



**Risk Assessment and Risk Management in Implementing the Cartagena  
Protocol: Proceedings of Asia Regional Workshop**

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## Preface

January 2000 is a significant date in the history of Convention on Biological Diversity (CBD) because of the adoption of the Cartagena Protocol on Biosafety. The adoption of Cartagena Protocol on Biosafety heralded a new era of committed implementation of CBD by the participating countries. Discussions, arguments, compromises and trade-offs marked the adoption of the Protocol after a five-year debate.

The Biosafety Protocol provides a common and binding framework for countries to address issues of safety in biotechnology besides addressing issues of advance informed agreement, precautionary principle and information sharing. It is anticipated that the Protocol would come into force as soon as 50 countries ratify the protocol and the CBD Conference of Parties will guide implementation.

One of the significant issues of biotechnology and biosafety is that of risks the technology poses. Risk assessment and risk management issues often are controversial with challenges and counter-challenges. Examples of environmental and food safety data are contested. Even though scientific data and proof exist to assess impacts of genetically modified organisms on human and animal health, data on environmental impacts are still wanting.

Concern of technical and financial capacities in addition to legal training to address issues of biotechnology products is high in developing countries. The socio-economic as well as cultural impacts of biotechnology are also not well understood or documented - at least in Asia.

Considering these, IUCN Regional Biodiversity Programme, Asia (RBP) began implementing an Asia level "Regional Biosafety Capacity Building Initiative" in 2001. The objective of the initiative is to help countries in Asia develop suitable national mechanisms on safe use of biotechnology. In continuation of a series of activities through this initiative, IUCN-RBP partnered with Department of Biotechnology (DBT), Government of India, IDRC, CBD Secretariat, ICGB, Commonwealth Science Council, ASEAN Secretariat and others to organize a regional workshop on risk assessment and risk management in implementing the Cartagena Protocol on Biosafety. This was one of the first such workshops held on this topic and we hope that the proceedings of the workshop would guide future discussions of implementation of the Cartagena Protocol at global level as well as facilitate national actions.

We are very grateful to Dr. Mrs. Manju Sharma, Dr. P.K. Ghosh, Dr. T.V. Ramaniah, Dr. K.K. Tripathi and their colleagues at DBT; Prof. V.S. Chauhan of

ICGEB; Dr. Hamdallah Zedan of CBD Secretariat; Prof. James Seyani of Commonwealth Science Council; Ms. Liz Fajber of IDRC; Dr Raman Letchumanan of ASEAN Secretariat and all participants as well as resource persons who made this workshop possible.

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Colombo  
May 2003.

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## **1. OVERVIEW PAPERS**

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### **Inaugural Address**

**Mr. Bachi Singh Rawat**  
**Honourable Minister of State for Science and Technology,**  
**Government of India**

I congratulate the Department of Biotechnology and IUCN, the World Conservation Union, Regional Biodiversity Programme, Asia for taking this much needed initiative to organize an international workshop on risk assessment and risk management. I am extremely happy to note that nearly 50 experts comprising 30 from 18 Asian countries other than India and 20 from our country are participating in this workshop. I also welcome you all. I am sure that the deliberations in the workshop will result in specific recommendations for programs that will benefit not only the Asian region but also the world community at large. This workshop may provide a unique forum for learning through mutual exchange of scientific ideas and developing joint collaborative programs. We would like to see the development of regional programs that strengthen this part of the world significantly in the handling of Living Modified Organisms, (LMOs) which are also known in our country as Genetically Modified Organisms.

Today is the World Biodiversity Day. The significance of this day is our commitment to conservation and sustainable use of biodiversity for the benefit of mankind. This workshop is, therefore, being started on an auspicious day.

I understand that the Workshop is about our efforts for developing increased understanding of the risks, if any, that are perceived to be emanating from new genetic recommendations in LMOs, as happens in any other new technological developments. Developments of LMOs have become possible after the discovery of recombinant DNA technology in the early seventies. Once the risks from the use of LMOs are identified and methods for their containment are in place, mankind would be really confident to utilize this technology. The benefits from the use of such technologies in different facets are being increasingly perceived, but scientists, policy makers and the public would also like to be assured of any risk factor.

Three different types of life forms, namely microorganisms, plants and animals, are amenable to recombinant DNA technology. The recombinant microorganisms have been extensively used for the production of various life saving drugs like Insulin, Interferon, Streptokinase, Growth Hormones etc and these medicines have improved, prolonged and saved the lives of people. There has been great



confidence in the use of such products after they were exhaustively assessed for safety over a period of time.

In agriculture, during the last decade Genetically Modified Plants have been in use. The land used for such plants is on the rise in some developed countries. However, in many developed countries in Europe, as well as in some developing countries through out the world, the technology has not yet been practiced significantly. These countries are engaged either in the process of further exhaustive scientific evaluation or they do not have access to these materials in their public sector outfits and therefore, they are not feeling encouraged to apply this technology with confidence. Because of these issues there is a strong need to upgrade capabilities of individual countries to not only develop their own technologies but also to create competence for the assessment of risks and benefits on sound scientific basis in a stand alone manner. This requires improvement of scientific knowledge, creation of trained human resource and building up of sophisticated infrastructure so that meticulous testing and evaluation of such substances can be carried out.

The main issues of developing core competence in this area are: how to assess environmental safety and how food safety issues are to be handled when such materials enter into human food chain. There are no universally adopted set of guidelines on how the questions of environmental safety are to be addressed and what tests must be carried out to ascertain that the products are fully safe as human food. Scientists are addressing certain questions on safety and satisfactory answers to these questions provide considerable confidence. Scientists, however, should focus on certain issues of long term environmental risks. This would require improving competence in risk assessment and risk management measures. In this context this workshop is going to be very useful for this region as I am sure that this workshop will address questions of developing competence individually as well as regionally so that the benefits of use of safe genetically modified substances can be shared to the maximum extent by the region.

In the Indian context, let me tell you that work is being done in raising transgenic plants in rice, wheat, potato, mustard, pulses, groundnut, tomato, cauliflower, cotton, brinjal etc. Transgenic plants are being developed for pest resistance, viral disease resistance, stress tolerance, improving nutritional quality and so on. Some industries like Maharashtra Hybrid Seeds Company Ltd., (MAHYCO), Mumbai; Pro-Agro PGS India, Gurgaon; Syngenta Ltd., Mumbai, etc., are involved in the development of certain transgenic hybrid plants of economic benefits, and some of these companies have conducted contained field trials. Transgenic insect resistant Bt Cotton of MAHYCO has successfully completed the risk assessment studies and the government of India has given permission to the company to market their three Bt. Cotton hybrids in April 2002 under certain conditions. Scientists at

Jawaharlal Nehru University, New Delhi have succeeded in transferring a gene coding for a seed protein from *Amaranthus* spp. (popularly known as Ram-dana) into potato. The protein is rich in lysine, an essential amino acid. Herbicide resistant mustard has been developed at Delhi University. Insect resistant paddy, potato, tomato and brinjal have been developed at Indian Agricultural Research Institute, Pusa. There are many more developments in other public funded institutes like the Central Tobacco Research Institute, Rajamandri, Directorate of Rice Research, Hyderabad; CPRI, Simla; Bose Institute, Calcutta, ICRISAT, Hyderabad etc.

India has also evolved a firm, strong, reliable and trustworthy regulatory mechanism for development and evaluation of transgenic substances. The legal framework was notified in 1989 and the recombinant DNA safety guidelines were announced in 1990. These guidelines have been constantly updated to be consistent with scientific developments. Indian developments in science as well as the regulatory structure are working complementary to each other in order to ascertain that every product is evaluated on a precautionary principle and the regulatory system is also upgraded with time in order to effectively handle sophisticated scientific developments in this complex area, within a structured legal framework.

India has further given considerable attention to developing its manpower by initiating biotechnology courses in different universities and public funded institutions. India produces over one thousand trained biotechnologists every year. In addition India has also created useful R&D infrastructure that provides opportunities to the researches to conduct different kinds of scientific experiments in biotechnology.

I would also suggest that scientists try and answer concerns raised by the non-government organizations (NGOs). It has also been projected that the benefits from the use of transgenic substances are small as compared to their properties to instill damage to the environment including human health. This has happened primarily due the fast scientific development on several facets of this technology and very fast use of transgenic plants in commercial agriculture in certain countries probably without creating public awareness. Further, the developments in LMOs globally have remained mostly in the hands of a handful of multinational companies who had purchased, procured, merged or teamed up with companies that were specializing in this technology. Therefore the general public world over felt that the agricultural seeds or planting materials which were generally in the public domain and were considered to be as public goods were going to be controlled by a handful of companies. In order to dispel some negative concerns there is a need for consultations between countries to provide

a platform for the exchange of scientific information among the people on a case-by-case basis so that public trust is built in. This obviously requires initiation of scientific process that makes use of the best up-to-date scientific knowledge and experience. It may also be noted that in this context there has not yet been any evidence of any adverse effect to the environment or to human health from the use of several LMOs that have been released for use commercially in different countries.

Building of scientific institutions for risk assessment and training of personnel in specific areas of assessment and management of risks are important components of capacity building. More over, regional co-operation would also benefit countries of this region. The issues of risk assessment of genetically modified substances include: intense scientific knowledge about the host organism that has been modified, knowledge about the transgenic nucleic acid sequences including the hereditary materials that have been transferred into sexually non-compatible species, the behaviour of the transgenic propagating substances in the open environment including the stability of the introduced trait and the effect of the expressed transgenic materials on other life forms on a short term as well as on a long term basis. Wherever such transgenic substances enter into the human food chain the nutritional data, the toxicity information as well as the allergenicity potential needs to be examined. These are, in short, all about capacity building on risk assessment and risk management of genetically modified substances. Complementary to these are the installation of fast communicating infrastructure that facilitates information exchange on LMOs on a fast-track mode among the governments and regional institutions.

I am sure, this workshop will discuss in detail all such issues. It would also be useful to work out sound mechanism for regional co-operation for capacity building through identification of scientific programs and enhancing regional co-operation through initiation of joint scientific work and scientific manpower exchange. Wherever possible, the workshop could identify the funding support from international bodies in order to strengthen the capacity building efforts. In addition, certain socio-economic consideration related to the use of some LMOs need also to be given due importance. The indicators that address the socio-economic considerations in absorbing the genetically modified substances commensurate with regional requirements could also be broadly identified.

I have full faith and confidence in the abilities of the experts and the participants. I look forward to a stimulating technical discussion followed by implementable recommendations that could be made available to the governments in order to use them for strengthening the capacity building needs of this region of the world. Our preparedness to face new problems of human kind in the 21st century

would depend to a great extent upon the scientific communities' collective wisdom and efforts.

I wish the workshop a great success.

*22nd May 2002  
New Delhi, India*

**Risk Assessment and Risk Management Provisions of the  
Cartagena Protocol on Biosafety\***

**Ryan Hill and Cyrie Sendashonga**

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**Introduction**

Proponents of biotechnology argue that it has the potential, among other things, to boost production of food resources and to reduce annual variability in production due to pests, disease and other factors. In the case of crops, this could reduce the need to clear more land for farms, and also reduce the need for irrigation and agrochemicals.

While advances in biotechnology have great potential for improving human well-being, it is widely recognized that Living Modified Organisms (LMOs) produced through techniques of modern biotechnology should be subject to adequate safety measures because of their potential risks to biological diversity and human health. Such measures, known collectively as biosafety, seek to ensure the safe transfer, handling and use of LMOs.

With the biotechnology industry growing at a rapid rate, the international community agreed on the need to develop a legally binding biosafety protocol under the Convention on Biological Diversity. Governments recognized that, while many countries with biotechnology industries already had national biosafety legislation in place, there was no binding international agreement addressing the movement of LMOs across national borders.

In 1995, the Conference of the Parties (COP) to the Convention on Biological Diversity set up an open-ended ad hoc Working Group on Biosafety to draft a protocol. After several years of talks, the COP adopted the Cartagena Protocol on Biosafety in Montreal on 29 January 2000. The Protocol is named to honour the city of Cartagena, Colombia, which had hosted the COP's first extraordinary meeting intended to finalize and adopt the Protocol in 1999. The Biosafety Protocol was finally adopted in January 2000 with a stated aim 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".

A key aspect of the Protocol is the provisions regarding the assessment and management of risks to biological diversity and human health associated with LMOs. This paper is intended to provide an overview of these provisions and their application.

### **Advance Informed Agreement and Decision-Making Under the Protocol**

A central mechanism of the Biosafety Protocol is the Advance Informed Agreement (AIA) procedure, which includes the following steps:

1. A Party of export must notify a Party of import prior to the first intentional transboundary movement of a Living Modified Organism for intentional introduction into the environment of the Party of import.
2. The Party of import must acknowledge receipt of the notification and indicate whether it will proceed according to its domestic regulatory framework, consistent with the Protocol, or according to the decision procedure specified in the Protocol.
3. The Party of Import will take a decision regarding import within a specified period, in accordance with the Article 15 of the Protocol, which requires the Party of import to ensure that a risk assessment is carried out in support of a decision.

The purpose of the AIA procedure is to ensure that recipient countries have both the opportunity and the ability to assess risks that may be associated with an LMO before agreeing to its import. As specified in step 1 above, the AIA procedure applies to the first intentional transboundary movement of a Living Modified Organism for intentional introduction into the environment of the Party of import. The AIA procedure is not required for LMOs in transit through a country, LMOs destined for contained use, or LMOs intended for direct use as food or feed, or for processing.

### **Risk Assessment Provisions of the Protocol**

Risk assessment is covered by Article 15 and Annex III of the Protocol. Risk assessment is required as part of the AIA procedure described above, and may also be used by a Party, in the absence of a domestic regulatory framework, to support a decision regarding LMOs intended for direct use as food or feed, or for processing. Article 15 specifies that risk assessments are to be undertaken in a scientific manner based on recognized risk assessment techniques, in accordance with the guidance provided in Annex III. Article 15 also allows for the Party of import to require the exporter to conduct the risk assessment and to require the notifier to bear associated costs.

Annex III contains more specific guidance for conducting the risk assessment. Firstly, Annex III lists a few general principles. These include the following concepts:

- Risk assessments should be carried out in a scientifically sound and transparent manner.
- Lack of scientific knowledge or scientific consensus is not an indication of a particular level of risk, absence of risk, or acceptable risk.
- Risks should be considered in the context of risks posed by non-modified recipients or parental organisms in the likely receiving environment (i.e., comparative risk assessment).
- Risk assessment should be carried out on a case-by-case basis.

Secondly, Annex III also provides some general guidance with respect to the methodology of risk assessment. In this regard, the guidance follows the conventional approach to risk assessment whereby risk is characterized based on evaluation of (a) the likelihood of adverse effects, and (b) the consequences of those effects if realized. These two components are often referred to as ‘exposure assessment’ and ‘effects assessment’ respectively, or similar terminology which varies among risk assessors and regulatory frameworks.

Finally, Annex III provides some guidance on additional points to consider in light of the requirement that risk assessments be carried out on a case-by-case basis. These include case-specific details regarding the characteristics of:

- Recipient organism or parental organisms
- Donor organism or organisms
- Vector
- Insert or inserts and/or characteristics of modifications
- Living modified organism
- Detection and identification of the living modified organism
- Information relating to the intended use
- Receiving environment.

### **Risk Management Provisions of the Protocol**

Article 16 of the Protocol addresses risk management. The first two paragraphs of Article 16 oblige Parties to manage and control risks identified in risk assessments carried out under the Protocol.

The last three paragraphs of Article 16 are aimed at risk management but not in the specific context of risk assessments carried out under the Protocol. The third paragraph of Article 16 obliges Parties to take measures to prevent unintentional transboundary movements of LMOs. The fourth paragraph of Article 16 obliges Parties to ensure that an LMO is observed for an appropriate period before being approved for its intended use. Finally, the fifth paragraph of Article 16 obliges Parties to cooperate regarding identification of LMOs or specific traits thereof which may have adverse effects on biological diversity and human health, and implementation of appropriate management measures.

### **Implementation of Risk Assessment and Risk Management Provisions of the Protocol**

When the Biosafety Protocol was adopted in January 2000, the Conference of the Parties to the Convention established the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), and gave it a mandate to undertake preparations for the first meeting of the Parties to the Protocol, which will occur once the Protocol enters into force. In May 2000, the fifth meeting of the Conference of the Parties to the Convention specified the work plan for the ICCP, requesting it to focus on a number of particular issues that will need to be considered by the first meeting of the Parties to the Protocol. Risk assessment and risk management per se (i.e., Article 15 and Article 16 of the Protocol) were not among the issues identified on the work plan of the ICCP. However, issues relevant to implementation of the risk assessment and risk management provisions of the Protocol have been addressed by the ICCP in preparation for entry into force, in the context of other issues on the agenda for discussion. The work of the ICCP regarding two issues has been particularly relevant in this regard. These are:

- (a) Capacity building and the roster of experts
- (b) Information sharing and the Biosafety Clearing-House



## **Capacity-Building and the Roster of Experts**

Capacity-building is needed in order to support implementation of the Protocol by developing countries and countries with economies in transition, in particular for implementing AIA-related decision-making procedures under the Protocol by Parties of import. In this regard, the ICCP has made significant efforts to put in place mechanisms to build capacity for developing country Parties and countries with economies in transition. Most importantly, the ICCP has developed an Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety. The ICCP has also proposed a coordination mechanism for the implementation of the Action Plan, with a view to promoting partnerships and maximizing complementarities and synergies between various capacity-building initiatives related to biosafety.

