characterization of Genetic Modification
- Stability of Introduced Genetic Traits
- Heredity of Genetic Inserts
- Level of expression and regulation of transgenes
- Traces of recombinant vectors in the final construct (where applicable)

11.2 Effects of Genetic Modification
- Changes in Phenotype and Novel Physiological Traits

11.3 Evolutionary Potential
- Competitive or Selective Advantage, conferred by genetic modification
- Potential for Mutation and/or Adaptation to field conditions

11.4 Noxious or Harmful Characteristics
- Nature of the Harmful Agent
- Known and/or Likely Modes of Transmission

11.5 Ecological Context (Auto-Ecology)
- Viability in Open Environments
- Known predators and parasites
- Natural Crossing Possibilities to Related Species
- Propensity for Transfer of Genetic Inserts

12. History of Prior Field Work (with the experimental organism(s) or with related biological systems)

13. Assessed Course of Work
- Anticipated direct, and indirect ecological effects
- Possible secondary genetic effects

14. Intended Date of Commencement; Expected Date of Completion

Section C - Personnel Involved with Research Work Proposed

15. Details of Personnel
- Name, Qualifications and Experience
- Responsibilities and Duties
- Medical History

16. Signature (of Project Supervisor) and Date

Instructions for Completion of the Project Proposal Form for Assessment of Genetic Manipulation Field Work

The project supervisor must submit two typed, completed project proposal forms to the supervising IBC (one of which shall be forwarded to the NBC for information) and should retain a copy for records and reference. For work supported by two or more institutions, all IBCs of authority must be notified.

Project proposal forms must be signed and dated by the project supervisor to be received by the IBC and the NBC. For research work employing multiple project supervisors or head researchers, the name and professional address of the supervisor preparing and submitting the proposal should be indicated under heading (1). Said individual shall sign and date both proposals before submission to the IBC of authority. As many additional sheets/pages may be attached as necessary. Incomplete proposals will delay IBC endorsement as further information is sought.

Important Directive

Researchers must procure a copy of the corresponding Project Proposal Form for Assessment of Laboratory Genetic Manipulation Work, which precedes the initial genetic engineering of this biological system to be field tested. Attach this form to the back page of the Project Proposal Form for Assessment of Genetic Manipulation Field Work before submission to the responsible IBC. Some information on the latter form is critical to IBC and NBC assessment.

Commercial-In-Confidence

Researchers who wish to restrict access to information of commercial significance (e.g. trade secrets or confidential business reports) provided to the IBC and NBC in project proposals should mark the relevant material or portions "Commercial-In-Confidence."

3.3.5. Framework of the IBC Assessment Form for field work

The IBC Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work serves, above all, to guide the Institutional Biosafety Committees in the consideration and evaluation of project proposals. These forms are meant to provide a framework for IBCs in assessing the experimental parameters of proposed research leading up to the decision on whether to endorse the work at hand and culminating in the preparation of amendments and provisions to be adopted as necessary. The IBCs must be clear in their evaluation of each component of the experimental system identified in the assessment form. Additionally, the committees should be thoughtful and thorough in drafting the various amendments and provisions to ensure an acceptable standard of biosafety for field work under consideration. Special attention should be paid to determine which issues require direct NBC endorsement. Completed IBC assessments shall be submitted to the NBC, together with corresponding project proposals, and the efforts of the committee, will assist the NBC in reviewing the work proposed, as required.

Institutional Biosafety Committee
Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work

Section A - IBC Assessment of Project Proposal

1. Name and Institutional Address of Project Supervisor who submitted the proposal
2. Affiliations
   - Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee.
3. Project Title
4. Experimental Parameters
   - Indicate whether approved, not approved or inconclusive (insufficient information provided); and
   - Include a concise explanation for IBC's position on each of the following.

4.1 Project Objective and Methodology
4.2 Biological System
4.3 Site or Location of Trial
4.4 Timing and Period of Work
4.5 Safeguards and Contingency Plans
4.6 Details of Personnel
- Experience and Expertise
- Training and Instruction
- Health
- Other (please specify)

Section B - Results of Assessment and IBC Recommendations (where applicable)

5. Experimental Plants are recognized as
[ ] 5.1 ...genetically modified species with a history of safe use in field work. (let work proceed in accord with the standards appropriate to the particular plant, and as has been)
[ ] 5.2 ...not falling under condition 5.1, precedent. (let work proceed under the advice or counsel of the IBC and NBC) (where applicable)

6. Experimental Microorganisms are recognized as
[ ] 6.1 ...genetically modified species with a history of safe use in field work. (let work proceed in accord with the standards appropriate to the particular microorganism, and as has been)
[ ] 6.2 ...not falling under condition 6.1, precedent. (let work proceed under the advice or counsel of the IBC and NBC)

7. The project proposal form attached has been reviewed by the IBC and as assessed above, the committee
[ ] endorses the research work proposed (results of assessment are found to be consistent with conditions 5.1 or 6.1, precedent).
[ ] does not endorse the research work proposed (direct NBC endorsement is sought and required).

8. The following special provisions must be adopted and implemented in conjunction with the BIOTEC Biosafety Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release, 1993 during the conduct of research work.

9. ignature (of IBC Chairperson) and date

Section C - NBC Assessment of Project Proposal

10. The project proposal form attached has been reviewed by the NBC and as assessed above, the committee
[ ] endorses the research work proposed, unconditionally.
[ ] endorses the research work proposed, on the following conditions:
[ ] does not endorse the research work proposed, for the following reasons:

11. Signature (of NBC Chairperson) and Date

Instructions for Completion of the IBC Form for Assessment of a Proposal to carry out Genetic Manipulation Field Work

The IBC must submit a typed, completed assessment form to the NBC, attached to the corresponding project proposal, and should retain a copy for records and reference.

Assessment forms must be signed and dated by the IBC Chairperson to be received by the NBC. Where appropriate, IBC advice and copies of the completed assessment form should be sent to those regulatory agencies duly constituted to manage the planned release of genetically modified organisms, or with the legal responsibility to approve the end use of such organisms.

A clear and concise explanation is required for the IBC's position on each of the experimental parameters identified in the assessment form. The NBC shall expect some justification on IBC decisions to approve or not to approve of the various components of the experimental system proposed. Where inconclusive, the IBC must indicate what information is lacking. Details of personnel need to be checked by the IBC but the relevant attachments should not be forwarded to the NBC.

3.4. The Administration systems for Monitoring, Inspections and Enforcement on Biosafety

3.4.1. Biosafety Monitoring

The term "***monitoring***" describes the scientific collection of biosafety data to support the scientific basis for biosafety decisions. It also describes the systematic measurement of the effects of GMOs over time. The aim of GMO monitoring is to identify direct, indirect, immediate, delayed, or unforeseeable harmful effects that GMOs and their application might cause to the environment, and human health. The data obtained by such monitoring measures will, among others, be used to impose conditions, or to maintain, renew, or withdraw an approval for placing a GMO on the market.

Effective monitoring requires that appropriate methodology is available prior to the commencement of monitoring programmes, and advisors need to be clear in what they are looking for from the monitoring, how they want it to be done and what value they hope to get from the data. Designing an effective monitoring strategy includes:

1. The monitoring strategy:
    - Identification of the potential effects to be monitored as indicated from the risk assessment.
    - Background information pertaining to the particular GMO.
    - Baseline status of the receiving environment.
    - Timeframe and frequency of data collection.
    - Assignment of responsibilities.
2. The monitoring methodology:
    - Identification of the relevant parameters to be monitored, as indicated by the risk assessment.
    - Place and area to be used for the monitoring
    - Approaches for sampling and analysis.

3. The design of the monitoring plan:
    - Be undertaken on a case-by-case basis;
    - Take into account the characteristics of the GMO, the type and scale of the activity and the conditions of the release site;
    - Incorporate specific monitoring provisions focusing on adverse effects identified in the risk assessment, and general surveillance for unanticipated adverse effects;
    - Be carried out for a period of time long enough to detect immediate or delayed effects which were identified in the risk assessment;
    - Make use of established routine surveillance practices where appropriate;

- Identify who (applicant, users) will carry out the various monitoring tasks and who is responsible for ensuring that the monitoring plan is carried out;
- Ensure that data are analysed and used in determining future risk management strategies;
- Ensure that there is a route by which the applicant and the competent authority will be informed of any observed adverse effects;
- Provide appropriate remedial measures to use if significant adverse effect is noted; and
- Provide feedback mechanisms during the monitoring to enable the process to be stopped or modified if inadequate data is being generated from the methodology.

3.4.2. Biosafety Inspections

The term "***inspection***" describes the check for compliance with biosafety conditions for activities with GMOs. This may include the review and investigation of facilities, materials and documents related to GMOs. Not all activities will require monitoring plans. Where they are deemed necessary, careful consideration by the regulators of the data needed, and how it will be used, is essential for the monitoring to be useful.

The **purpose of inspections** is to ensure compliance with the conditions set out in decision documents or approvals, and also to ascertain whether the agreed risk management strategies are adhered to. One of the functions of the National Biosafety Authority is to provide and update inspection and guidance manuals to assist in the inspectorate functions for GMOs.

Risk management procedures are generally proposed by the applicant, then reviewed and possibly changed by the scientific advisors. The conditions of any GM activity are appended to the approval documents and used by inspectors to check for compliance. The administration officers in the biosafety office are responsible for triggering inspections.

The inspectors submit inspection reports that are reviewed by the administrators and follow up actions are initiated as needed. In most instances, the applicant must supply an activity report at the end of an approved activity; compliance or alterations to risk management procedures are recorded in this document. In some cases, evaluating the effectiveness of risk management procedures may form part of a monitoring programme that functions before, during, and even after an approved GM activity.