Following are some of the activities that have been initiated under the Action Plan with a view to improving capacity in developing countries:

- Development of a capacity building projects database
- Identification of the coverage and gaps in capacity-building initiatives and resources
- Development of indicators for evaluating capacity-building measures
- Development of an implementation tool kit which provides a checklist of obligations found in the Protocol
- Building partnerships with key organizations and initiatives involved in capacity building in support of implementation of the Protocol (e.g., the International Centre for Genetic Engineering and Biotechnology, the UNEP/GEF global project on the development of National Biosafety Frameworks, etc.)
- Preliminary identification of the roles of different entities in supporting capacity-building
- Preliminary identification of some of the key required capacities.

In addition, specific capacity-building activities in various regions have been implemented, such as regional training workshops on the use of the Biosafety Clearing-House.

A key component of capacity-building under the Biosafety Protocol is the roster of experts on biosafety. The roster is not a provision in the Protocol as such but was established by a decision of the COP when the Protocol was adopted. It is intended to be a regionally balanced roster of Government-nominated experts

with expertise in fields relevant to risk assessment and risk management related to the Protocol, whose role is to provide advice and other support, as appropriate and upon request, to developing countries and countries with economies in transition Parties to the Protocol, to conduct risk assessments, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of LMOs.

There has been significant development of the roster of experts. The roster has been established and can be searched as part of the Biosafety Clearing-House. More than 400 experts have been nominated by more than 50 Governments. The ICCP has developed interim guidelines for the use of the roster, including a detailed nomination form, which are currently being used as the basis for administering the roster pending their adoption by the first meeting of the Parties to the Protocol. In addition, a pilot phase of a voluntary fund for the roster of experts has been established to allow developing countries and countries with economies in transition Parties to the Protocol to use experts from the roster. The roster of experts has not yet been used to support risk assessments under Article 15 because the Protocol has not yet entered into force, but the mechanisms are in place to ensure that the roster will be operational at the time of entry into force of the Protocol.

### **Information Sharing and the Biosafety Clearing-House**

The Biosafety Clearing-House (BCH), established by Article 20 of the Protocol, is a central component for implementation of the Protocol. The ICCP has developed a pilot phase of the BCH to facilitate building of experience and identification of needs of countries that will make it possible to have a fully functional BCH at the time of entry into force of the Protocol. Among other things, the BCH plays a critical role in supporting the risk assessment and risk management provisions of the Protocol by:

- Providing access to and a searching mechanism for the roster of experts on biosafety
- Housing summaries of risk assessments conducted under the Protocol and links to more details of those assessments
- Providing links and searching mechanisms for accessing detailed scientific information from other sources in support of risk assessments, including but not limited to information on particular LMOs and scientific literature related to risk assessments

- Providing access to information on capacity building initiatives and opportunities for participation in such initiatives
- Providing access to information regarding relevant domestic laws and regulations

## **Conclusions**

Parties to the Cartagena Protocol on Biosafety have obligations with respect to the assessment and management of risks associated with LMOs, within the scope of activities covered by the Protocol. The ability of developing countries and countries with economies in transition Parties to the Protocol to meet these obligations will depend largely on human and institutional capacity. Through the cumulative efforts of many organizations and initiatives, there has been progress in building the necessary framework to promote capacity building. The work of the ICCP has focused on putting mechanisms in place, including in particular the roster of experts on biosafety and the pilot phase of the Biosafety Clearing-House, which provide a basis for supporting developing countries and countries with economies in transition to fulfil the risk assessment and risk management related obligations under the Protocol. It is expected that future efforts will continue to promote capacity building regarding the use of the roster, the use of the BCH, and training at the technical level in support of risk assessment and risk management.

## **Further Information**

The Secretariat of the Convention on Biological Diversity also serves as the Secretariat of the Cartagena Protocol on Biosafety. The work of the Secretariat with respect to the Protocol currently focuses on promoting the ratification of the Protocol, making arrangements for organization and servicing of meetings of the ICCP (and later on the meetings of the Parties to the Protocol, after the Protocol enters into force), and facilitating assistance to the Parties, particularly developing countries and countries with economies in transition to implement the Protocol. Please contact us or visit the website for further information on the Convention or the Protocol:

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\* The views expressed in this paper do not necessarily represent the views of the Secretariat of the Convention on Biological Diversity.

## **MALAYSIA**

**Atikah Abdul Kadir Jailani**  
**Department of Agriculture**

### **Introduction**

There are various definitions of biotechnology. R. B. Singh in his paper “Potentials and Challenges of Biotechnologies and FAO’s Role” defined biotechnology as a continuum of traditional and modern technologies to investigate and manipulate organisms at various levels, from organismal to molecular, to make or modify biological products to meet particular needs. The CBD (Convention on Biological Diversity) defines it as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Biodiversity provides raw materials for various biotechnology industries such as in the pharmaceutical and chemical sectors. The growth of the biotech industry in the past two decades has been closely associated with the systematic search for genetic material and the transformation of this into new products i.e. chemicals and drugs. Genetic resources have increased in value with a major resurgence in screening of genetic resources for their medicinal and biochemical properties.

The CBD established a clear link between the supply of genetic resources (from developing to developed countries), and access to and transfer of biotechnology (from developed to developing countries) which make use of these resources. Therefore, collaboration in biotech research to utilize biodiversity is very essential. Developing countries in particular must also invest in biotech infrastructure. There is a need to give priority to biotech development as a strategic sector that would enable the country to derive economic benefits.

In Malaysia, the focus of biotechnology work centers on the needs of the nation. Improving food production has been and always will be one of the top priority and commitment of government agencies involved in biotech. As far as agriculture is concerned, Malaysia is blessed with a lot of assets and features. The nation is rich in natural resources, blessed with favourable climate for most of the time for tropical agriculture. Malaysia has been a world leader in a number of plantation crop industries, such as oil palm, rubber and cocoa.

The economic crisis of the late '90s has prompted us to have a second look and stand on the importance of agriculture, especially in food production to the national economy. The Government has stressed the needs for producing a sufficient amount of food for national security and stability. The huge and

growing budget for food and feed import clearly indicate the need to transform our agriculture sector in order to produce enough food for the people. Research and development in biotechnology is geared to meet this challenge.

### **Biosafety in Malaysia**

In Malaysia, the Ministry of Science, Technology and the Environment (MOSTE) is the focal point and is responsible for coordinating all matters pertaining to biological diversity including biosafety under the CBD. A Genetic Modification Advisory Committee (GMAC) was established in March 1996 under the ambit of the National Committee on Biodiversity (NCB), MOSTE. Its objective is to ensure that any risks associated with the use, handling and transfer of GMOs be identified and safely managed and to advise the government about matters on genetic modification technology and its application.

Following its establishment in January 1997, GMAC has formulated the National Guidelines on Release of GMOs Into the Environment as an effort to provide a national framework for addressing biosafety issues with regards to regulation, assessment and management of risk associated with the use and release of GMOs into the environment. GMAC is responsible for monitoring and implementation of the guidelines. The Guidelines require the establishment of an Institutional Biosafety Committee (IBC) in all related research government institutions. IBC will ensure that experiments relating to genetic modification and release undertaken by the institution conform to the provisions of the Guidelines. As a result, many universities and government research institutions have established their own IBCs.

### **Implementing the guidelines**

The management of field testing is achieved through cooperation with various research institutions. The IBC is responsible for research work at its own institute, in consultation with the GMAC. The NBC established a secretariat to coordinate matters regarding biosafety. Currently, the importation of GMOs is regulated by sectoral legislation. Applications for importation of GMOs are sent to the Director General of the respective Government Department, which acts as the competent authority with a copy to the secretariat. For genetically modified plants, permission to import must be obtained from the Department of Agriculture. For genetically modified animals, fish and food permission to import must be obtained from the Department of Veterinary, Department of Fisheries and Ministry of Health respectively. All relevant information and documents concerning the GMOs (nature of genes, gene constructs, transformation process, etc.) has to be submitted to the competent authority and

GMAC. The GMAC will, after careful consideration of the proposal, make recommendation to the competent authority for final consideration and approval.

For every stage of experiment/trials i.e. from contained use to placing in the market, the proponent has to submit their application to the secretariat for consideration by the GMAC.

### **Monitoring**

In order to have an effective system to monitor the field release, NBC, GMAC and the competent authority work very closely. Experts from the competent authority, GMAC and NBC join hands in considering the design of experiments and other aspects of field testing. Reports on the field tests are required to be reviewed by the NBC, GMAC and the respective competent authority.

### **Biosafety Law**

Currently the GMOs are regulated by using the Guidelines formulated by GMAC, and this Guidelines are not law, meaning that there are no provisions to impose penalties to any party not following the guidelines. Genetic engineering is to be promoted with the necessary safeguards so that biotechnological processes are properly regulated along socially and ethically desirable channels. Being a country naturally endowed as one of the 12 megadiversity countries of the world, Malaysia is purported to harbour more than 150,000 species of invertebrates, 286 mammal species, 736 bird species and 15,000 flowering plant species. As such, it is very necessary for this country to carefully regulate gene technology so that, apart from other things, this vast natural treasure of biodiversity is not adversely affected. The weakness of the GMOs regulations in Malaysia needs to be strengthened through legislative means. Realising this fact, the government, in June 1997, directed GMAC to draft a Biosafety Bill. This Bills seeks to achieve the aforesaid objective.

The Malaysian Biosafety Bill has already been tabled at the National Consultation forum in September 2001. Based on the feedback received from the stakeholders during the consultation, some fine tuning needs to be undertaken especially with regards to the policy on scope, labeling, export and contained use. This part of the Bill will be tabled to the Parliament on June 12, 2002 for high level policy decision. The Bill is expected to be ready for discussion in the Parliament and gazetted by the end of 2002. This Bill is envisaged to be enabling, transparent and practical.

## Biotechnology in Malaysia

Biotechnology receives large-scale support from the Malaysian government. Biotechnology is earmarked as one of the areas of advancement under the 8th Malaysia Plan (2001-2005). To accelerate biotechnology development in Malaysia, the Ministry of Science, Technology and the Environment (MOSTE) set up the National Biotechnology Directorate (BIOTEK) in May 1995. BIOTEK is entrusted with the task of spearheading and coordinating biotechnology research in Malaysia.

To streamline biotechnology research, BIOTEK established seven biotechnology cooperative centres (BCC) in the areas of plant, food, animal, molecular biology, medical, environment/industry and biopharmacy. The BCCs help to coordinate biotech research in the various research organisations to improve cooperation and reduce duplication.

A list of research organizations and their research emphasis is provided below:

| Organisation  | Research   |
|---|--|
| Malaysian Agricultural Research and Development Institute (MARDI) | <ul style="list-style-type: none"><li>○ Disease resistance in rice, chilli and papaya</li><li>○ Delayed ripening in papaya</li><li>○ Floral colour and senescence in orchids</li></ul> |
| Malaysian Palm Oil Board (MPOB)                                   | <ul style="list-style-type: none"><li>○ Yield improvement</li><li>○ Improved oil quality</li><li>○ Production of bio-plastics</li></ul>  |
| Rubber Research Institute, Malaysia (RRIM)                        | <ul style="list-style-type: none"><li>○ Yield improvement</li><li>○ Disease resistance</li><li>○ Production of high-value proteins</li></ul>   |
| Institute of Medical Research                                     | <ul style="list-style-type: none"><li>○ Medical diagnostic kits</li><li>○ Screening of local herbs for pharmaceutical properties</li></ul>   |

|                                      |   |
|--------------------------------------|---|
| Universiti Kebangsaan Malaysia (UKM) | <ul style="list-style-type: none"> <li>○ Molecular biology of <i>Burkholderia pseudomallei</i></li> <li>○ Antibody engineering</li> <li>○ Gene and genome analysis of <i>Anopheles maculates</i></li> <li>○ Molecular biology of protozoan parasites</li> <li>○ Molecular studies of <i>Glomerella cingulata</i> and its pathogenesis of Cry proteins</li> <li>○ Molecular systematic studies of wildlife and domestic animals</li> </ul> |
| Universiti Malaysia Sarawak          | <ul style="list-style-type: none"> <li>○ Screening of local plants for anti-malarial drug</li> <li>○ Genetic studies of high-risk populations on nasopharyngeal carcinoma (nasal cancer)</li> <li>○ Transgenic sweet potato with Japanese encephalitis vaccine for pigs</li> </ul>  |
| University Putra Malaysia            | <ul style="list-style-type: none"> <li>○ Oil palm expressed sequenced tags (ESTs)</li> <li>○ Plant transformation</li> <li>○ Gene expression</li> <li>○ Floral/ meristem/ embryo development</li> <li>○ Plant defence stress response</li> </ul>  |

Biotechnology in Malaysia recently received a further boost with the announcement of the BioValley initiative. The BioValley will consist of a concentration of Biotechnology research institutions, universities and companies within the Multimedia Super Corridor (MSC). BioValley will include three new research institutions conducting research in genomics and molecular biology, nutraceuticals and pharmaceuticals, and agricultural biotechnology.

Another initiative to boost biotechnology in Malaysia is the Malaysia-MIT Biotechnology Partnership Programme (MMBPP). It is a collaborative effort between Malaysian academic, industrial and government research organizations, including six BCCs, through Malaysia's National Biotechnology Directorate and the Massachusetts Institute of Technology (MIT). The programme is supported by the MOSTE. The primary goal of this partnership is to build a foundation for a sustainable biotechnology industry in Malaysia through research development, as well as human resource training.

This programme hopes to facilitate the interaction, development and training of scientists in critical areas like genomics, bioinformatics and bioprocessing through the exchange of Malaysia and MIT research personnel. The aim of the training is to develop a group of professionals who will be able to spearhead the development of the biotechnology industry in Malaysia.



## **Risk Assessment and Risk Management in Malaysia**

In Malaysia, all research on genetically modified organisms (GMOs) irrespective of origin is still in the experimental phase and under confined use. To date, the Genetic Modification Advisory Committee (GMAC) of Malaysia has undertaken three risk assessment exercises as follows:

*a. Safety Assessment of the Import of Transgenic Soyabean (Glycine max) into Malaysia for Food and Feed*

In October 1996, the Malaysian government received an application for the importation of transgenic soyabeans for food and feed into the country. That application was the first for which the GMAC of Malaysia was requested to undertake a risk assessment for the release of a genetically modified organism into the environment. The transgenic organism was the glyphosate-tolerant “Roundup Ready Soyabean, produced by Monsanto Co. (USA).

“Roundup Ready Soyabean” was deregulated in the USA since May 1994. Thus the beans would not be differentiated from the conventional (non-transgenic) soyabeans when they are imported into the country. The glyphosate-tolerant soyabeans (GTS), line 40-3-2 contain two novel constituents, namely, the enolpyruvateshikimate-3-phosphate synthase (EPSPS) gene derived from *Agrobacterium* sp. Strain CP4 and its gene product, the EPSPS enzyme. Risk assessment was based primarily on scientific data provided by the proponent, information derived from literature search and similar risk assessment of the same genetically modified organisms (GMOs) conducted in other countries.

Based on the available data, GMAC concluded that Roundup Ready Soyabean line 40-3-2 was not different from conventional soyabeans and was safe for importation into the country for food and feed. In addition, it was not hazardous to agriculture and the environment and was unlikely to become a weed pest.

*b. Assessment For Confined Field Release of Transgenic Papaya Plants for Superior Post-Harvest Fruit Quality (Delayed Ripening).*

Malaysian Agriculture Research and Development Institute (MARDI) has submitted an application for a confined field release of transgenic papaya modified for delayed ripening, to the GMAC in January 2002.

The risk assessment was based primarily on the data provided by the proponent. Based on the available data, GMAC concluded that transformed papaya with antisense ACC oxidase cDNA sequence is safe to eat and is not hazardous to agriculture and environment. Therefore, GMAC approved the confined field release be performed in a netted house as requested by proponent.

*c. Assessment For Confined Field Release of Transgenic Oil Palm that is Tolerant to herbicide Glufosinate Ammonium (Phosphinothricin, Basta 15)*

The application for confined field release of transgenic oil palm was submitted by the Malaysian Palm Oil Board (formerly known as PORIM - Palm Oil Research Institute of Malaysia) in March 2002.

The risk assessment was also based on data provided by the proponent. Based on the data provided, GMAC was not convinced on the location of the field release and required additional information. The proponent was requested to submit a new location for the confine field release and furnish GMAC with the additional information required.

### **Conclusion**

The Malaysian government is well aware of the potential benefits of genetically modified crops, however it has the responsibility to assure the public of the safety of the genetically modified crops as well as to safeguards against their adverse (if there is any) effects on human health and the environment. Malaysia along with other ASEAN member countries is supportive of activities that relate to Biosafety capacity building. Activities such as practical training programmes in risk assessment and management would be supportive of Malaysia's as well as ASEAN needs.

## **COUNTRY PAPERS:**

# **Access to Genetic Resources and Traditional Knowledge for Biodiversity Conservation in China**

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## **1.0 General**

China is one of the richest countries in the world for genetic resources. It is also one of the main origin centres for crops and livestock. China has a farming history more than 5000 years old and during this long period a great deal of traditional knowledge and practice for biodiversity conservation and sustainable use have been created and accumulated. However, with the wider use of modern agricultural methods and unsustainable use, biodiversity is under serious threat. Genetic diversity and traditional knowledge are quickly being lost.

To conserve global biodiversity and ensure its sustainable use, China actively participated in the negotiations of the Convention on Biological Diversity (CBD). During the CBD's preparation, China expressed its concern on access to genetic resources and contributed to CBD Article 15. At the United Nations Conference on Environment and Development (UNCED) (Rio, 1992), Premier Li Peng, on behalf of the Chinese Government, signed the CBD on 11 June 1992. China became the sixty-fourth State to sign the Convention.

At the Earth Summit on 12 June, Premier Li Peng pointed out that China was aware of its responsibility and role in protecting the global environment and ecology and, therefore, from this perspective China attached great importance to and actively participated in the discussion on environment and development issues. He emphasised that China was willing to shoulder the international responsibility and obligation corresponding to its level of development. The National People's Congress supported ratification of the CBD. On 7 November 1992 the Congress examined and approved the CBD at the twenty-ninth meeting of its Standing Committee. On 5 January 1993, China submitted its letter of ratification and became one of the first countries to ratify the CBD.

Immediately after UNCED closed China began to take actions to follow the spirit of the Conference including the CBD's implementation. At the twenty-third Meeting of the Committee of Environmental Protection under the State Council

held on 2 July 1992, it was decided that the National Environmental Protection Agency (NEPA) would be the lead agency in China to implement the CBD. Early in 1993, an inter-ministerial co-ordinating group for CBD implementation, the National Biodiversity Unit (NBU), was set-up with the approval of the State Council. The NBU is headed by NEPA and joined by twenty governmental sectors under the State Council.

To materialise the spirit of UNCED, a ten-point strategy for environment and development, according to China's actual situation, was recommended by the Ministry of Foreign Affairs and NEPA. The State Council approved the Ten-Point Strategy in November 1992. The document pointed out that China will establish, in a planned way, centres to protect and breed endangered wild species and species and varieties of domesticated animals, crops and herbs. China will also take practical efforts to protect and use species and inherited genes and better manage the export of such species and genes, in order to fulfil the obligation under the Convention.

To fulfil its commitments under the CBD, China proposed to formulate its national action plan for biodiversity conservation even before the CBD negotiations were concluded. With the support of UNDP and the World Bank, ten ministries headed by NEPA worked together to formulate the China Biodiversity Conservation Action Plan. From 1995 to 1997, with the assistance of UNEP, NEPA brought together 14 ministries to conduct and formulate the China Country Report for Biodiversity. The State Council issued this report in December 1997.

## **2.0 Genetic Resources and Benefit Sharing**

To conserve and manage biological resources, China has formulated and issued a series of laws and regulations. Some provisions for access to biological resources, especially genetic resources, are included in these statutes. Some examples are provided in Box 1.

**Box 1: Selected Laws from China that Apply to Access to  
Biological Resources**

**Wild Animal Protection Law (adopted by the Standing Committee of the People's Congress and enacted on 1 March 1989)**

**Article 3:** Wild animal resources belong to the State.

**Article 8:** The State protects wild animals and their habitats, and any illegal hunting and destruction by any organisation or individual is banned.

**Article 16:** It is prohibited to hunt and kill the national protected wild animal species. When capture is needed for the demands of scientific research, breeding, exhibition and other species uses, it should be certified by the responsible department of provincial government for the species with second level.

**Article 20:** Selling and buying nationally protected animals and their products are banned. When the selling, buying and using are necessary for scientific research, artificial breeding, exhibition and other special uses, it should be approved by the responsible ministry of the central government or by the institution authorised by the ministry for the animal species with first-level for protection, and approved by the responsible department or its authorised institution of provincial government for the protected ones with second-level.

**Article 24:** Approval must be obtained from the responsible ministry or the State Council itself for exporting national protected animals and their products and for importing and exporting wild animals limited by the international conventions to which China is a party. Additionally a permission certification for exporting or importing must be obtained from the national administrative office for exporting and importing the endangered species. Based on the permission certification, Customs will let the animals pass.

**Article 26:** Field surveys or taking photos, movies and videos by foreign people within the jurisdiction of China should be approved by the responsible ministry or its authorised institution. Establishing hunting resorts open to foreigners will be subject to ratification by the responsible ministry under the State Council.

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### **Box 1: Selected Laws from China that Apply to Access to Biological Resources**

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#### **Wild Plants Protection Regulation (issued by the State Council and enacted on 1 January 1997)**

**Article 9:** The State will protect wild plants and their living environment, and prohibit illegal collection for wild plants or any destruction to their living environment.

**Article 16:** Collecting the national protected plants with first grade is banned. When it is necessary to collect the first-grade protected plants for scientific research, artificial breeding and other special uses, the collector must apply for collection permission from the responsible ministry under the State Council or from the institution authorised by the ministry. Additionally, and before the collector submits his application to the responsible ministry, it should be signed by the responsible department of the local provincial government. For the second-grade protected plants, the collection should be permitted by the provincial corresponding institution with an advanced signature by the authority of the local county.

**Article 18:** Selling and buying first-grade national protected wild plants are prohibited. For the second-grade protected wild plants, selling and buying should be approved by the responsible department of the local provincial government or by the institution with an advanced signature by the authority of the local county.

**Article 20:** Exporting the national protected wild plants, or both exporting and importing the wild plants limited by the international conventions to which China is a party, should be examined by the responsible local provincial department and then approved by the State Council. Additionally, a permission certification for exporting or importing from the national administrative institution for endangered species should be obtained. Based on the permission certification Customs will let the plants pass. The export of unnamed or new wild plant species with important values is banned.

**Article 21:** Foreigners cannot be permitted to collect or buy the national protected wild plants distributed inside China. For field investigations to the habitat of national protected plants inside China, application should be made to the responsible local provincial department for its first examination and then submitted to the central responsible ministry for approval.

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### **Box 1: Selected Laws from China that Apply to Access to Biological Resources**

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#### **The Regulation for Seeds Management (issued by the State Council and enacted on 1 May 1991)**

- Article 2:** Seeds are the reproductive materials that can be used in agriculture and forestry production, such as seeds, fruits, nuts, roots, stems, seedlings and shoots.
- Article 8:** Germplasm resources are protected by the State. The State, in a planned way, selects, organises, identifies, preserves and utilises the germplasm of crops and trees.
- Article 9:** Organisations or individuals that introduce germplasm from abroad should register in the responsible administrative institution, and provide with appropriate amount seeds for preservation and utilisation.
- Article 10:** Organisations or individuals that exchange germplasm with foreigners are subject to the rules issued by Ministry of Agriculture and Ministry of Forestry.

#### **The Detailed Enforcement Rules of the Regulation for Seeds Management on Crop Seeds (issued by Ministry of Agriculture and enacted in June 1991)**

- Article 12:** Crop germplasm is wealth belonging to the State and it is protected by the State. Any organisation or individual cannot damage the germplasm that is listed for national protection.
- Article 16:** The exchange of crop germplasm between countries and the introduction of a small amount for research experimentation will be administered uniformly by The Institute of Crop Germplasm Resources, Chinese Academy of Agricultural Sciences.
- Article 17:** The State encourages actively organisations and individuals to introduce crop germplasm from abroad; the introduced crop type, variety name, source, origin place, introduced time and other information is to be reported to the Institute of Crop Germplasm, Chinese Academy of Agricultural Sciences. A small amount of the introduced seeds is needed for attachment to the report for identification and preservation.

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### **Box 1: Selected Laws from China that Apply to Access to Biological Resources**

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**Article 19:** Any organisation or individual who provides crop germplasm to foreign countries must apply and get approval pursuant to the classified germplasm resources management rules.

**Article 55:** Organisations that export and import commercial seeds must report regularly on such things as the imported or exported crop types, variety names, amounts, qualities and production locations.

#### **The Detailed Enforced Rules of the Regulation for Seeds Management on Tree Seeds (issued by the Ministry of Forestry and enacted in September 1995)**

**Article 10:** Tree germplasm is the basic material with various genetic substances that can be used for tree breeding, including all reproductive materials involved in any individual or group of tree species or taxons under species.

**Article 11:** Tree germplasm is protected by the State.

**Article 13:** The introduction of tree germplasm resources by any organisation or individual should be registered with the authorised institution for tree seed administration and a small amount of introduced seeds is to be attached for identification and preservation.

**Article 14:** The exchange of tree seeds with foreign countries should be approved by the institution of tree seeds administration authorised by the Ministry of Forestry.

#### **The Regulation of Breeding Stock and Poultry Management (issued by the State Council and enacted on 1 July 1994)**

**Article 2:** Stock and poultry are the domestic animal and poultry that can be used in breeding, including for example domestic pig, cattle, sheep, horse, ass, camel, rabbit, dog, chicken, duck, goose and pigeon, and their genetic materials including eggs, semen, and embryos.

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### **Box 1: Selected Laws from China that Apply to Access to Biological Resources**

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**Article 6:** The State protects stock and poultry germplasm resources in a classified way and formulates the germplasm list for protection and the specified protection methods.

**Article 7:** The Livestock Administration under the State Council and provincial government will establish, in a planned way, stock and poultry germplasm resource protected areas (on farms), gene pools and monitoring stations, in order to enforce special protection for some valuable and endangered stock and poultry.

**Article 9:** Importing breeding stock and poultry from abroad or exporting them to foreign country will be subject to the national rules concerned.

## **3.0 Traditional Knowledge and Benefit Sharing**

China is a multi-national country consisting of fifty-six different nations or nationalities. Han nation is the major nation, while the others are minor. Sixty percent of the territory is occupied by minority nationalities that make up only ten percent of the total population. In these areas communication is usually inconvenient and biological resources are usually abundant. The unique culture and traditions, and the styles of life and production play an important role in nature and biodiversity preservation.

### **3.1 Forest ecosystem protection**

Nearly all nationals have their own “fengshui (geomantic) forest”. Especially in the regions where Dai, Miao, Buyi and other ethnic groups live, there are always “holy mountains”, “holy trees”, “dragon mountains” and other specially delineated mountains and forests, together with all animals, plants, and other landscapes in these areas. All are subjected to strict protection.

For example, in the “Ba” areas where Dai people live in Xishuangbanna, Yunnan Province, the “Dragon Mountains” around their villages are believed to be the place where their God lives. All the animals and plants are companions of the God or members of his homeland. It is prohibited to cut, hunt, destroy, graze, or

reclaim in the “Dragon Mountains”. This practice has existed for a thousand years.

In the area of Xishuanbanna, there are more than 400 “dragon mountains” with a total area of 30,000 - 50,000 ha. The dominant vegetation in the area is seasonal rain forest. Most of the forest has been destroyed but some forest has been preserved in the “Dragon Mountains”.

Similarly, Dong people are distributed in the remote mountainous regions contiguous to the provinces of Hynan, Guangxi and Guizzhou. Fengshui (geomantic) forests, ranging from 7-8 ha. exist in most of the mountains of the Dong villages. Despite the destruction in some during the last decades, many mountains have been well preserved owing to the worship of the fengshui forests. Fengshui forests have multiple ecological functions such as soil and water conservation, local climate adjustment, tourism, and species protection.

### **3.2 Individual species protection**

Many of the minorities believe in primeval religion that recognises that “everything has its spirit” and they adore mountains, waters, forests and other matters. For example, Tibetans used to hang scriptures on trees. The trees, and the forests that they make up, are strictly protected from felling and destruction. Consequently, trees ranging from several hundred to even a thousand years old are still seen in these areas. The Kirgiz people revere snow leopards and oxen. In the worship rites of the Gaoshan people it is popular to revere trees, bamboo, bottle gourds, stones, soils, snakes, birds, insects, eggs and the sun. All of these worship rites undoubtedly contribute positively to biodiversity preservation.

The Dai people believe in Hinayana Buddhism. Its doctrine has a clear feature of nature worship. It is stipulated that fifty-eight species of ornamental plants should be planted in their temples, including *Corypha umbraculifera*, *Ficus religiosa*, *Mesua nagassarium*, and *Dipterocarpus turbinatus*. Among these *Ficus religiosa* is the most important.

The Han people also have traditionally treasured old trees and rare woods that spread throughout the whole country in huge number. For example, the “ancient Xuanyuan juniper” (*Platycladus orientalis*) in the Xuanyuan temple, Shaanxi Province, is more than 4000 years old. A ginkgo tree, more than 3000 years old, is found in the Dinglin temple of Ju County, Shandong Province. The junipers in Jinci temple of Shanxi Province are also more than 3000 years old.

In addition, it must be mentioned that herdsmen in vast pastoral areas have preserved various strains of horse, cow, sheep and other livestock. Hundreds of upland rice strains are preserved among the people of minorities in Southwestern China instead of in the National Crop Germplasm Bank.

### **3.3 Lifestyles and social customs contributing to biodiversity preservation**

Jinuo people living in the mountain region of Yunnan Province practice a rotating fallow (slash and burn) system. Land is divided into thirteen lots. Each year, only one lot is used to ensure a thirteen-year fallowing period for each lot. With favourable tropical conditions, after 13 years it is covered again by dense forest. Biodiversity is not necessarily decreased due to land use, but may even be enhanced, with some species adapting to the farming system to a certain extent.

The tea gardens of the Jinuo people also play an excellent role in biodiversity preservation. Tea (*Camellia sinensis* var. *assamica*) is cultivated within natural forests. The forest cover provides important shadow for tea and this contributes to increased quality and yield. In turn, forests are preserved especially when they have additional cultural or economic values.

Dong people deliberately open a few forest gaps and use them as “cattle-grazing slopes”. The cattle are bounded so those young trees in the forest are saved from gnawing.

The Dai people used to cultivate artificial *Cassia siamea* forests around their villages for firewood. *Cassia* grows and branches very rapidly. Pruning only promotes its growth. *Cassia* has become the main firewood resource in this region. Consequently, the destruction of natural forests is greatly alleviated.

Mongolian, Kazak and other minorities in the arid and semi-arid regions of Northern China have practised nomadic systems. They move around vast areas in different seasons looking for the best range or grazing conditions for their animals: alpine and sub-alpine meadow ranges in the summer; lower altitudes in the fall and piedmont and basins in the winter. This helps to relieve the burden on and speed up range restoration and contributes to the goal of rational use of range resources.

Settled grazing has become popular in recent years. A new system of “Kulun”, or enclosed pasture, has been created to accelerate range restoration and to raise range carrying capacity. These techniques all play a splendid role in biodiversity preservation.

## 4.0 National Access and Benefit Sharing Planning

Currently, China has no specific national policy or planning process to deal with access and benefit sharing. But the Chinese Government has paid attention to it. Some policy and planning to enforce access and benefit-sharing management has been initiated. This has been recognised in two State documents: the China Biodiversity Country Study Report and First China National Report to the Convention on Biological Diversity.

### 4.1 *China Biodiversity Country Study Report*

The State Council issued the China Biodiversity Country Study Report in December 1997. Chapter 6 (National Strategy of Capacity Building for Biodiversity Conservation and Sustainable Use) stresses that China is a big agricultural country and frequently introduces and exports genetic resources. Therefore China should formulate a specific law or regulation and develop suitable planning to manage access and benefit-sharing, as well as traditional knowledge. Several paragraphs dealing with these issues are provided in Box 2.

#### **BOX 2: References to Access to Genetic Resources in the China Biodiversity Country Study Report**

##### **Section 6.1.3. Formulate corresponding laws and regulations for implementing international conventions**

##### **1. *Formulate domestic laws and regulations on access to genetic resources***

Article 15 of the Convention leaves to the law of the nation who supplies the resources, the determination of access to genetic resources. This requires the genetic resources supplier to examine its legislation in this field to see if it is sound. China is one of the richest nations in the world in terms of genetic resources. As a major genetic resources supplier, China must work out her own national laws and regulations in conformity with her interest, in line with the Convention's obligations and the national conditions. This will protect her genetic resources and ensure a favourable share of benefits with the user of the genetic resources. Meanwhile the law and regulations can also serve as the legal basis for the other Convention Contracting Parties to acquire genetic resources from China.