Biosafety inspectors need four types of skills: legal, technical organizational, and personal:

- The **legal skills** usually come through legal training and qualification as officers of law in the country.
- The **technical skills** include a good understanding of ecology, general biology, molecular biotechnology and gene transfer, a willingness to read

scientific literature critically and a good understanding of what is needed to run a biotechnology laboratory and testing facilities.

- Good **organisational skills** are the most critical for effective performance. The biosafety inspector must develop processes and systems that enable him/her to cope with increasing numbers of approvals. A slow increase in issued approvals will give inspectors an opportunity to understand their role and to streamline and prioritise their time and procedures.
- In addition to these skills, inspectors would also require **personal qualities** that would give them credibility to do their job. These qualities include trustworthiness, noncorruptibility, good conduct, a willingness to take oaths of duty, a high work ethic, and good interpersonal skills. The regulatory authority may also require a disclosure of possible conflict of interests.

3.4.3. Biosafety Enforcement

The legal authority for enforcement is determined by Biosafety Law. Biosafety Enforcement follows identification of non – compliance. For the purpose of biosafety enforcement is needed:

1. **Administrative tasks**

When the inspectors or regulators become aware of an infringement they need to take action immediately. Many infringements are unintended and easily corrected. The corrections need to be implemented quickly to maintain safety levels and the credibility of the system.

Where an infringement cannot be quickly or easily corrected, the activity may need to be stopped until the corrections can be implemented to the satisfaction of the regulators. Most regulatory regimes provide for this and the process must follow the legal requirements. In extreme cases where the infringement may have resulted in harm, or the negligence is deemed unacceptable, the enforcement agency may wish to prosecute the applicant. Prosecution is usually carried out under the country's existing legal system.

2. **Roles and responsibilities**

The responsibility for enforcement falls primarily on the enforcement agency. These officers will rely on the biosafety administrators and inspectors for evidence to support any legal action that is taken. The biosafety administrators need to provide documentation to support an infringement claim. These documents may include:

- the approval document with the conditions clearly stated;
- the inspection reports identifying the infringement; an assessment of the impact of the infringement with respect to safety; and
- an assessment of the impact of the infringement with respect to safety; and
- any evidence seized or collected to support the claim, such as soil or plant analyses, photographs, signed statements, etc..

Chapter IV

Mechanisms for public education awareness and participation (PEAP)

4.1. The overall objectives, Lao concepts and principals for PEAP on biosafety

4.1.1. The overall objectives of PEAP

Make Lao PDR "be safety from biotechnology", the public have biosafety knowledge and skills, to know how to use of living modified organisms and their product in individual daily life, actively participate and contribute to the conservation and sustainable use genetic resources, taking also into account risks to human health.

4.1.2. The key principals of PEAP on biosafety

For completing the goals and objectives mentioned as above, the PEAP is not only can be incorporated into current formal activities, e.g. at schools, training courses, projects, mass organization program, but also in the individual daily activities: at home in the daily life and at work places. So PEAP on biosafety is not only a subject to learn and teach, but it is something you live. In order to complete all of PEAP process, much better implement biosafety PEAP Key Principles as are:

- PEAP on biosafety should be open to everyone. Because the environment is very important and related to all people. Therefore, PEAP on biosafety should not focus on specific persons or group of people in the society. It is a responsibility of all people including the government, government staff, workers, students, business people, and the public;
- PEAP on biosafety should be a long term and continuing process. Data and information on biosafety have been often changed and adjusted based on the past experience and lessons. There is opportunity to improve technology, knowledge and skills that can be used to mitigate challenging biosafety issues. In order to achieve this, therefore, every person has to improve their knowledge and skills;
- Formal and non-formal education should be jointly developed in order to complement each other. That means biosafety information should come from two main sources: formal and non-formal education. Although, some knowledge on biosafety mainly come from formal education, but some of them may come from non-formal education. Therefore, formal and non-formal education will complement and support each other and improve the content of subject mater and spread out widely which can be implemented with other activities;
- Participatory approach should be used in the planning and implementation of PEAP on biosafety. Starting by giving explanation about direct and

indirect benefit of biosafety protection to learners to make them interested in the subject. PEAP on biosafety is related to many people in the society. Therefore, it is important to use ideas and opinions of different people in the planning and implementation then it will make those plans appropriate and can provide benefit to participant, and the plans will be implemented more smoothly;

- PEAP on biosafety should start from small to large scale based on concerned community's capacity. Community's institution should be used as a place to support and promote PEAP on biosafety. In addition, we should strengthen and support existing institutions such as village administration offices, Youth Organisation, Women Union, national Front for Construction, schools, temples and cultural centres that can be important parts for implementation of PEAP on biosafety activities;
- We should select and analyse relevant issues in order to define characteristics and the needs of different target groups aiming to improve and protect their fundamental interest, knowledge, culture and tradition to make them participate actively in PEAP on biosafety activities, and to promote local cultural value;
- Different curriculum and methodologies, and contents should be used in PEAP on biosafety for family, community, school, work place, temple, mass media, recreational centre and other, which were designed and constructed should be used for study purpose. Content and methodology that used in PEAP on biosafety should be appropriate to target groups, and concerned sectoral agencies;
- PEAP on biosafety activities should be related to sectoral development and to find appropriate way to use natural resources, facilities that suitable to existing infrastructure, lessons and experience. Therefore, development will provide opportunity and job allocation to Lao people;
- Monitoring and evaluation is a key component to assess, improve and extend initiative on PEAP on biosafety. Monitoring the result of PEAP on biosafety is aiming to learn and improve theory and practice in PEAP on biosafety and make them consistent with each other.

4.2. The existing system of public education awareness and participation on biodiversity

Based on draft of National Biodiversity Strategy upper to year 2020, 2010 and Action Plan for 5 year (2001-2005), the PEAP on biodiversity as well as the PEAP on Environment, are necessary to promote the general public, public sectors, private sectors, mass organization, mass media and different group people in society, understand better about the benefits of environment as well as the biodiversity in order to attach them to participate more in the biodiversity management, conservation, and sustainable use.

In Lao PDR, EE as well as biodiversity issues have been incorporated into the curriculum of common schools (formal and non-formal) and vocational colleges. These curricula and teaching materials were developed by various organizations and have not been standardized. To this concern, the National Research Institute for Education Science (NRIES), STEA, National University of Lao, and Different Institutes are enough strong coopering and conducting a discussion on biodiversity education curriculum development as well as on environment, in particularly the Faculty of Natural Science of National University of Lao is improving existing teaching curriculum on biodiversity for fulfilling of the teaching need and for relevant technicians.

Attempts to raise Awareness on environmental and biodiversity have also been conducted in form of dissemination meetings, campaign, lectures and in forms of dissemination include the publishing of information in the mass media namely in newspapers, magazines, radio, television broadcasts and others.

The biodiversity training for building the capacity of technical staff has been conducted by different ministries and institutions which aim at meeting their own, specific demands. For example, Ministry of Agriculture and Forestry conducts training courses on biodiversity as such: wildlife survey and Protected Areas management, while STEA conducts courses in Environmental Impact assessment, public participation and public awareness on biodiversity and the different sectors at central as well as local level also are conducting the own biodiversity training activities based on dissemination of own main tasks. Based on the past activities can be evaluated as are following:

- Key Issues:

- Low incentives for staff working in remote areas.
- Inadequate materials and means of dissemination.
- A lack of good PEAP system to promote the best understanding of the importance of biodiversity among local communities and government staff due to the inadequate dissemination of information.
- Insufficient numbers of professional staff are currently working in this field and a lack of capable staff and inadequate dissemination techniques.
- Education levels of the majority of rural people remain low and many are illiterate.
- Limited budget allocations to finance PEAP programmes and curriculum development.
- The majority of people do not like to read.
- Inadequate coordination among sectors.

Intervention Options:

- Enhance PEAP regarding the significance of biodiversity resource conservation and its sustainable use.
- Increase PEAP by focusing on the government, as well as the private and public sectors.

- Improve the communication process between all stakeholders.
- Disseminate the principles and targets of the CBD.
- Provide information on the status of biodiversity to the public.
- Create an awareness among the younger generation both within and outside of the education system.
- Address gender issues.
- Upgrade the provision of education for people living in remote areas.
- Ensure that budget allocations for this field are put in place.
- Improve the coordination of training among the relevant sectors.

4.3. The frameworks for PEAP on biosafety

Based on Cartagena Protocol article 23, the existing system of PEAP on environment as well as on biodiversity as mentioned above and Environment protection law And National Environment Education and Awareness Strategy upper to year 2020, 2010 and Action Plan for 5 year (2001-2005), National Biodiversity Strategy upper to year 2020, 2010 and Action Plan for 5 year (2001-2005), the Lao framework for PEAP on biosafety should be incorporated to the existing PEAP on environment as well on biodiversity been well developed already, such as Environment Training System, Environment Education System, Environment Awareness System, Environment Public Participation System.

For Promotion and facilitate public awareness, education and participation concerning the biosafety, particularly the safe transfer, handling and use of living modified organisms; and for ensuring that the strategy, vision of PEAP system as mentioned above will be successful, the Lao PDR should focus on 5 frameworks as are following:

First framework: Incorporate the biosafety education activities at all levels of general education (formal and non-formal education) as part of Environment Education curriculum.

Second framework: Develop the biosafety awareness activities as part of Environment awareness system.

Third framework: Develop the biosafety training mechanism.

Fourth framework: Develop the biosafety public participation mechanism in decision making.

Fifth framework: Create the Biosafety network and to develop the biosafety information provision mechanism.

4.3.1. *First framework:* Incorporate the biosafety education activities at all levels of general education (formal and non-formal education) as part of Environment Education curriculum.

The biosafety education should be part of environment education at all level of formal and non-formal as following:

a. Formal education

Objective 1:
Conduct a survey to determine the present level and status of biosafety education in formal education across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety education in formal education across country.
2. To conduct the analyses of gathering baseline information on biosafety education in formal education across country.
3. Report of biosafety education status in formal education across country.