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## **BOX 2: References to Access to Genetic Resources in the China Biodiversity Country Study Report**

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### **2. Set up and perfect a patent protection system**

Article 8(j) of the Convention provides that each Contracting Party shall, subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote their wider application.

China is a nation with a long history of civilisation. It has accumulated abundant traditional knowledge and technology in her thousands of years of agricultural practice. China is also a multi-national country, where in their regions some minority nationalities still keep their traditional eco-farming technology and medical knowledge, and are considered conducive to conservation and sustainable use of biodiversity. According to Article 8(j), this traditional knowledge and technology must be respected by the national legislation. Nevertheless, the Patent Law in China has not yet touched upon the protection of traditional knowledge and technology. China has joined in the Treaty of the World Intellectual Property Organisation and the Paris Treaty on Protection of Industrial Properties. Therefore it is essential to strengthen legislation to protect this type of intellectual property as soon as possible, so as to harmonise with the international patent laws.

#### **Section 6.4.4. Intellectual property right protection policies**

Among the fields under the protection of China's current national patent system, there are still some inventions and innovations that have not received any patent protection, for example animal breeds and plant varieties, including crop varieties, poultry and livestock breeds, created with various technologies. In addition, the several thousand years of agricultural practices have left in the hand of farmers many native fine crop varieties and fine breeds of poultry and livestock. These contain a huge amount of genes of fine quality, disease resistance and pest resistance, and precious materials for modern genetic breeding. Consequently the patent system in China needs to be perfected to put crop varieties and animal breeds under its umbrella.

In China, minority nationalities often have a huge variety of traditional knowledge, innovations and practices that are suitable to their own region. It is desirable to work out a proper patent system and policies to encourage good preservation and application for the local and indigenous fine germplasm resources and to promote the inventory, application, protection of the traditional knowledge and technology, and sharing fairly the benefits from using them.

## **4.2 *China's first National Report to the Convention on Biological Diversity***

In Chapter 5 of the China First National Report to Convention on Biological Diversity (Further Actions to Implement CBD Article 6), there is a section on Legal Construction for Biodiversity Conservation. It particularly refers to the issue of access to genetic resources and benefit sharing.

It was pointed out in the section that genetic resources conservation legislation is rather weak. It points out:

although the State Council has already issued the Regulation of Seeds Management and Regulation of Breeding Stock and Poultry, they are neither sufficient nor detailed. In these regulations, the targets to be protected, measures to be taken and the management system are not elaborated. In particular, there are no detailed regulations for genetic resources collection, storage, introduction, transportation and benefit sharing. In this regard, the present Regulation should be modified according to the international situation and the requirements of the CBD.

In light of the analysis above, the section also proposes that a new genetic resources regulation for access to genetic resources and benefit sharing should be drafted. The content of the regulation is considered as follows:

The under-considered projects of drafting national genetic resources laws or genetic resources management regulations should clearly state: the type of classification and annex a list of names; the principle of prior to consent; benefit sharing and how to achieve the distribution of genetic resource development; rules of intellectual property rights, etc. In addition, the relevant regulation should also be worked out, which might include the report system for introduction and export of genetic resources; a reviewing system and a quarantine system for the imported and exported genetic resources, etc.

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## **Strengthening Capability of ASEAN in Biosafety- Scientific, Technical, Institutional and Legal Aspects**

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The conclusion of the Cartagena Protocol on Biosafety at Montreal on January 29, 2000 marks a cornerstone for the regulation of transboundary movement, handling and use of Genetically Modified Organisms (or Living Modified Organisms as referred to in the Cartagena Protocol). For the first time, the international community dealing with the development, handling, transport, use, transfer and release of any GMO have a set of obligations to comply with. Since all Parties to the Protocol (and even non-Parties in order to protect their trade interests) have to take necessary and appropriate legal, administrative and other measures to implement their obligations under the Protocol, it is essential that countries in the ASEAN region be prepared to meet these new challenges. Whilst the science of biotechnology are in various stages of development in these countries, expertise in risk assessment and risk management of Genetically Modified Organisms however is lacking. Notwithstanding that trade in GMOs is expected to increase exponentially in the future, concern for safety of GMOs to human and animal health and the environment, including its impact on our rich biological diversity, cannot be ignored.

It is therefore imperative that ASEAN member countries prepare themselves to meet the legal, trade, environmental, human health, religious and ethical requirements pertaining to biosafety. Of immediate concern is the need to set in place or strengthen the legal and institutional framework to address biosafety concerns arising the demands of consumers and the international community. Capacity building in terms of risk assessment and risk management, enhancing networking in biosafety, information sharing and increased public awareness of biotechnology and its products are measures that need to be commenced immediately and on a sustained basis in the long term.

### **Current regional situation and context**

ASEAN member countries are in various stages of development in terms of biosafety measures. While some countries have developed guidelines for R&D and field testing of biotechnology products, none have a comprehensive legal framework to address the commercial and consumers' concerns as regards biosafety as mandated by the Cartagena Protocol. Many of these regulations are guidelines in nature and do have legal compliance status. The efficacy of these guidelines is being challenged in the face of growing interest in biotechnology



research and increasing availability of GMO products. In October 1999, the ASEAN Ministers for Agriculture and Forestry adopted the ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs. The Guidelines would provide a common framework for ASEAN Member Countries to undertake risk assessment of agriculture-related GMOs and would focus on a science-based risk assessment. However, these are merely guidelines that only pertain to risk assessment of agriculture related products. Issues such as compensation, and liability, labeling, socio-economic and religious factors would not be covered under the Guidelines. National regulatory frameworks need to be set in place within the framework of these guidelines.

### **ASEAN Cooperation related to Biosafety**

ASEAN has adopted biotechnology as a tool for improving agricultural, forestry and fishery production as spelled out in the Hanoi Plan of Action (HPA) particularly

2.4.2 (a) - Conduct collaborative research to develop new/improved technologies in food, agriculture, and forestry production, post harvest and processing activities and sharing of research results and available technology.

2.4.2 (b) - Conduct R&D in critical areas to reduce the cost of inputs for food, agriculture and forestry production.

2.4.5 (a) Strengthen ASEAN's cooperation and joint approaches in addressing issues and problems affecting trade in the region's food, agriculture and forestry products including environment and labour issues.

3.4 - Intensify R&D in application of strategic and enabling technologies

5.8 - Begin to implement the ASEAN Science and Technology Human Resource Development Programme addressing the needs of industry and business

6.7 - Strengthen institutional and legal capacities to implement Agenda 21 and other international environmental agreements by the year 2001

The ASEAN Ministers on Agriculture and Forestry have adopted the ASEAN Guidelines on Risk Assessment and Management of Agriculture Related GMOs in an attempt to enhance harmonization of national laws and regulations pertaining to biosafety

The ASEAN Senior Officials on the Environment, through the ASEAN Regional Center on Biodiversity Conservation are implementing a number of projects related to biodiversity and in particular biosafety. An ASEAN Regional Workshop on Biosafety of GMOs was held in Kuala Lumpur in April 2000 to

assess the status of biosafety in ASEAN member countries, and to raise awareness and deepen understanding on this issue. As a follow up to the recommendations of the Regional Workshop in Kuala Lumpur, ASEAN, in collaboration with the United Nations University, organized a Workshop on Capacity Development for the Integrated Approaches to Biosafety of Genetically Modified Organisms in Jakarta in November 2001. The workshop was pivotal in identifying the specific needs of ASEAN relative to risk assessment and the management of genetically modified organisms.

ARCBC has also embarked on a region-wide biodiversity database system, which will eventually incorporate the Biosafety Clearing Mechanism, an essential part of the biosafety regulatory framework.

The Sub-Committee on Biotechnology (SCB) under the ASEAN Committee on Science and Technology (COST) is currently implementing joint R&D projects such as Plant Biotechnology for Crop Improvement and Better Utilisation of Natural Resources, Formulation of Biotechnology Atlas etc. SCB is also developing project proposals on R&D on transgenic plants.

### **Challenges faced in ASEAN**

- (a) Biosafety concerns are global in nature, and the Cartagena Protocol places a legally binding commitment on member countries to set in place legal and institutional mechanisms to address these issues. Since the issue is highly technical and affects a multitude of stakeholders and impacts on the socio economic aspects of ASEAN member countries, a sharing of experience provides the synergy to undertake this task on a most cost effective manner.
- (b) ASEAN member countries are basically agricultural in nature and have similar agricultural products. Hence developments in biotechnology and biosafety are expected to have similar concerns and impacts among ASEAN member countries, and a coordinated approach in this area is necessary.
- (c) Most of the ASEAN countries have also similar cultural and religious concerns. As such, the socio cultural concerns of biosafety could be effectively addressed if there is collaboration and harmonization of regulations based on these socio cultural concerns.
- (d) ASEAN member countries are rich in biological diversity. The impacts to the biological resources are a major concern in biosafety. Hence the harmonization of regulations with respect to its impact on biological diversity is important to ensure GMOs imported or developed in one country does not impact adversely the biological diversity of the region.

- (e) Risk assessment and management procedures are highly technical and require highly skilled manpower and facilities. If the regulations are harmonized, it creates the opportunity for ASEAN member countries to share resources and specialize among themselves in risk assessment and risk management. Wastage of scarce resources through duplication in each member country could therefore be avoided.
- (f) Similarly shared expertise and resources could enhance development in biotechnology, both in increasing productivity and reducing wastage through pest control etc. by having similar regulations in the region.

#### **Technical assistance required**

- (a) Development or reinforcement of national laws or regulations on biosafety in line with international practices. Many countries have some regulations, but these are mostly guidelines pertaining to R&D and field-testing only. Regulations pertaining to the import, use and transboundary movement of GMOs from the trade, religious and cultural perspectives need to be developed.
- (b) Development and refinement of regulations pertaining to R&D, field testing and commercialisation to promote biotechnology research in the region and in line with international practices.
- (c) Development of science-based approaches to risk assessment and management of biotechnology products.
- (d) Development of institutional mechanisms to address biodiversity concerns. This includes strengthening the competent authority to regulate biosafety, capacity building for risk assessment and risk management, establishment of biosafety clearing house mechanisms.
- (e) Public awareness programs to consumers and the public at large on biosafety of GMOs

## **BANGLADESH**

**Mohammad Fazlur Rahman**  
**Ministry of Environment & Forest**

### **Introduction**

Bangladesh is situated at the complex interface of the Indian, the Himalayan and the southeast Asian biogeographic regions, and historically is well- endowed with a very diverse complement of terrestrial and aquatic flora and fauna.

Of the total land surface of 14.4 million ha, 9.1 million ha are used for agriculture, 2.85 million ha are under tree cover (forest), 2.31 million ha are settlements and the remaining areas are regarded as fellow and miscellaneous land. Land use is a dynamic process and changes in land use pattern in Bangladesh have been driven by 1) expansion of agricultural land including HYV agricultural areas ii) water management intervention iii) development of rural infrastructure iv) urbanization and v) industrialization.

The percentage of forestland has declined over the past few decades and presently stands at about 14 percent. The actual tree cover is however much less. Bangladesh has a rich biological heritage. There are about 5700 species of angiosperms in Bangladesh, including 68 woody legumes, 130 fibre yielding plants, 500 medicinal plants, and 29 orchids. Of these, 2260 species are available in the Chittagong Hill Tract (CHT) region. The natural forests of Bangladesh have been facing an onslaught for a long time and consequently a considerable portion has already been lost. This has resulted in the loss of wild biodiversity. There is only little reliable information on gene pools or varieties within species.

Factors affecting the loss of biological diversity in Bangladesh include: (i) population pressure, (ii) natural hazard (cyclone, tidal surge, flood etc.) (iii) overexploitation of biological resources, (iv) deforestation, (v) destruction of habitat, (vi) flood control related activities causing destruction of wetlands, (ix) shifting cultivation in the hills etc.

Bangladesh, being the party to the Convention on Biological Diversity (CBD), has undertaken an international commitment to prepare a National Biodiversity Action Plan. Quite a good number of biodiversity-related programs and projects are now under implementation or in the design stage.

Bangladesh has achieved self-sufficiency of food grain production through the introduction of biotechnology. The Government has established the National Institute of Biotechnology under the Ministry of Science, Information and Technology Communication. The Ministry of Science, Information and Technology Communication takes care of the research activities and the Ministry of Environment and Forest takes care of management aspects of biotechnology activities. Bangladesh is cautious about the bad effects of the biotechnology use and transportation of GMOs/LMOs. For smooth implementation of the Cartagena Protocol, the first priority is to formulate National Biosafety Framework.

#### **Implementation of Article 19**

The Government of Bangladesh has formulated and released bio-safety guidelines for facilitating biotechnological research. For the protection of LMO/GMO/GEO, the formulation of national biosafety act is in process. Moreover, the Biodiversity and Community Knowledge Protection Act and Plant Diversity Act are under review for consideration of enactment. The Ministry of Environment & Forest will be the national focal point for the biosafety protocol. The competent authorities to implement Article 19 are the Ministry of Environment & Forest in collaboration with the Ministry of science, Information and Technology Communication, Ministry of Agriculture, Ministry of Fisheries and Livestock and Ministry of Health and Family Welfare.

#### **Institutional set up for Biotechnology Activities**

A legal institutional set up to take care of the biotechnology activities will be established after finalization of the National Biosafety Framework. After agreement on the Cartagena Protocol on Biosafety, the Government has considered at present, the following ministries are involved in biotechnology activities -

- a) Ministry of Environment & Forest (MOEF)
- b) Ministry of Fisheries and livestock (MOFL)
- c) Ministry of Agriculture
- d) Ministry of Science, information and Technology Communication (MOSITC).

The institutes under the ministries working on Biotechnology issues include.

(A).Ministry of Environment & Forest (MOEF)

1. Bangladesh Forest Research Institute
2. Department of Environment
3. Forest Department

(B). Ministries of Fisheries and livestock:

1. Bangladesh Fisheries Research Institute.
2. Bangladesh livestock Research Institute.

(C). Ministry of Agriculture

1. Bangladesh Rice Research Institute
2. Bangladesh Agricultural Research Institute.
3. Bangladesh Agricultural Research council.
4. Bangladesh Agriculture University

(D).Ministry of science, Information and Technology communication

- a. Bangladesh centre for Scientific and Industrial Research.
- b. National Institute of Biotechnology

**Capacity development**

For proper implementation of biosafety Protocol, the following fields need attention for capacity development.

a) In house capacity building

- 1) Technical and technological
- 2) Training
- 3) Human Resource Development
- 4) Laboratory training
- 5) Workshop
- 6) Technical information and guidance on
  - a) A regulatory system
  - b) An administrative system
  - c) A decision making system that includes risk assessment and management for bio-technology.

- d) Mechanism for public participation and information
- e) Current use of modern biotechnology as defined in the Cartagena Protocol on Biosafety
- f) Capacity building related to the safe use of biotechnology
- g) Logistics and financial support will be provided to review existing legislation or legal instrument related to biotechnology/biosafety
- h) Access to relevant information for all stakeholders in accordance with the requirement of the Cartagena Protocol on Bio-safety
- i) Development of a National Biosafety Database and linkage to the Biosafety clearing House
- j) Mechanisms for adequate involvement of all stakeholders, including public and private sector, on issues related to biosafety.

For proper implementation of bio-safety protocol, it is very urgent to formulate National bio-safety framework. The framework for such action will include:

- a) Position paper on biotechnology use
- b) Action plan in consultation with all stakeholders
- c) Rosters of relevant experts within the country, identifying their experience and expertise, so that adequate coverage in all areas is obtained and potential gaps can be identified.
- d) System for risk assessment and management, including audits, which takes into account national and sub-regional/ regional levels.
- e) Mechanisms for sharing of scientific assessment at sub-regional levels,
- f) Identification of country needs and mechanisms for Participation in the Bio-safety clearing House.
- g) Mechanism for public consultation in decision making process regarding LMOs.
- h) A report on existing sub-regional bio-safety frameworks and mechanism for harmonization of risk assessment management.

## **Conclusion**

Bangladesh need technical and financial support to implement the Cartagena Protocol. Regional cooperation is seen as a key element in building capacities. Research and development on biotechnology is receiving prime attention and hence it is hoped that political support for safe use of biotechnology will be forthcoming.