Objective 2:
To identify sector, staffs and roles of responsibility about biosafety education at all levels of formal education across country

Action:

1. To conduct discussion workshop for decision makers (main technical staffs) between STEA and relevant sectors such: Department of General Education, Ministry of Education, school administrators at all levels, concerning biosafety education development in formal education.
2. To identify sector, staffs and its roles of responsibility about biosafety education at all levels of formal education across country
3. Conduct seminar workshop, training for school administrators, teachers to enhance understanding of biosafety and promote commitment to the conservation and sustainable use of genetic resources, taking also into account risks to human health.

Objective 3:
To develop a biosafety education curriculum for all levels of formal education across country

Action:

1. Organize multisectoral workshop to plan, design and formulate a multidisciplinary curriculum framework for the integration of biosafety topics at all levels of formal education between STEA and relevant sectors such: Department of General Education, Ministry of Education, school administrators at all levels, concerning technical staffs.

2. Pilot-test the biosafety education curriculum, particularly the objectives, content, learning activities and assessment procedures.
3. Undertake a review of the curriculum for teacher training colleges to reorient teacher education towards biosafety education for sustainable use of genetic resources.

Objective 4:
To develop and produce support materials for biosafety education at all level of formal education across country

Action:

1. Prepare guidelines for the development and production of biosafety education support materials in the different formats (multimedia, module, poster, etc) for formal education.
2. Conduct workshops to develop biosafety education support materials, involving subject experts, scientists and computer technologists for formal education.
3. Produce biosafety education support materials for preschool, primary, secondary and tertiary education levels, involving classroom teachers, subject experts and computer technologists for formal education.
4. Incorporate all of biosafety issues, experiences and practices (such as indigenous farming and fishing practices) in biosafety education support materials for formal education.

b. Non-formal education

Objective 5:
Conduct a survey to determine the present level and status of biosafety education in non-formal education across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety education in non-formal education across country.
2. To conduct the analyses of gathering baseline information on biosafety education in non-formal education across country.
3. Report of biosafety education status in formal education across country.

Objective 6:
To identify sector, staffs and roles of responsibility about biosafety education at all levels of non-formal education across country

Action:

1. To conduct discussion workshop for decision makers (main technical staffs) between STEA and relevant sectors such: Department of General Education, Ministry of Education, school administrators at all levels, concerning biosafety education development in non-formal education.
2. To identify sector, staffs and its roles of responsibility about biosafety education at all levels of non-formal education across country
3. Conduct seminar workshop, training for non-formal education administrators, teachers to enhance understanding of biosafety and promote commitment to the conservation and sustainable use of genetic resources, taking also into account risks to human health.

Objective 7:
To develop a biosafety education curriculum for all levels of non-formal education across country

Action:

1. Organize multisectoral workshop to plan, design and formulate a multidisciplinary curriculum framework for the integration of biosafety topics at all levels of non-formal education between STEA and relevant sectors such: Department of General Education, Ministry of Education, school administrators at all levels, concerning technical staffs.
2. Pilot-test the biosafety education curriculum for non-formal education, particularly the objectives, content, learning activities and assessment procedures.
3. Undertake a review of the curriculum for teacher training in non-formal education to reorient teacher education towards biosafety education in non-formal education for sustainable use of genetic resources.

Objective 8:
To develop and produce support materials for biosafety education at all level of non-formal education across country.

Action:

1. Prepare guidelines for the development and production of biosafety education support materials in the different formats (multimedia, module, poster, etc) for non-formal education.

2. Conduct workshops to develop biosafety education support materials, involving subject experts, scientists and computer technologists for non-formal education.
3. Produce biosafety education support materials for non-formal education.
4. Incorporate all of biosafety issues, experiences and practices (such as indigenous farming and fishing practices) in biosafety education support materials for non-formal education.

4.3.2. *Second framework:* Develop the biosafety awareness activities as part of Environment awareness system.

Objective 9:
Conduct a survey to determine the present level and status of biosafety awareness across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety awareness across country.
2. To conduct the analyses of gathering baseline information on biosafety awareness across country.
3. Report of biosafety awareness status across country.

Objective 10:
To identify sector, staffs and roles of responsibility about biosafety awareness at all levels of mass media across country

Action:

1. To conduct discussion workshop biodiversity awareness development between decision makers (main technical staffs) of STEA and relevant sectors such: Department of Mass media, Ministry of Information and Culture, mass media administrators at all levels.
2. To identify sector, staffs and its mandates in biosafety awareness at all levels across country.
3. To conduct training for administrators, mass media to enhance understanding of biosafety.