## **BHUTAN**

**Kumbu Dukpa, National Environment Commission  
Medon Yaganagi, National Biodiversity Center, Ministry of Agriculture**

### **Introduction**

The Cartagena Protocol, which was adopted under the Convention on Biological Diversity (CBD) on 29th January 2002, is a guiding framework for activities on biosafety. The main focus is on transboundary movement of living modified organism (LMO) resulting from modern biotechnology that may have an adverse effect on the conservation and the sustainable use of biological diversity. The protocol aims to derive the maximum benefits from biotechnology while minimizing the risks to natural environment and to human health. In accordance with Article 36, the Protocol was open for signature at the UN Headquarters in New York until 4th June 2001 and thereafter the Protocol has been left open for ratification only.

As the Cartagena Protocol was developed under the Convention of Biological Diversity, the next section deals with Bhutan and our position with regards to the CBD, followed by Bhutan and the Cartagena Protocol.

### **Bhutan and the Implementation of the CBD**

Recognizing the importance and concerns associated with biological diversity at both the national and international arenas Bhutan became a Party and signed the CBD in 1992 at the Rio Earth Summit, which was later ratified by the Royal Government of Bhutan (RGoB) in 1995. Since the ratification of the CBD, Bhutan has taken many steps in trying to fulfill its obligations under this international undertaking and is continually in the process of complying with the objectives and conditions set out under the different articles of the convention.

In line with Article 1 of the CBD, the RGoB has made the ‘conservation of biological diversity and the sustainable use of its components’ a priority during both its 8th Five Year and 9th Five Year Plan periods focusing on national strategies and programs to achieve this goal. During the 9th FYP period (i.e. July 1992- June 1997), the RGoB’s interests has also been directed towards the field of bioprospecting to address issues such as the appropriate access to genetic resources and technologies and the equitable sharing of the benefits as outlined in Article 1.

In accordance with Article 6 CBD, required to address the needs for national strategies, plans and programs towards the conservation and the sustainable use of biodiversity, Bhutan has taken many initiatives. One main step has been the

development of a document titled “The Middle Path” in 1999, outlining the National Environment Strategy for Bhutan. The document was produced by the National Environment Commission (NEC), mandated to be the RGoB’s main instrument to the undertakings of the CBD.

Additionally, to address the concerns, policies and action plans towards the nation’s biological diversity the Ministry of Agriculture (MoA) developed the Biodiversity Action Plan (BAP) document for Bhutan in 1998. The 2nd edition of this document was presented in April 2002 to the COP-6 at The Hague in Netherlands thus fulfilling Bhutan’s obligations to the CBD under Article 26. Further the RGoB has established a National Biodiversity Center (NBC) within the MoA, mandated to coordinate and facilitate all the nations activities with regards to biodiversity and to integrate the conservation and the sustainable use of the biological diversity into the nations plans and programs. Further a “National Biodiversity Management Board” has been established with cross-sectorial representation. It is to be the executive and policy decision making body for all biodiversity issues in Bhutan.

In line with Article 8, towards the conservation of biological diversity *in-situ*, the RGoB has established the Nature Conservation Division (NCD) under the Ministry of Agriculture (MoA). The NCD manages the nations protected area systems, which currently covers a total area of about 36%. Additionally, the RGoB has set out numerous policies, legislation and acts to protect the country’s natural ecosystems and resources.

More recently in compliance with Article 9 towards *ex-situ* conservation, the NBC has taken many initiatives; a national seed gene bank is being constructed at Serbithang, near the capital city Thimphu. Additionally the construction of a National herbarium has been completed to house more than 20,000 specimen and a Royal Botanical Garden for the *ex-situ* conservation of the flora of Bhutan has also been established, the development of the garden is underway at Serbithang.

For the 9th FYP period of the RGoB which commences in July 2002 many provisions have been made under different externally funded donor assisted projects to address the RGoB’s commitments made under the CBD, specially with regards to Articles 7 (identification and monitoring), 10 (sustainable use), 12 (research and training), 13 (public education and awareness), and 14 (impact assessment). To cater to the needs above, and in line with Article 17 addressing information exchange, the RGoB through the NBC has developed a multi-stakeholder project to establish an integrated biodiversity Information web-based system in Bhutan. The project titled “Bhutan Integrated Biodiversity Information Systems (BIBIS) is in the pipeline awaiting implementation at the start of the RGoB’s 9th Five year Plan (FYP) period.

With the RGoB planning on embarking on Bioprospecting during the 9th FYP issues under Article 15 (access to genetic resources), 16 (access and transfer of technology), 18 (technical and scientific cooperation) and 19 (use and benefits of biotechnology) will to be addressed. New establishments within the MoA such as the Quality Control and Regulatory Services (QCRS) and the NBC will be making initiatives towards addressing such issues. Given that Bhutan will be embarking on programs such as bioprospecting, we need to be aware of issues such as biosafety, LMO's and the Cartagena Protocol.

### **Bhutan and the Cartagena Protocol**

As Party to the CBD and on the positive recommendations by participants to the 1st and subsequent meetings of the “Inter-governmental Committee for the Cartagena Protocol on Biosafety” (ICCP), the RGoB decided to sign the Protocol on Biosafety, but unfortunately missed the deadline for signature. Although the RGoB is keen to ratify the Cartagena Protocol, we are aware of the drawbacks with respect to in-house technical and financial capability to implement its requirements. Furthermore, the Bhutanese government currently does not have adequate legal and policy frameworks and institutions with the required mandates to successfully implement such an undertaking. In spite of all these shortfalls, the RGoB attaches a huge importance to the Cartagena Protocol and the principles and objectives outlined. With inherent globalization and technological advancement, Bhutan is not in a position to be isolated from the emerging issues associated with biosafety.

The Cartagena Protocol on biosafety is very pertinent to Bhutan given that we have a large biodiversity resource base and is considered as one of the prominent biological hotspots and ecological wonders in the world. While aiming towards the conservation and the sustainable utilization of our biological resources we are aware of the need to exercise caution and control when allowing the import and use of LMO's and their products into our country, while at the same time we do appreciate the benefits that biotechnology can have on the sustainable economical and environmental development of the nation.

To achieve the philosophy of the “Middle Path’ approach in this context, the RGoB realizes that Bhutan needs at the foremost the following;

- Technical ability to assess the safety or other wise of LMO's in order to make appropriate and intelligent decisions
- Capacity Building in three key fronts:

1. Biosafety regulations,
2. Scientific capacity
3. Monitoring and Enforcement capabilities.

With these points in mind and with the opportunity provided by UNEP/GEF on the possibility of financial assistance, Bhutan is in the process of developing a project proposal titled “Development of National Biosafety Framework”. This is being done following set guidelines that address building the institutional and technical national capacity in the field of biosafety to meet the obligations under the Cartagena Protocol. On the successful completion of the national activities foreseen in the project we have the provision of becoming a Party to the Cartagena protocol.

The Asia regional workshop to address issues on the “risk assessment and risk management to implement the Cartagena protocol” in Delhi will be a timely contribution in our endeavors to develop a biosafety project for Bhutan, which will also take into consideration regional and global concerns.

### **Bhutan and Biotechnology**

Bhutan’s track record with respect to biotechnology has been almost non-existent. Until now the RGoB has not identified the need to use biotechnology as a tool for the sustainable environment and economic development of the nation. The RGoB has invested in establishing two tissue culture labs, one for the commercial propagation of selected crop specimens and the other for research and development of agro-biodiversity. However in both the labs only propagation work has been initiated to date. One of the major drawbacks for the slow adoption of biotechnology has been the poor development of infrastructure and facilities compounded by the lack of trained specialized human resource capacity.

As biotechnology is an important aspect that has been referred to in the CBD Article 8, subparagraph (g) Article 16 and Article 19 and the resulting Cartagena Protocol the remaining sections of this paper will specifically address biotechnology and related issues focusing at the national and regional levels. Starting with the implementation of Article 19 of the CBD, “Handling of Biotechnology and Distribution of its Benefits”, followed with the current institutions in Bhutan to handle biotechnology and its aspects and emphasizing the capacity building needs. The last section covers the regional mechanisms and some recommendations from our side.

## **Implementation of Article 19 of the CBD in Bhutan**

Article 19 of the CBD focuses on the “Handling of Biotechnology and Distribution of its Benefits”, within four sub-paragraphs. The sub-paragraphs focus on Contracting Parties to establish appropriate policy and legislative measures for biotechnology research, establish access and benefit sharing mechanisms resulting from biotechnology, develop protocols associated with LMO’s resulting from biotechnology and provide information for the safe use and handling of such organisms, respectively.

This section of the paper attempts to address the steps undertaken by Bhutan to address such issues and identifies the focal points and competent authorities involved.

### ***Article 19, sub-paragraph 1***

With regards to Article 19, subparagraph 1 on legislative and policy measures, Bhutan does not have any existing policies or legislation on biosafety. Bhutan is yet to develop concise and appropriate national legislative and policy measures on biosafety that would guide us on embarking in future biotechnology associated research.

Although Bhutan does not have the appropriate legislation in place there have been instances we have provided genetic material for use in breeding and biotechnology for research purposes. For example we have contributed hundreds of local rice germplasm to the International Rice Research Institute (IRRI) in the Philippines and have developed institutional linkages with them for further research activities. The MoA within the RGoB has four Renewable Natural Resources Research Centers (RNRRC’s) established in the country to undertake possible research-orientated activities in biotechnology.

Additional to the CBD and to meet the obligations under the Cartagena Protocol Bhutan needs to enact national biosafety legislation. This will have the force of law and its implementation can be backed by corrective measure. Comprehensive national legislation will also ensure that the unique risks and hazards of LMO’s are fully taken into account and regulated specifically and appropriately. The formulation of national biosafety legislation must benefit from an open and participatory process. Given the volume and strength of worldwide public concern and consumer opposition towards genetic engineering and biotechnology, a national process that is transparent, accountable and one, which involves all levels of public participation, will be crucial.

The legal section under the NEC will have to take the critical role to implement the process. Currently under the MoA there are adhoc projects dealing with different conditions of access and benefit sharing mechanisms and legal framework for biological diversity. The NBC under the MoA with external technical assistance is in the process of developing a legal and policy frameworks for Plant Genetic Resources. Another section facilitated by the MoA is dealing with food safety and concerns of LMOs in this aspect have been highlighted. The QCRS dealing with import permits have developed formats for monitoring the transboundary movement of biological resources but are yet to include LMOs in their quest.

***Article 19, sub-paragraph 2***

With respect to subparagraph 2, access and benefit sharing resulting from biotechnologies, it is apparent that given the present technological capacity in Bhutan that we would be a contracting party permitting access to our rich biological and would gain benefits from biotechnological activities undertaken in collaboration efforts. With this in mind the NBC has developed the first draft of the National access legislation for Plant Genetic Resources in Bhutan, which is in the nations best interests and suitable to the national and international conditions. The conditions for benefit sharing have also been outlined where the transfer of technology and capacity building for partners has been emphasized. This document however needs to be formally presented to and approved by the RGoB.

***Article 19, sub-paragraphs 3 and 4***

Regarding subparagraphs 3 and 4, associated with LMOs resulting from biotechnology, we would like to state that so far Bhutan has not had the provision to develop any LMOs using biotechnology in the country and hence we have not adversely affected the biological diversity of any nation. There have also been no instances or reports of any LMOs being imported in the country, in the future the QCRS will be the focal point and authority that will monitor the movement of LMOs. The procedures and protocols are yet to be developed, which will address the safety measures in transfer and handling and advance inform agreement contracts highlighting potentially adverse impacts on human health and the environment. Such concerns will probably be addressed through the “Biosafety Project” being initiated by the NEC to implement the Cartagena protocol.

## **Institutional setup for Biotechnology activities in Bhutan**

In order for Bhutan to ratify the Cartagena Protocol, national level capacity needs to be developed including the institutional capacity to deal with the various aspects of the protocol. Since ratifying the CBD, the RGoB of Bhutan has established additional organizations to deal with the conservation, management and the sustainable utilization of the nations biological resources. However none of the organizations have had mandates directly linked to biotechnology. These organizations will play a different role with regards to the biotechnology activities in the country. Given the current situation and programs being implemented it is apparent that strong institutional linkages and an integrated approach needs to be taken into consideration.

This section thus provides brief details of the ministries and agencies involved with biotechnology activities in Bhutan, including their roles responsibilities.

### **Autonomous Agencies**

#### ***The National Environment Commission***

The NEC is an autonomous agency of the RGoB and the national focal point for the environment policies. NEC is also the RGoB's instrument to the undertakings under the CBD. With regards to biosafety and biotechnology, NEC has taken the initiative to develop a project proposal for support under UNEP/GEF for the development of Bhutan's Biosafety Frameworks. It will be the national executing agency and the legal entity responsible for the biosafety project. Within its internal staff structure, legal personnel are recruited in the NEC. Other staff include the environment impact assessment officers who will probably play an important role in the future in assessing and advising the RGoB on the impact of externally introduced or internally created LMO's in the country.

### **Corporations**

#### ***1. Druk Seed Corporation***

Attached to the MoA also deals with biotechnologies for small-scale commercial purposes where to date the main focus has been on tissue culture of some economically important crop plants.

The role of the private sector in Bhutan with regards to the sustainable utilizing of biotechnological applications for commercial gain is in its infancy.

## ***2. Food Corporation of Bhutan***

Established in 1974 deals with the procurement and distribution of essential food items in the nation. One of its mandates is to maintain food reserves and undertake business in agriculture and related products.

### ***Organizations under Ministry of Agriculture (MOA):***

Under the MoA the institutional setup to deal with biotechnology activities are mainly centered with the NBC, RNRRC's and the QCRS.

### ***The National Biodiversity Center***

The NBC was formally established as the non-departmental agency under the MoA to oversee and ensure the implementation of Biodiversity Action Plan, 1998 and to promote biodiversity conservation and the sustainable use of biological resources on equitable terms of benefit sharing. The NBC was established as the RGoB recognized the need for organizing and coordinating the national biodiversity activities under a single administrative and management structure to establish the foundation for local, regional and global efforts in biodiversity conservation and sustainable uses of its components.

It is mandated to be a framework for organizing Bhutan's biodiversity related activities; be a mechanism for national decision-making on biodiversity concerns, cutting across sectors, divisions and institutions; be a mechanism to guarantee a better national balance between conservation and sustainable utilization of biological resources in general, and between in situ and ex situ conservation in particular; be a mechanism to facilitate sub-regional, regional and international cooperation; and assure the continuity of biodiversity related activities over time.

Within its framework the NBC has sections to deal with the conservation and the sustainable utilization of Agrobiodiversity. With assistance of the Netherlands government a National Gene bank is under construction, which will be completed by the end of 2002, with the provisions of a biotechnology lab attached to its premises. Through the same project there is a provision to train a technical staff for a six months course in biotechnology. The NBC is in the process of identifying a donor to assist in the development and implementation of a bioprospecting program in Bhutan. Where the need for a biotechnologist will be emphasized. Bhutan currently lacks trained specialists in this field although many individuals would have been partially exposed to biotechnological applications and procedures during their studies abroad.



### ***The Renewable Natural Resources Research Centers***

There are four RNRRC's in the country under the Department of Research and Development Services of the MoA. Each of these integrated centers has a national mandate to coordinating research in one of the four major fields of research i.e. Forestry (Yusipang in western Bhutan), field crops (Bajo in Wangdue, located in the western central part of the country), livestock (Jakar in Bhumthang, central Bhutan) and horticulture (Khangma in the far Eastern region of Bhutan). Each of these centers has a multi-disciplinary team of scientists.

### ***The Quality Control and Regulatory Services***

The QCRS is a non-departmental agency within the MoA and mandated to promote and regulate the quality of goods and products in Bhutan; to ensure that the quality of food is safe for consumption; to check the flow of diseases in agriculture and livestock in collaboration with the Department of Health and Services. Other mandates include implementation of acts and bylaws of the RGoB related to RNR sector and to initiate amendments where necessary. Application and Permit forms for the import and export of agricultural goods, livestock etc have been developed by the analytical and certification division within QCRS. Phytosanitary certificates are also issued by QCRS depending on the importing country's regulations to facilitate trade.

### ***Other Ministries of the RGoB***

The other Ministries that would probably have institutional setups for biotechnology applications in the country would include the Ministry of Health and Education in Bhutan and the Ministry of Trade and Industries for license permits and trade negotiations for biotechnology industries. The former in its relationship with the scientific capacity and infrastructure to perform tests related to the affects of LMO's to human health, the facilities and infrastructure for primary health care in the country is relatively well established. Additionally the institute of traditional medicine and services under the Health department, involved with the processing of raw materials into medicinal products has well established laboratories and processing units, with the potential of expanding to biotechnological applications.

## Capacity Development

The table below provides an overview of the existing capacities including the specific capacities needed to implement Biosafety procedures in the country.

| SL. No | National Biosafety Actions to be implemented  | Existing Capacities   | Capacities Needed   |
|--------|---|---|---|
| 1      | Development of a legal framework and the instruments to implement biosafety procedures in the nation. (through multi-stakeholder involvement) | Lawyers addressing concerns and issues for environment exist but less than 5 in the whole country   | External legal Expertise and training of the national existing lawyers in biosafety issues to develop an appropriate framework.   |
| 2      | Development of the institutional capacity and defining specific roles and responsibilities to implement the frameworks for biosafety          | Institutions such as NEC, NBC, QCRS in place.   | Technical Assistance required for Institutional Development, to determine specific roles and responsibilities related to biosafety.   |
| 3      | Strengthen the scientific knowledge base and documentation procedures in the country required for biosafety and biotechnology.                | Information sections established within most of the RGoB agencies with limited manpower and facilities.   | Manpower required to collect and enter data and information. Infrastructure such as computers with access to the internet need to be purchased and established                                |
| 4      | Build a national scientific and technical capacity to deal with biotechnological research   | RGoB personnel available but lack specific training in biotechnology. Basic lab facilities for biotechnological based activities available in the country | Specialized training in biotechnological required for selected RGoB staff<br>Establishment of biotechnology labs around the country and purchase of appropriate equipment for laboratory work |

|   |   |  |  |
|---|---|--|--|
| 5 | Develop appropriate Information management systems, and public awareness schemes and establish a Biosafety Clearing House mechanism | IMS systems being developed within different Ministries for different purposes | Technical Assistance in IT required to help establish appropriate IMS for biosafety information. Procurement of equipment related to IT in relevant institutions                           |
| 6 | Monitoring and evaluation of LMO's  | QCRS in place but lacks trained personnel in this field.                       | Technical assistance required to help in setting some standard protocols for risk assessment (to human health and the environment assessment) Training of personnel in this field required |
| 7 | Development of risk management protocols for LMO's  | Not yet developed  | Need TA and relevant training in this field.   |
| 8 | Establish appropriate emergency measures for accidental movements of LMO's (including isolation and control chambers)               | Not yet developed  | Need TA to assist in developing appropriate measures. Need to build the required infrastructure.   |
| 9 | Training of field staff in the implementation of specialized biosafety activities in the country                                    | No specialists trained in this field   | TA required to develop training manuals for set protocols on biosafety. Specialized training and exchange programs with other regional centers involved in biotechnology and biosafety.    |

## **Capacity Building**

Bhutan needs to collaborate for financial and technical assistance with other international organizations to assist in capacity building, to address both the institutional and human resources needs to implement the Cartagena Protocol on Biosafety

The following are the capacities required urgently for the development, management and implementation of National Biosafety Frameworks in Bhutan.

- Assessment of existing laws and regulations pertinent to Protocol on biosafety to identify major gaps and weaknesses to develop appropriate legal and policy frameworks for biosafety and transboundary movement of LMO's.
- The strengthening of relevant existing institutions including coordination mechanisms;
- Development of national risk assessment and risk management capabilities;
- Promotion of public awareness and education;
- Human resources development to deal with biotechnological research and biosafety procedures, as well as increasing the knowledge base of legal experts and policy makers,
- Building capacities in monitoring compliance.

Bhutan is a developing country that does not have the infrastructure or know-how and experience in handling modern biotechnology. These gaps create difficulties in evaluating the risks of process and products of modern biotechnology. Access to biological resources, intellectual property rights to the products and biosafety are three inseparable issues, and capacity building in biosafety must take all these into account. The success of the Biosafety protocol depends on the indigenous capacities of the developing countries to fulfill the obligations under it. Human and financial resources, information exchange, technical assistance, capacity-building in various areas, and the creation of appropriate infrastructures will be essential elements to achieve the objectives of the protocol.

Bhutan is exploring the possibilities of requesting UNEP/GEF to support the NEC in meeting some of the obligations of the Convention on Biological Diversity and in building capacity to strengthen implementation of Biodiversity activities and development of the National Biosafety Framework. The activities will be carried out in close consultation and coordination with the National

Biodiversity Center, the Nature Conservation Division and other relevant institutions and stakeholders of the RGoB.

### **Regional Cooperation Mechanisms**

This section identifies some of the types of regional cooperation mechanisms that would be beneficial to Bhutan's biosafety program.

- Sharing of experiences through regional workshops and visits.
- Identification of national biosafety experts in respective countries to exchange and share relevant information, meet regularly as well as function as an informal multinational technical backstopping team.
- Development of "best practices" in Asia and sharing.
- Establishment of on the job training/ exchange programs among the countries in the region.
- Development and publication of a regular regional biosafety journal that documents experiences as well as the status of the implementation of biosafety procedures in the member countries.

### **Specific Recommendations**

These are listed for activities at the national, sub-regional and regional levels

- Nationally, need to secure funding to develop biosafety regulations, to develop the scientific capacity and to establish the monitoring and enforcement capability for biosafety.
- Information sharing and exchange on issues of relevance to the biosafety frameworks
- Regional Scientific committee to be established to provide technical assistance to countries requiring such services.
- Development of a website at both regional and national levels to facilitate information sharing
- Identification of regional institutions that provide training in this field

***Contact Details for Biotechnology Issues in the Country:***

Ministry of Agriculture

1. National Biodiversity Centre (for national policy coordination, information management and development of monitoring and management instruments related to biodiversity)  
Program Director: Dr Ugyen Tshewang (02) 351218 (ph) 351095 (fax) , nbc@druknet.bt
2. Department of Research and Development Services (for research purposes)  
Joint Director Research Division: Mr. Ganesh. Chettri (02) 322228(ph), 323562 (fax)
3. Quality Control and Regulatory Services (for access, material transfer permits etc)  
Executive Director: Mr Karma Dorji (02) 327030 (Ph) 327032 (fax)
4. Planning and Policy Division of the MoA  
Deputy Secretary: Dr. Pema Gyamtsho (02) 322545 (ph), 324189 (fax)

***Corporations and Autonomous Agencies.***

For International Undertakings and Policy Decisions

1. National Environment Commission.  
Honourable Deputy Minister: Dasho Nado Rinchen, 324374 (ph), 323385 (fax)

***For Commercial Applications in Biotechnology***

1. Druk Seed Corporation. Paro (limited to Tissue Culture)  
Managing Director: Jambey Dorjee: (08) 271462 (ph), (08) 271206 fax

**CAMBODIA**  
**Pisey Oum, Ministry of Environment**

**Introduction**

Biosafety and biotechnology is new for Cambodia, even though they have been applied partly in the country. The government is trying hard to put it into a formal framework for its implementation through the National Biodiversity Strategy and Action Plan, which consists of 98 priority actions and 17 thematic areas. Only one action among the 98 priority actions is dealing with a strategy for development and implementation of a biosafety.

In relation to the biosafety, humans have been manipulating organisms and exploiting their biological processes and characteristics for thousands of years. The earlier forms of biotechnology -selectively breeding animals and plants and using micro organisms to make, among other things, wine, beer, bread, cheese or soy products- have been adapted by societies around the world and have steadily improved over time. These traditional or conventional techniques are still used today in rural areas and industry alike and differ merely in sophistication and scale. In Cambodia, traditional biotechnology has been in use for hundreds of years for plant and animal selection, beer, soya products, rice and palm wine production.

In the last thirty years, new and more powerful techniques have emerged to supplement the traditional techniques. Some of these new techniques-tissue culture, cell fusion, embryo transfer, recombinant DNA technology and novel bioprocessing techniques- have enabled scientists to grow whole organisms from single cells, fuse different cell types to create hybrids with the qualities of both parent cells, impregnate animals with embryos from other valuable animals, isolate genes from one organism to insert them into another and process things such as food and waste, more efficiently. Some modern biotechnological techniques are presently being used to help conserve biological diversity and sustainable use its components, in particular, genetic resources.

But to many people genetic engineering is biotechnology. With genetic engineering techniques, a gene for a particular trait from one organism can be directly inserted into another, even if the two organisms are not from the same species. The potential power of genetic engineering has captured the imagination of many, and heightened concern over the ethics of its use, safety for humans and the environment and the socio-economic impact of its product.

Biotechnology potentially offers benefits for human welfare, but many people are concerned that greater use of the products of biotechnology is not without

risks to biological diversity and human health. Such risks will have to be identified and appropriately managed or controlled before new product enters the environment (Adapted from IUCN, 1997. Guide to the Convention on Biological Diversity).

The Convention on Biological Diversity and the newly adopted protocol on Biosafety require each contracting party to take steps to regulate, manage or control the risks to biological diversity and human health posed by the use and release of living modified organisms (LMOs) likely to have adverse environmental impacts. Parties may implement a program to address the risks through a hierarchy of measures - regulation, management or other means of control (Cambodia NBSAP, 2002).

Some of the main issues dealing with these include:

1. Lack of capacity in the field of modern biotechnology.
2. Lack of protection measures against living modified organisms.

The goals for biosafety and biotechnology is to:

- Develop biotechnology while preventing environmental and health hazards associated with the use and release of living modified organisms.
- Protect indigenous biodiversity from the introduction and use of living modified organisms.

### **Implementation of Article 19**

In implementing the article 19 of the CBD Convention, the Royal Government of Cambodia, led by Ministry of Environment has formulated the National Biodiversity Strategy and Action Plan (NBSAP) in 2002. The NBSAP in page 53 clearly addressed the action for biotechnology and biosafety management. The NBSAP is positively signed by the government in May 2002. This is the first time for Cambodia to implement and pay a close look on biosafety and biotechnology even though its adoption of modern technology is low.

Under the NBSAP, it indicates the strategic objective for the government to take care and build the its own capacity for biosafety and aims to:



1. Develop a national strategy on Biosafety (decree adopted by Government).
2. Develop national capacity in the field of modern biotechnology (number of students or experts reached by training programs)

Because, most of biosafety and biotechnology is related to agriculture, priority action has been given to Ministry of Agriculture, Fisheries and Forestry to coordinate in implementing the action.

### **Institutional Arrangement for Biotechnology**

The Ministry of Environment is playing a crucial role in setting a policy for biosafety and biotechnology including developing a number of action plans, rules and regulations in relation to the biodiversity protection and conservation of natural resources such as National Wetland Action Plan and National Biodiversity Strategy and Action Plan. However, because most of genetic resource lies more within the agricultural sector than in the environmental sector, a coordinating role seems to lie with Ministry of Agriculture Forestry and Fisheries (MAFF). Ministry of Industrial, Mine and Energy (MIME) and Ministry of Commerce (MOC) who are also involved in implementing the biosafety provisions.

### **Capacity Development**

Capacity development for biosafety and biotechnology is limited, as it has happened in other sectors such as the capacity of the line ministries to implement the NBSAP in terms of individual, institutional and systemic capacity. The NBSAP Add-On (2002) identifies the capacity needs for relevant line ministries including MOE and MAFF to implement the priority actions from NBSAP.

The big problem lies within the institutional capacity to implement the NBSAP including the biosafety thematic area. There should be a commitment of policy change from the government side to ensure the effective implementing the NBSAP document.

Government institutions are facing many constraints both at national and local levels due to the unstable political situation and lack of financial resources. More specifically constraints exist in the areas of human resources, law enforcement, management systems and finances some of the issues are:

- ❖ Inadequate knowledge, skill and experience among staff in the provincial government institutions in the field of coastal resources and environmental management. Also at the village level there is generally a lack of awareness on causes and effects of environmental degradation;
- ❖ Existing laws are not well implemented due to the following constraints; ‘political’ influence, uncontrolled development, wealthy people’s interests and technical constraints (such as human resources, monitoring equipment, local awareness of the laws and lack of provincial power in the control of natural resource use);
- ❖ There is a large degree of crossover in the existing management system whereby more than one ministry shares responsibility, leading to management overlaps and conflicts between and among the responsible authorities. The current move to centralization has added to the confusion, as the lines of authority are unclear; and
- ❖ The main income for the provinces and municipalities comes from the government budget, from tax collection. However, only a small amount of the taxes collected are used for the provinces and municipalities and typically only small amounts go to the provinces, and as such they have difficulty in collecting money for their budgetary needs. Currently Cambodia is generally dependent on foreign financial assistance. The lack of funds from both internal and external sources prevents the ministries and other agencies from fulfilling their mandates.

Individual capacity is increasingly being developed within involved ministries on the assistance from foreign donors, however, low salary cannot keep overseas trained staff to work for the ministry for a long period. Finance is also a problem since the government gives priority to human resource development and poverty alleviation. Biosafety and biodiversity is not in that priority except from external aid. Fortunately, it is one of 17 thematic areas in the NBSAP that the government would approve in late May 2002 for implementation.

This kind of risk can not be well managed unless there is a policy change the from line ministries toward human resource development and institutional commitment for capacity development in this field.

## **Capacity Building**

Individual capacity, the institution capacity and the capacity for the whole system are the key areas of capacity building.

Increased knowledge of risks from biotechnology is required. This should be addressed through regional and international cooperation with human resource development or bilateral agreement. Learning-by-doing is an essential process to constantly build the capacity for officers to effectively use biosafety in relevant sectors.

Institutional capacity should also be strengthened to reflect the capability to handle biosafety in terms of technology transfer, ability to absorb the technology, national rules and regulations that can be enforced. Sustainable finance is essential to keep the institution working and ensure the effective implementation of priority actions and the law enforcement.

The government should make a strong commitment to make an administration reform to increase the salary for government employees to ensure they keep employees working for the government and to promote transparency and accountability as an effort to elevate the capacity for its system. This would complement capacity building for the institution and individual as well.

## **Regional Cooperation Mechanism**

Biosafety and biotechnology is a new frontier for Cambodia to be addressed through inter-ministerial and international cooperation. However, Cambodia more or less has achieved this through its commitment in accession to a number of international conventions.

## **Convention on Biological Diversity (CBD)**

The United Nations Convention on Biological Diversity was adopted in June 1992 at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro. Article 1 of the Convention specifies that; the objectives of the Convention, 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.

On 9 February 1995, Cambodia ratified the Convention on Biological Diversity (CBD). The Ministry of Environment views the CBD as a framework to achieve sustainable development through the sustainable use and protection of biodiversity. Currently a GEF funded Enabling Activity is working to assist

Cambodia to meet the requirements of the CBD, and develop the Cambodian Biodiversity Strategy and Action Plan, which will guide the country's approach for achieving sustainable development.

#### **Frame Work Convention on Climate Change (FCCC)**

Cambodia ratified this Convention on 18 December 1995. The Convention's objective is to regulate levels of greenhouse gas concentrations in the atmosphere so as to avoid a change in the global climate to a degree that would be harmful to economic development and that would impede food production activities. Currently a GEF funded Enabling Activity is working to assist Cambodia meet the requirements of the FCCC.

#### **Convention on Wetlands of International Importance (Ramsar Convention)**

In 1996 Cambodia's National Assembly approved a ministerial request to accede to this Convention, and in 1999 became a Contracting Party to the Convention. The Ramsar Convention has the aim of stemming the progressive encroachment upon, and loss of, freshwater and coastal wetlands. There are 3 proposed Ramsar sites that have been nominated in Cambodia: Boeung Chhma and the associated river system (Siem Reap/Kampong Thom); Kaoh Kapik and associated islets (Koh Kong); and the upper Mekong River to the border of Laos PDR (Stung Treng).

#### **Convention on International Trade in Endangered Species (CITES)**

Cambodia signed the CITES Convention in December 1975, but did not adhere to it until 1999. CITES establishes lists of endangered species for which international trade is either prohibited or regulated through a permit system. The objective is to combat illegal trade and overexploitation.

#### **United Nations Convention on the Law of the Seas (UNCLOS)**

UNCLOS came in to force in 1994. This convention establishes numerous rights and obligations for conservation of marine living resources and biodiversity, and protection of the marine environment in a way, which complements the Convention on Biological Diversity. For the conservation of living marine resources (article 61), Cambodia's UNCLOS obligations are:

- ❖ To determine the allowable catch of the living resources in the Exclusive Economic Zone (EEZ);
- ❖ To ensure proper conservation and management measures to avoid overexploitation of living resources in the EEZ;
- ❖ To take such measures to restore populations of harvested species at levels which can promote the maximum sustainable yield; and
- ❖ To contribute and exchange available scientific information, catch and fishing effort statistics and other data relevant to the conservation of fish stocks through competent international, regional and local organizations.

### **Convention Concerning the Protection of World Cultural and Natural Heritage (World Heritage Convention)**

Cambodia became a signatory in January 1994. The World Heritage Convention has the objective of creating international support for the protection and maintenance of sites demonstrating outstanding cultural and natural heritage of universal value. The temples of Angkor are on the World Heritage list as a cultural site of international significance.

### **Convention on the Prevention of Marine Pollution from Ships (MARPOL)**

Cambodia ratified the MARPOL convention in November 1994. The Convention deals with various forms of marine pollution from ships and other vessels. In Cambodia's case the implementation of MARPOL is the responsibility of the Harbor Master Office of the International Port of Sihanoukville.