Objective 11:
To develop a biosafety awareness mechanism at all levels of mass media across country

Action:

1. To conduct the workshop to plan, design and formulate a biosafety awareness mechanism for mass media program between STEA and relevant sectors such: Department of Mass media, Ministry of Information and Culture, mass media administrators at all levels.
2. Pilot-test the biosafety awareness program in all of media and evaluate the results, content, and procedures of awareness activities.
3. To undertake a review of the existing awareness program in all of mass media across country for improving.

Objective 12:
To develop and produce support materials for biosafety awareness at all level of mass media across country.

Action:

1. Prepare guidelines for the development and production of biosafety awareness support materials in the different formats (multimedia, module, poster, etc).
2. Conduct workshops to develop biosafety awareness support materials, involving subject experts, scientists and computer technologists.
3. Produce biosafety awareness support materials.
4. Incorporate all of biosafety issues, experiences and practices (such as indigenous farming and fishing practices) in biosafety awareness support materials.

4.3.3. *Third framework:* Develop the biosafety training mechanism.

Objective13 :
Conduct a survey to determine the present level and status of biosafety manpower capacity building across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety manpower capacity building across country.
2. To conduct the analyses of gathering baseline information on biosafety man power capacity building across country.
3. Report of biosafety man power capacity building status across country.

Objective 14:
To discuss and identify the roles of responsibility about biosafety manpower cacity building across country

Action:

1. To conduct discussion workshop on manpower capacity building between decision makers (main technical staffs) from STEA and relevant sectors.
2. To identify the mandate and roles of responsibility of relevant sectors about biosafety manpower capacity building at all levels across country.
3. To conduct training for biosafety manpower capacity building administrators, trainers to enhance understanding of biosafety across country.

Objective 15:
To build the capacity of trainers, teachers, curriculum-training manual developer on biosafety across country

Action:

1. To conduct the workshop on biosafety manpower capacity building curriculum-training manual, training and teachers building between STEA, relevant sectors, curriculum-training manual developers, trainees, teachers across country.
2. To identify and priority the short and long term training courses,
3. To build Biosafety Manpower Capacity Building Training Center as appropriate,
4. To undertake a review of the topics, contents, and approach of biosafety manpower capacity building for appropriate modification.

Objective 16:
To develop and produce support materials for biosafety manpower capacity building across country.

Action:

1. To organize the discussion workshop on development and production of biosafety manpower capacity building support materials in the different formats, methods.
2. To produce biosafety manpower capacity building facilities and support materials for biosafety manpower capacity building relevant staffs.

4.3.4. *Fourth framework*: Develop the biosafety public participation mechanism in the decision making.

Objective17 :
Conduct a survey to determine the present level and status of biosafety public participation across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety public participation across country.
2. To conduct the analyses of gathering baseline information on biosafety biosafety public participation across country.
3. Report of biosafety public participation status across country.

Objective 18:
To develop support mechanism for biosafety public participation across country.

Action:

1. To conduct discussion workshop on develop support mechanism for biosafety public participation between decision makers (main technical staffs) from STEA and relevant sectors.
2. To conduct the development support mechanism for for biosafety public participation across country.

Objective 19:
To develop the policy and legislation on biosafety public participation across country

Action:

1. To organize the discussion workshop on development of biosafety public participation policy and legislations between decision makers from STEA and relevant sectors.
2. To develop the biosafety public participation policy and legislations.

4.3.5. *Fifth framework:* Create the Biosafety network and to develop the biosafety information provision mechanism.

Objective20:
Conduct a survey to determine the present level and status of biosafety networking and biosafety information provision mechanism across country.

Action:

1. To conduct the gathering baseline information regarding the status of biosafety networking and biosafety information provision mechanism across country.
2. To conduct the analyses of gathering baseline information on biosafety networking and biosafety information provision mechanism across country.
3. Repot of biosafety networking and biosafety information provision mechanism status across country.

Objective 21:
To discuss on biosafety networking and biosafety information provision mechanism across country

Action:

1. To conduct discussion workshop on biosafety networking and biosafety information provision mechanism between decision makers (main technical staffs) from STEA and relevant sectors.
2. To identify the mandate and roles of responsibility for biosafety networking and biosafety information provision mechanism between relevant sectors.
3. To conduct training for relevant staffs in order to biosafety networking and biosafety information provision mechanism are going on.

Objective 22:
To develop biosafety information provision mechanism (Biosafety Clearing House) across country

Action:

1. To organize discussion workshop on development of Biosafety Clearing House Mechanism across country.
2. To promote and establish the Biosafety Clearing-House as part of the Clearing-House Mechanism that was created by the Convention of Biodiversity, getting support for exchange, provision of information to public.

Objective 23:
To facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs.

Action:

1. To conduct the collection and types of information to be exchange are broadly described as scientific, technical, environmental and legal information on, and experience with, LMOs;
2. To create the web site on BCH (use electronic) and other systems for the exchange of information relevant to the protocol.
3. To conduct the relationship with the CBD's CHM for consulting the website at: http://bch.biodiv.org/pilot/ or the main CBD website at: http://www.biodiv.org.

Chapter V:
Capacity building Program to implement Cartagena Protocol on Biosafety

The objective of Capacity building Program to implement Cartagena Protocol on Biosafety is to identify specific need of Lao PDR in the following iterms:

5.1. Institutional capacity building

1. Legislative and regulatory framework

1. Biosafety standards
2. Compliance mechanisms
3. Development of legal frameworks
4. Harmonization of biosafety-related sectoral laws/policies
5. Implementation of legal frameworks
6. Mainstreaming biosafety into other sectors
7. Multidisciplinary strategic planning
8. Negotiation of bilateral, regional and multi-lateral agreements
9. Regulatory training (legal, policy, enforcement, inspection etc.)

2. Administrative framework

1. Administration of the AIA procedure
2. Customs and border control procedures
3. Decision-making system and administrative procedures
4. Institutional entities for handling biosafety issues
5. Inter-agency communication and coordination
6. Mechanisms for considering socio-economic impacts
7. Mechanisms for private sector and community involvement
8. Mechanisms for review of decisions
9. Monitoring and reporting on implementation of the Protocol

3. Technical, scientific and telecommunication infrastructures

1. Border control and inspection facilities
2. Computer hardware, software and networks
3. Database infrastructure and protocols
4. Internet connectivity and information security
5. LMO containment (quarantine) facilities
6. LMO disposal facilities (e.g. incinerators)
7. LMO research facilities
8. LMO testing laboratories and equipment

9. Office facilities, equipment and supplies, including maintenance
10. Telecommunications facilities
11. Transportation means

4. Funding and resource management

1. Financial assistance (grants or loans)
2. Financial management skills
3. Fundraising skills, including proposal writing
4. Information on funding sources
5. Promoting public-private sector partnerships

5. Mechanisms for follow-up, monitoring and assessment

1. Emergency measures for unintentional movements
2. Inspection procedures and control measures
3. Long-term LMO monitoring and surveillance
4. Mechanisms for detecting unintentional or illegal LMO movement

5.2. Human Resources Development and Training

1. Scientific and technical expertise

1. Applied ecology
2. Assessment of characteristics of LMOs
3. Assessment of effects of promotor and marker genes
4. Assessment of the extent and effects of gene flow
5. Detection, testing and quantitative analysis of LMOs
6. Evaluation of genetic modifications
7. Molecular biology skills (e.g. gene isolation, sequencing etc.)
8. Scientific methods and protocols relevant to risk assessment and management
9. Specialists in IT, information management, database management, data analysis, etc.

2. Legal, social and economic expertise

1. Analysis of the linkages between other international agreements and Protocol requirements
2. Assessment and integration of socio-economic considerations
3. Assessment of trade impacts of biosafety-related measures
4. Legal drafting and analysis

5. Support for case-by-case cost-benefit analysis, review of ethical considerations and relevance of LMOs in addressing societal needs e.g. food security and nutritional requirements, etc
6. Training of policy-makers and regulators

5.3. Risk assessment and other scientific and technical expertise

1. Access to reference materials / databases on risk assessment
2. Competence to review and audit risk assessments
3. Establishment of risk assessment review mechanisms, including consideration of risk assessment review bodies (e.g., independent scientific advisory committees).
4. National biosafety research
5. National risk assessment frameworks, principles, procedures and mechanisms
6. Risk assessment methodologies
7. Risk assessment scientific expertise

5.4. Risk management

1. Detection, management and prevention of unintentional transfer of LMOs
2. Emergency measures for unintentional LMO releases
3. Mechanisms for cooperation with other Parties regarding risk management
4. Risk management frameworks, strategies and mechanisms
5. Tools for monitoring the handling and use of LMOs

5.5. Public awareness, education and participation

1. Biosafety awareness activities (seminars, radio talks, etc)
2. Biosafety awareness materials and equipment
3. Media engagement skills and strategies
4. Public access to the Biosafety Clearing-House
5. Public participation in decision-making
6. Risk communication skills and strategies
7. Timely public access to information on impending LMO imports

5.6. Information exchange & data management

1. Collaborative mechanisms to ensure synergies and information-exchange
2. Data collection, management and storage
3. Information exchange and data management infrastructure

4. Interoperability of national databases with the Biosafety Clearing-House
5. IT specialists (e.g. communication technologies, information management, database management, data analysis)
6. National Node of the BCH
7. Non-Internet based mechanisms to access the BCH, e.g. CD-ROMs, fax
8. Secure systems to manage confidential information
9. Staff dedicated to handle IT needs
10. Standardized formats and procedures for information-exchange
11. Sub-regional and regional node for the BCH

5.7. Scientific, technical and institutional collaboration

1. Access to information on available opportunities for collaboration and sharing of experiences
2. Establishment of inter-institutional networks and communications, and interaction with the public
3. Establishment of mechanisms for regional and international cooperation and sharing of experiences

5.8. Technology transfer

1. Access to proprietary technologies on preferential terms
2. Analysis of appropriate technologies
3. Enabling policies and incentives for technology transfer
4. Management of intellectual property rights
5. Technologies for handling, transport, packaging and identification of LMOs
6. Technologies for information exchange / data management
7. Technologies for monitoring of LMOs
8. Technologies for risk assessment of LMOs