### **International Plant Protection Convention (IPPC)**

The purpose of the IPPC is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control. Cambodia adhered to the convention in 1952.

### **Agreements**

Cambodia has also joined various regional agreements with surrounding countries, which are of relevance to biodiversity management, use and protection. These agreements include: specific country agreements with Laos PDR, Thailand and Vietnam; ASEAN - Agreement on the Conservation of Nature and Natural Resources; Mekong River Commission (MRC); COBSEA - Coordinating Body of the Seas of East Asia; and PEMSEA - Partnerships in Environmental Management for the Seas of East Asia.

### **Association of South East Asian Nations (ASEAN) Agreement on the Conservation of Nature and Natural Resources**

Cambodia became a signatory to ASEAN in April 1999. ASEAN has called for measures to combat climate change and ozone depletion, protect ocean and marine ecosystems from pollution, protect freshwater resources, ensure sustainable management of all forests and conserve biological diversity.

### **Mekong River Commission (MRC)**

The Agreement, signed on 5 April 1995, immediately established the Mekong River Commission (MRC) replacing the former Mekong Committee (1957) and the subsequent Interim Mekong Committee (1978). The MRC is an intergovernmental organization, with the mandate “to cooperate in and promote, in a constructive and mutually beneficial manner, the sustainable development, utilization, conservation and management of the Mekong River Basin water and related resources for navigational and non-navigational purposes, for social and economic development and the well-being of all riparian States, consistent with the needs to protect, preserve, enhance and manage the environmental and aquatic conditions and maintenance of the ecological balance exceptional to this river basin”.

The four members agree “to cooperate in all fields of sustainable development, utilization, management and conservation of the water and related resources of the Mekong River Basin, including, but not limited to irrigation, hydro-power, navigation, flood control, fisheries, timber floating, recreation and tourism, in a manner to optimize the multiple-use and mutual benefits of all riparian countries and to minimize the harmful effects that might result from natural occurrences and man-made activities”.

### **COBSEA - UNEP Coordinating Body of the Seas of East Asia**

COBSEA was established in 1981, at the same time as the action plan for “the protection and management of the marine environment and coastal areas of the East Asian region” was adopted. The present coverage includes the marine and coastal environments of; Australia, Brunei, Darussalam, Cambodia, China, Indonesia, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam. Cambodia became a member of COBSEA in 1995 but for political and economic reasons, Cambodia has not paid the Environmental Trust Fund to COBSEA since 1997.

### **PEMSEA - Partnerships in Environmental Management for Seas of East Asia**

PEMSEA, a project of the Global Environment Facility, is an initiative supported by the United Nations Development Program (UNDP) and the International Maritime Organization (IMO). PEMSEA was launched in April 2000 and is made up of 11 countries including; Brunei, Darussalam, Cambodia, China, Democratic People's Republic of Korea, Indonesia, Japan, Malaysia, Philippines, Republic of Korea, Singapore, Thailand and Vietnam. PEMSEA was organized to protect the life support systems, and enable the sustainable use and management of, coastal and marine resources through intergovernmental, interagency and intersectoral partnerships, for improved quality of life in the East Asian Seas region.

### **Country Agreements**

There is a range of cooperative agreements between the Governments of Cambodia, Thailand, Laos and Vietnam, on a variety of regional issues. These agreements include; natural resource management and capacity building and typically cover cross-boundary issues as well as specific cooperation, such as between educational institutions.

### **Recommendations**

Based on the current status of the biosafety and biotechnology of Cambodia, following recommendations are relevant:

- Initiate research and studies on microbial biodiversity.
- Use biotechnology to reduce the use of chemicals.
- Use biotechnology to control pollution and to improve environmental health and other aspects of environment.
- Utilize biotechnology to produce protein rich products that could be used as food, animal feed, organic fertilizers, soil conditioners and soil stabilizers.
- Promote sound genetic manipulation to increase fish and crop production.
- Promote the production of biogas, bio-fertilizers, and energy as a by-product of fermentation processes.
- Establish a national directory of human resources working on subjects concerned with biotechnology and biosafety.

- Develop biotechnology training program.
- Increase resources for biotechnology research and development.
- Include, in the educational curricula, the concept of genetic diversity, its importance and application in genetic engineering and technology.
- Develop a National Code of Ethics and Guidelines for the use of biotechnologies, LMOs and GMOs (Cambodia NBSAP, 2002).

### **References**

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## CHINA

Wang Changyong,  
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State Environmental Protection Administration

### Introduction

The government of China is large among the developing countries and has paid more attention to the conservation and sustainable use of biodiversity as well as the safety of genetically modified organisms (GMOs). In the past 10 years, a lot of important activities were undertaken for the implementation of The Convention on Biological Diversity (CBD). For example, the “China Biodiversity Conservation Action Plan” was developed and issued; three books, entitled “The Report of Country Study on Biodiversity”, “Information Network and Data Management on Biodiversity” and “National Biosafety Framework of China”, were published. The First and Second National Report for the implementation of CBD were submitted to United Nations Environment Programme (UNEP). In order to effectively coordinate the activities related to the implementation of CBD, which will be done by the departments under the State Council, a “National Coordinating Group for the implementation of CBD” was formed in 1993. The Group is currently composed of 20 departments, including the Ministry of Education (MOE), the Ministry of Construction (MOC), the Ministry of Science and Technology (MOST), the Ministry of Agriculture (MOA), State Forestry Administration (SFA), State Oceanic Administration (SOA), Chinese Science Academy (CSA) and so on. The State Environmental Protection Administration (SEPA) heads the Group.

Biosafety is an important component of CBD. In the process of the environmental release and marketing of GMOs, which will have a threat to biodiversity, environment and human health, much of the potential risks associated with GMOs, for instance, their invasiveness in environment, their effect on non-target organisms and gene pollution, have attracted high concerns and attention all over the world. UNEP organized and held many workshops and meeting for the drafting, discussion and negotiation of an International Protocol on Biosafety which was adopted at the extraordinary fifth meeting of the Conference of Parties to CBD at January 29, 2000. The Chinese government signed the Protocol and is now preparing relevant procedures for its final ratification in this country.

This paper will first give an overview of the *status quo* of work in risk assessment and risk management (RARM) of GMOs, then make a description and analysis of the capacity development and building in RARM and finally make some recommendations on regional cooperation in RARM in Asia.

### **The Research and Development of GMOs and their Environmental Release**

Since biotechnology was placed into the list of “Programme 863, a hi-tech one”, set up by Chinese government in 1986, over one hundred institutions have engaged in the research and development (R&D) of biotechnology, involving the departments of education, science and technology, agriculture, forestry, ocean, medicine, hygiene, environment and so on. At present, Chinese scientists have used genetic engineering technology to produce many GMOs with traits of herbicide, insect, virus resistance and nutrient improvement.

According to the 1996 statistics, 47 genetically modified plants (GMP) have been transformed using genetic engineering technology. Among them, there are 7 grain crops, 5 economic crops, 10 vegetables, 11 fruit trees, 3 forest trees, 2 fodder crops, 5 medicine and ornamental plants (Table 1), with an involvement of 103 genes (excluding marker genes) (Table 2). Some of them are still being studied in the laboratory and others have proceeded to the stages of immediate trial, environment release and even commercialization. According to data from MOA, 55 applications for the immediate trial, environment release and commercialization were received in 1997, 68 applications in 1998, and 72 applications in 1999 (Table 3). Up until 2000, 6 crop varieties, for example transgenic cotton, tomato and sweet pepper etc., have been planted at commercial scale. It is reported that the area of commercially planted transgenic crops in China reached 10,000 hectare in 1998, over 140,000 hectare in 1999 and 340,000 hectare in 2000 for transgenic cotton only.

**Table 1 The plants used in genetic transformation**

| <b>Groups</b>               | <b>Number of Species</b> | <b>Examples</b>   |
|-----------------------------|--------------------------|---|
| Grain crops<br>sweet potato | 7                        | Rice, wheat, corn, potato, sorghum, millets,  |
| Economic & oil crops        | 9                        | Cotton, tobacco, sugar cane, sugar beet,<br>soybean, oil rape, peanut etc.                    |
| Fruits & vegetables         | 21                       | Tomato, cabbage, carrot, pepper, sweet peeper,<br>Chinese cabbage, cauliflower, broccoli etc. |
| Others                      | 10                       | Polar, alfalfa etc.   |

**Table 2 Genes that are used in plant genetic transformation**

| Modified traits                 | Foreign Gene of interest   |
|---------------------------------|--|
| Virus-resistance                | TMV-cp, TMV-rep, CMV-cp, PVX-cp, PVY-cp, RSV-cp, BYDV-cp, BYDV-rep, MDMV-cp, TuMV-cp |
| Disease-resistance<br>Glucanase | Cecropin B, Shiva A, Lysozyme gene, Xa21, Chitinase,                                 |
| Insect- resistance              | Truncated cryIA(b), synthetic CryIA(b), CpTI, Pin2, GNA, AHPI                        |
| Herbicide-resistance            | Bar, tfd A, psb A  |
| Others                          | Pro A, BADH, mtl D, gut D, barnase, anti-sense ACC, anti-sense PG                    |

**Table 3 GMOs applied for intermediate experiment, environment release and Commercial production**

| Applications   | Years |      |      |
|--|-------|------|------|
|  | 1997  | 1998 | 1999 |
| Total Applications   | 55    | 68   | 72   |
| Applications for GMP   | 45    | 45   | 59   |
| Applications for GM microorganisms (GMM) used for plants             | 8     | 17   | 8    |
| Applications for GMM used for domestic animals                       | 0     | 6    | 4    |
| Applications for GM aquatic organisms                                | 2     | 0    | 1    |
| Applications for intermediate experiment (IE) which were approved    | 8     | 39   | 18   |
| Applications for environment release (ER) which were approved        | 30    | 10   | 18   |
| Applications for commercial production (CP) which were approved      | 4     | 2    | 20   |
| Applications for the IE, ER, CP which were not approved in that time | 13    | 17   | 16   |

In the R&D of genetically modified animals, the transgenic mouse, rabbit, goat, chicken, cattle, pig and fishes are under development. These transgenic animals are currently in contained conditions without any species being released into the environment in consideration of environmental safety.

Genetically Modified Microorganism (GMM) includes three groups: the nitrogen fixation bacteria, the microorganisms used for killing pest insects or disease protection, and the microorganisms used in the production of animal food additives or animal vaccines. The genetically modified nitrogen fixation bacteria and rhizobia have been approved for field release.

### **Biosafety work in China**

In recent years, the Chinese government has taken administrative, legal and technical measures to regulate and monitor the GMOs which are intended to be released into the environment, commercially planted and put into the marketplace. In the meantime, the activities in capability-building, scientific research and information communication on biosafety management have also been launched.

### **Legislative work on Biosafety**

To legally strengthen the management of GMOs, the relevant departments under the State Council have formulated and issued in the past years several departmental regulations on biosafety. These administrative regulations include “Safety Administration Regulation on Genetic Engineering”, issued by former State Science and Technology Commission in December, 1993; “Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering”, issued by the MOA in July, 1996; “Safety Administration Implementation Regulation on Tobacco Genetic Engineering”, issued by State Tobacco Monopolistic Administration in March, 1998; “Regulation on Approval of New Biological Products”, issued by the State Drug Administration in April, 1999. These regulations played positive roles in the management of the research, development, environmental release and commercialization of GMOs.

However, in view of the fact that most existing GMOs and their products are centralized on agricultural species and drugs, the State Council of China first issued the “Safety Administration Regulation on Agricultural GMOs” in May 23, 2001. The regulation established four basic management systems aimed at the safety management of agricultural GMOs:

- (1) A joint meeting system on the safety management of agricultural GMOs was established under State Council. The meeting is composed of responsible officials from MOA, MOST, SEPA, Ministry of Public Health (MOPH), State Inspection and Quarantine Administration (SIQA), and relevant departments. The important issues on agricultural GMOs will be discussed and coordinated in the meeting.
- (2) The management of agricultural GMOs was implemented in line with their safety level. Agricultural GMOs will be divided into four safety levels from level I (the most safe), II, III, to IV (the least safe), according to their potential risk to the humans, animals, plants and microorganisms.
- (3) A safety assessment system of agricultural GMOs was established. For GMOs that are intended for intermediate trial, environmental release and commercialization it is necessary to make safety assessments and to obtain the approval from the competent department.
- (4) A labelling system of agricultural GMOs was established. The species which are written into the “The List of Agricultural GMOs” need to be labeled by manufacturers and distributors before they are placed into the marketplace.

In addition, The Regulation also included provisions related to research and experimentation, production and processing, operation, import and export, supervision and inspection of agricultural GMOs.

#### **Technical guidelines for the RARM of transgenic organisms**

A technical guideline for RARM of release of transgenic organisms into the environment was drafted to provide technical guidance to RARM of general GMOs. In addition, MOA issued three departmental rules: “Management Rule on the Safety Assessment of Agricultural GMOs”, “Management Rule on the Safety of the Importation of Agricultural GMOs” and “Management Rule on the Labeling of Agricultural GMOs”. The rules fully described the procedures and methods of the RARM of agricultural GMOs, the test of imported GM products, and the label method of Agricultural GMOs.

#### **Attention to basic research work on risk assessment of GMOs**

Biosafety is a new environmental issue. At present, the scientific data available for risk assessment of GMOs is very limited. In addition, the environmental and health risk posed by GMOs is long-term and large-range. Hence, it is necessary to conduct basic research into GMOs. In the past 3 years, MOST, SEPA, MOA, CSA and National Science Foundation of China have funded relevant scientific

institutes and universities to conduct research into risk assessment of GMOs. These research themes mainly focused on comparative ecology of transgenic and non-transgenic crops, the effect of insect-resistant transgenic crops on microorganisms and invertebrates in the soil and insects as well as the test of gene flow.

In the following five years (from 1990-1995), relevant departments under the State Council set up many projects and provided financial assistance for the research activities of the following:

- (1) Assessment of environmental risk associated with GMOs, including the ecological fitness and invasiveness of GMOs in natural ecosystem; the impact of the products expressed by foreign transgene on target and non-target organisms; the mechanisms and the consequences of the transfer of the gene from GMOs to other organisms; the indicators, methodology, model test system and experiment protocols for the risk assessment.
- (2) Monitoring of environmental impact of GMOs, including the environmental behavior and ecological effect of products of transgene; the adverse influence of GMOs by means of the food web and gene transfer on the population of the species which are conserved at the national level; the development of the indicators and methodology of environmental impact of GMOs.
- (3) Prediction and control of the harms caused by GMOs, including the development and application of the models which can predict the potential harms to the environment; the technologies for prevention, control, handling of the harms and other measures aimed at the emergence; the strategy and technical countermeasures for the control of the potential harms.

### **Establishment of Biosafety Information Clearing House**

In order to reinforce the information sharing on biosafety and implement the obligation for the establishment of biosafety information clearing house under Article 20, paragraph 1, of the “The Cartagena Protocol on Biosafety”, SEPA has organized the experts to develop “the web site of biosafety information in China”. Until now, the system design for the web site and the application for the domain name have been completed and submitted to SEPA for review. The information contents in the web site include: “The Cartagena Protocol on Biosafety”, the national focal points, the competent national authority, the policies and regulations on biosafety, the technical guidelines for biosafety, the databases of contained use, field trial and commercialization of GMOs, the database of transboundary LMOs, the list of biosafety experts, the biosafety

news, and other biosafety web sites. What is to be done next is to survey, collect and reorganize the data and information and transform them into the databases.

### **Education, Publicity and Training on Biosafety**

To improve the expertise in RARM of GMOs, some departments under the State Council held in the past several years a lot of workshops and training seminars on biosafety. In the implementation period of the “National Biosafety Framework” project, funded by UNEP through GEF from 1998 to 1999, SEPA held three workshops attended by officials and scientists from different departments. During these workshops, the advances in biotechnology, the principles, procedures and methodology of RARM of GMOs and the biosafety legislation in the world were presented and discussed. In 1998, SEPA, in collaboration with Biotechnology Advisory Center, Stockholm Environment Institute of Sweden, held a workshop concerning the regulation and practice on biosafety. Officials and scientific experts from Sweden, USA, UK, Japan, Germany, Netherlands and domestic representatives from relevant departments attended the workshop, made presentations and held discussion on biosafety legislation and its implementation, the risk assessment of GMOs and their environmental monitoring and capacity building in biosafety. In 2001, SEPA and Canadian Food Inspection Agency jointly implemented a project, entitled “Capacity Building on Legislation and Technical Guidelines in China”. During the implementation of the project, officials and scientists in biotechnology from Canada came to China to hold a training seminar on RARM of GMP for trainees from the environmental protection agencies at provincial level and researchers from national institutes and universities. In addition, SEPA, MOA, MOST, MOE and other departments also held workshops and training seminars on GMOs and GM food.