5.9. Identification of LMOs

1. Documentation systems for LMOs shipments
2. Guidelines for safe handling, packaging and transport of LMO shipments
3. Inspection systems for LMO shipments
4. Methods and systems for identification of LMOs, e.g. unique identification systems
5. Systems for segregation of LMOs

Chapter VI:
Project Priorities to implement
Lao National Biosafety Framework

6.1. Support the Implementation of the Lao National Biosafety Framework

1. Project Objective:

- To implement legislative framework on the safe use of biotechnology through decrees, orders, guidelines and manuals;
- To prepare specific technical guidelines;
- To strengthen appropriate institutional structures for risk assessment and decision making;
- To reinforce the existing infrastructures (laboratories) to strengthen monitoring
- To set up a mechanism for monitoring and enforcement
- To strengthen the communication and information exchange relating to biosafety both at the national level as well as through the BCH
- To strengthen public awareness, education and participation in decision making on LMOs.

2. Project Duration: 48 months

3. Source of Funding: **GEF FUNDING (**not exceed US $1 million inclusive of PDFA costs**)**

4. Contact Persons

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6.2. Building Capacity for effective participation in the Biosafety Clearing House of the Cartagena Protocol

1. Project Objective:

- To strengthen capacity in Lao PDR through support for capacity building including training activities for key stakeholders that the training programmes will cover:
  (i) data management;
  (ii) identification and access to information required for decision-making under the Cartagena Protocol on Biosafety and
  (iii) access to, and registration of information in the BCH.
- To create an enabling environment for Parties to meet the obligations for implementation of the Protocol by providing participating countries with appropriate computer hardware and software, as well as appropriate software for the storage and exchange of data with the BCH through Internet connectivity or other means.
- To support further capacity building activities through the development and dissemination of an interactive computer-based training package including the BCH toolkit. This training package will be developed at the global level and used for training as well distributed in participating countries.

2. Project Duration: 36 months

3. Source of Funding: UNEP- GEF

4. Contact Persons:

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6.3. Asia – Link Human Resources Development (*Asia-Link HRD*) to Strengthen Scientific Authorities of Lao PDR to implement Cartagena Protocol and Convention on International Trade in Endangered Species

1. Project Objective:

- to Strengthen Scientific Authorities of Lao PDR to implement Cartagena Protocol and Convention on International Trade in Endangered Species by following activities:
    - short teaching/training missions in Europe/Asia, especially those combining lectureship or training with activities such as seminars, research collaboration, thesis supervision, outreach conferences, or joint work with local staff;
    - short intensive overseas programmes to permit attendance at relevant intensive courses (e.g. summer courses or joint modules) or seminars/workshops, the gathering of teaching/research material and the preparation/development of actions of other programme components leading to longer-term partnerships;
    - study/research abroad for programmes at the Ph.D. and Master's level (such as "split" or "sandwich" programmes);
    - internships when integrated within a structured co-operation between university and industries;
    - The Capacity-Building Actions strand seeks proposals for the organisation and implementation of workshops and/or other training activities and tools in eligible Asian countries – particularly LDCs – in order to improve the knowledge skills of representatives of staff within Higher Education Institutions (HEIs) in the principles of project design and project management. Training should principally be given on the use of the logical framework and on Project Cycle Management (PCM) as the basis for project design, management and evaluation.

2. Project Duration: 48 months

3. Source of Funding: 2005 Asia-Link Programme,
Europe Aid (750,000 EUR)

4. Contact Persons:

- **EU:** ***European Commission***
  Europe Aid Co-operation Office
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6.4. Development of National Framework on Access and Benefit Sharing of the Genetic Resources

1. Project Objective:

- To collect and analyze existing laws and policies that regulate land ownership systems, ownership of biological resources, Intellectual Property right and traditional knowledge,
- To collect biological resources and conserve and sustainable use of biological diversity;
- To collect and analyze information about local genetic resources, traditional uses and practices of genetic resources, and existing markets and industries that use genetic resources;
- To identify key government, NGO, grassroots, and industry representatives for the development of a proposal for an ABS law and policy;
- To design a participatory plan for the development of a proposal for a national ABS law or policy; and
- To develop the proposal for a national ABS law or policy in a participatory manner.

2. Project Duration: 24 months

3. Source of Funding: ASEAN - USA partnership

4. Contact Persons:

- **USA:**

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6.5. Establishment of National Research Institute of Science and Technology

1. Project Objective:

- To establish biotechnology research and development progrmmes that followed by National Policies on Biotechnology and Biosafety
- To establish infrastructures of biotechnology research and development.
- To strengthen capacity building of National Research Institute of Science and Technology.

2. Project Duration: 60 months

3. Source of Funding:
- Government loans
- World Bank, Asian Development Bank
- UNDP
- JICA
- Others

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