To improve understanding of biotechnology and awareness for biosafety, the domestic media, such as newspapers, TV and radio, introduced and reported on the development in biotechnology abroad and at home, the roles of biotechnology in social progress and economic growth, and its potential risk to our environment and human health. In addition, the media informed the general public of the news on biosafety.

### **Main national departments involved with the management of Biotechnology**

In China, biological resources are managed by different departments under the State Council. MOA is in charge of crops, domestic animals, grasslands and fishery resources; SFA is responsible for forest and wildlife; SOA is responsible

for marine biological resources; SEPA is responsible for comprehensive environmental issues; MOST is responsible for the research and development of biotechnology; SDSA is responsible for the drugs produced by biotechnology. Hence, work on the RARM of GMOs in China is currently related to many administrative departments under the State Council, such as MOST, MOE, MOA, MOPH, SDSA, SEPA, SFA, SOA and CSA. At the present time, these departments function as follows in the management of GMOs: MOST is in charge of the organization of important research projects on RARM of transgenic organisms; MOA is responsible for production and application of agricultural GMOs; MOPH is responsible for GM food; SEPA is responsible for the environmental safety of GMOs; SFA is responsible for the research and use of GMP in forestry; SOA is responsible for the research and the research and use of marine GMOs; SIQA is responsible for the test of imported and exported GMOs; CAS is responsible for the implementation of the important basic research projects on biosafety.

Based on the institutional reform plan formulated by the State Council in 1998, SEPA was appointed as the competent authority for national biosafety management. However, it must be acknowledged that the responsibilities of different departments in the management of biosafety somewhat overlap. Therefore SEPA is currently preparing to draft a higher layer of “Biosafety Law” to clearly determine the rights and responsibilities of different departments in biosafety in environmental safety of all GMOs. At present, the general framework for biosafety management in China is that SEPA is responsible for reporting to and making contact with CBD Secretariat as a national focal point and a competent national authority under the Protocol. In the meantime, SEPA is also responsible for the united supervision for domestic biosafety affairs and activities, while other departments under the State Council manage relevant activities on biosafety based on their responsibilities. SEPA has established a Biosafety Office to be responsible for the national biosafety activities.

### **Developing capacity in RARM of GMOs**

Capacity development in RARM of GMOs mainly involves development of the technical guidelines for RARM, establishment of risk assessment institutions, improvement of expertise in RARM and also the establishment of a biosafety laboratory. The existing capacities and further capacity development needs in RARM of GMOs in China are showed in table 4.



**Table 4 The capacity development and its needs in RARM of GMOs**

| <b>Contents of capacity development</b>   | <b>Capacity developed</b> | <b>Capacity to be developed and to be perfected</b>   |
|---|---------------------------|---|
| The legislation on RARM   | +*                        | Existing regulations were formulated for only agricultural GMOs, and hence its scope need to be widen to include all GMOs |
| The technical guidelines for RARM   | +                         | The existing guidelines need to further harmonize with the regional and international guidelines                          |
| Institutions of risk assessment   | +                         | Need to issue the certificates for the institutions which make risk assessment  |
| Expertise in RARM   | +                         | Need to hold training seminars to scientifically improve assessment level   |
| Basic research on RARM  | +                         | Need to do long-term basic research on RARM of GMOs   |
| Information and data on RARM  | +                         | There is a little data available to RARM  |
| Methodology for the monitoring of environmental impact of GMOs                    | -**                       | Need to develop the indicators and methods to monitor of the environmental impact of GMOs                                 |
| Establishment of biosafety laboratory   | +                         | The labs are be establishing, but the number is few and the funds are not enough.   |
| Technologies for the prediction and control of environmental harms caused by GMOs | -                         | Need to develop relevant predictive model and control technologies  |

\* indicates the capacity has been developed but is not necessarily perfect; \*\* indicates the capacity needs to be developed.

In order to scientifically assess the risk posed by the domestic and transboundary GMOs, conserve and use biodiversity in sustainable way, promote the sound development of biotechnology, capability building in RARM of GMOs needs to be strengthened mainly in the following ways:

- (1) Develop the parameters and methods at the experimental level for the risk assessment of GMOs. Because the conclusions of risk assessment are based on scientific information and experimental data, which mainly originate from the results of lab experiments and field trials, it is necessary to seek proper parameters and methods to describe and measure the risk of GMOs. Development of the parameters and methods can occur in two ways: The first way is to utilize parameters and methods from related disciplinary subjects; the second way is to do long-term research for GMOs.
- (2) Collect, reorganize and develop the fundamental information on RARM of GMOs. The RARM need to know and be familiar with the information on recipient, genetic manipulation, vector, donor and GMOs. Apart from the information on GMOs, which must be provided on the basis on experiment, other relevant information can generally be obtained through scientific papers, databases and expert experience.
- (3) Improve expertise and the numbers of qualified experts in RARM. The risk assessment is technically complicated, which requires the experts with different professional backgrounds and experience in GMOs. According to “UNEP International Technical Guidelines for Safety in Biotechnology”, at least ten branches of biology, for instance molecular biology, population genetics, ecology, taxonomy, microbiology, virology, botany, zoology, biochemistry, entomology etc., are need for a scientifically sound risk assessment of GMOs. Additionally, the practice of RARM is also related to computer modeling, the management science, legislation, economy and politics.
- (4) Promote information exchange in RARM. Information exchange can improve the sharing of the data, information and experience in RARM among different countries, among regions or among different institutions within the country. The exchange of the information on biosafety can be made through the information clearing-house mechanism at global, regional and national level. In addition, it is very useful and effective to hold workshops, training seminars, make a study tour to the developed countries and use internet resources.

- (5) Strengthen the infrastructure of biosafety laboratories in RARM. Because RARM is a new research field, existing experiment facilities and equipments can not completely meet the requirements for RARM of GMOs. Therefore, it is very necessary to urgently raise money to improve existing experience levels and train relevant professionals.

#### **Regional Cooperation in RARM of GMOs and relevant activity recommendations**

Compared with the western developed countries, in Asian countries a big gap exists in the field of biotechnology. In order to solve such issues as food shortage and for improvement of the environment, GMOs from the developed countries are inevitably imported into some of the Asian countries. In fact, a lot of Asian countries have taken biotechnology as a mainstay industry in the 21st century and many GMOs have been released into the open environment for field trial and commercial production. Therefore, it is necessary to set up appropriate Regional cooperation mechanisms in RARM to prevent GMOs from causing harm. Possible Regional cooperation mechanisms mainly include the following four aspects:

- (1) Strengthen the harmonization of the framework for RARM of GMOs. The main activities include the general principles, methods and standards in RARM of GMOs. The work may be done by ad hoc experts from Asian countries.
- (2) Establish an information center of RARM of GMOs in Asia region. The main activities include investigation for the R&D of biotechnology and existing biosafety work in Asia countries, development of the databases for environmental release, commercial production and marketing of GMOs. These activities may be conducted by the experts appointed by IUCN Regional Biodiversity Programme, Asia, in cooperation with the relevant governments in Asia countries.
- (3) Conduct a scientific cooperation in the field of RARM of GMOs. The main activities include joint research on RARM of GMOs, establishment of a joint biosafety laboratory and scholar exchange. The activities may be implemented by relevant scientific institutes, universities and international research bodies.
- (4) Hold workshops and training seminars on RARM of GMOs. The activities may be implemented by IUCN Regional Biodiversity Programme, Asia, UNEP, CBD Secretariat and other international organizations and NGOs, in cooperation with the relevant governments in Asia countries.

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\* The opinions in the paper do not necessarily reflect those of the organizations with which authors worked.

## **INDIA**

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### **Introduction**

It is the expectation that Genetically Modified Organisms (GMOs) are going to play an important role in the economic uplifting of India in its various facets of applications including human and animal health care systems, agriculture, industrial products and environment management. Concurrently it is also realized that there could be unintended hazards and risks from the use of GMOs and products thereof, if the new technology is not properly assessed before use.

A gene construct comprising a host compatible promoter, a gene of interest and a terminator sequence or a polyadenylation sequence is integrated in a stable manner into the genome of the organism/cell line of the target gene to be expressed and stably inherited. A genetically modified (GM) organism can be safe but can be unsafe too. This depends upon the trans-genes, the host organism and the environment where the GMO is being tested. In case of GM plants, in laboratory experiments, viral disease resistant transgenic plants have given rise to newer viruses by recombination. Transgenic rape seed plants containing bar genes transferred the transgenic trait to near relatives of Brassica spp. Insect resistant Bt plants coding for specific Bt proteins developed bt protein resistant insects in laboratory experiments. Transgenic soybean genetically modified to increase its sulfur containing amino acids by incorporating Brazillian nut 2S gene was allergenic to serum of people who were allergenic to Brazillian nut 2S protein. Potatoes genetically modified with specific lectin genes were protected from insect attack but such potatoes were not safe to rodents that were fed with such potatoes. The transgenic pollens of corn coding for Bt proteins killed the monarch butterfly larvae when they were forcibly fed with such pollens. It is expected that transgenic pollens coding for Bt proteins would affect the silkworm larvae, as these are insects that are susceptible to Bt proteins. There are examples of microorganisms, especially genetically modified viruses that turned virulent after modification. The longevity of GM fish was found to be shortened, compared to the non-transgenic controls. Consequently, a case-by-case analysis of the safety of each GMO needs to be conducted to assess environmental safety as well as safety to human and animals. Keeping these in view, the Indian Government had issued Rules and procedures (Rules) for handling GMOs and hazardous organisms through a Gazettee Notification G.S.R. 1037(E) dated 5.12.1989 from the Union Ministry of Environment and Forests. The Rules cover

all kinds of GMOs and products thereof, which are controlled commodities for handling and use in the country under the Environment (Protection) Act (EPA).

Indian EPA Rules define Competent Authorities and compositions of such Authorities the landing of all aspects of GMOs and products thereof. The GMOs include microorganisms plants and animals. Presently, there are six competent authorities as stated below, indicating their broad responsibilities and authorities too:

#### **The Recombinant DNA Advisory Committee (RDAC)**

This RDAC, constituted by the Department of Biotechnology of the Union Ministry of Science & Technology, is to monitor the developments in biotechnology at National and International levels. The RDAC submits recommendations from time to time that are suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This Committee prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990, which was adopted by the Government for conducting research and handling of GMOs in India.<sup>2</sup>

#### **The Review Committee on Genetic Manipulation (RCGM)**

The RCGM, constituted by the Department of Biotechnology, is to monitor the safety aspects of ongoing research projects and activities involving genetically engineered organisms. The Committee is also mandated to bring out Manuals containing Guidelines specifying procedures for regulatory processes with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensuring environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed by the RCGM, which can lay down procedures restricting or prohibiting production, sale, importation and use of GMOs.

RCGM can approve applications for generating research information on transgenic microorganisms.

The growth of microorganisms under sterile conditons in a submerged fermentation vessel can be carried out in large bioreactors. However, RCGM can approve experiments in bioreactors having geometric volume of up to 20 liters. All experiments for the use of larger bioreactors require the approval of the Genetic Engineering Approval Committee (GEAC). RCGM applies the condition of contained use of the bioreactors in order to prevent the escape of genetically modified microorganisms into the open environment.

The procedures for safe handling of microorganisms have been stated in the Recombinant DNA safety Guidelines - 1990.

RCGM can also approve applications for generating research information on transgenic plants. Such information is generated, under authorization of RCGM, in contained green houses as well as in small plots. Small experimental field trials are limited to a total area of 20 acres in multi-locations in one crop season. In one location where the experiment is conducted with transgenic plants, the land used cannot be more than 1 acre. The design of the trial experiments requires the approval of the RCGM. The design of the experimental plot in an open environment is made to seek answers to relevant and necessary questions on environmental hazards including risks to animal and human health. Data are required to be generated on economic advantage of the transgenics over the existing non-transgenic cultivars. RCGM can also direct the generation of toxicity, allergenicity and any other relevant data on transgenic materials in appropriate systems including animal models.

For generating research information on transgenic animals, RCGM can authorize the investigator to conduct experiments in the lab as well as in contained and enclosed conditions so as to prevent the escape of the transgenic animals into the open environment. The experiments are designed to generate information about the growth characteristics and the health conditions of the transgenic animals, using the non-transgenic animals as controls.

The RCGM can issue clearances for import/export of etiologic agents and vectors required for producing genetically modified microorganisms, plants and animals. Clearances for import/export are also provided for transgenic microorganisms, transgenic germplasms including transformed calli, seeds, plants and plant parts, as well as transgenic animals of various kinds for research use only. As elaborated in the guidelines, all experiments using GMOs which belong to risk category-III and above require authorization (permit) to be issued by the Department of Biotechnology for conducting such experiments. All such permits are issued on the basis of the recommendations of the RCGM.

According to the Indian classification of risks, Category-I risks involves routine recombinant DNA experiments in the lab and work involving defined genes/DNA of microbial, plants or animal origin, which are generally considered as safe. Category-II risks involve lab and contained greenhouse experiments involving genes or DNA of microbial, plant or animal origin, which are non-pathogenic to human, but can have implications on plants and insects. Fermentation experiments with GMOs conducted in fermentation vessels of up to 20 litre geometric volume can be Category-II risk experiments, if the

transgenic microorganisms or cell lines used are harmless and non-pathogenic. Such experiments can also belong to Category-III risks, if the GMOs are coding for toxins or are infective to humans and animals. Other Category-III risk experiments involve genes/DNA of microbial, plant or animal origin, which can cause alterations in the biosphere and do not fall in Category-I & II. All open field experiments of GMOs however organized, are considered to belong to Category-III risks although they may be carried out under reasonably contained conditions by taking all the precautions to prevent the escape of GMOs or parts thereof that have propagating traits into the uncontrolled open environment.

The RCGM can put in place conditions in order to generate long-term environmental safety data from the applicants seeking the release of transgenic microorganisms, plants and animals into the open environment. RCGM can also setup expert committees to monitor the research experiments. For monitoring contained field experiments with GM plants, the RCGM has setup a Monitoring cum-Evaluation Committee (MEC) with many agricultural experts as its members. MEC makes on the spot visits to the experimental sites and advises the RCGM about the steps to be followed in conducting the experiments for assessing agronomic benefit, in addition to conducting environmental risk assessments.

The RCGM revised the 1990 Guidelines for conducting research using GMOs in May, 1994 Ref 3 and subsequently in August, 1998 (incorporating further amendments in September 1999) Ref 4. The present guidelines have emphasis on genetically modified microorganisms and plants. The latest guidelines capture detailed procedures for conducting contained field experiments using GM plants. They also provide guidance for generating food safety data for transgenic plants or plant parts or seeds set in the plants into the open environment and are also designed to create a reasonably effective barrier to prevent the escape of the transgenic pollen into the open environment.

### **Institutional Biosafety Committee (IBSC)**

This Committee is constituted by organizations involved in research with GMOs. The Committee requires the approval of the Department of Biotechnology. IBSC also has a nominee from the Department of Biotechnology who oversees the activities to ensure the safety aspects in accordance with the safety guidelines are fully adhered to by the organization. Every R&D project using GMOs has to have an identified investigator who is required to inform the IBSC about the status and results of the experiments being conducted. Experiments belonging to Category I and II risks as well as all experiments conducted with GMOs in the contained lab, contained green house conditions for plants as well as contained



lab, caged or enclosed conditions for animals can approved by the IBSC; however, the synopsis of all such experiments is required to be reported to the RCGM in the Department of Biotechnology in the form of reports from time to time in a prescribed format. Such information along with the progress of research work is also required to be reported to the RCGM as a mandate at least one in six months. All IBSC meetings are to be held at the premises of the R&D setup of the organization so that the representative of the DBT who oversees the activities can visit the premises of the experiments area and check the records along with other members of the IBSC to ensure that all work is being carried out in accordance with the Biosafety guidelines of the RCGM.

#### **Genetic Engineering Approval Committee (GEAC)**

This committee functions as a body in the Ministry of Environment & Forests and is responsible for approval of activities involving large-scale use of GMOs in research, industrial production and applications. The clearance of GEAC is only from environmental angle under the EPA. All other relevant laws would apply even though EPA clearance is available for using GMOs and products thereof; for example, drugs made through GMOs would require separate approval for manufacture and use under the Indian Drugs Act; production of GMOs is also authorized under Indian Industries (Development & Regulation) Act, and therefore these clearances are also mandatory.

Large-scale experiments beyond the limits specified within the authority of RCGM are authorized by GEAC only. The GEAC can authorize approvals and prohibitions of any GMOs for import, transport, manufacture, processing, use or sale under Rule 7,8,9,10 & 11. All such authorizations are usually conditional, and Rule 13 guides such conditions.

#### **State Biotechnology Coordination Committee (SBCC)**

This Committee, headed by the Chief Secretary of the State is constituted in each Indian state where research and applications of GMOs are contemplated. The Committee has the powers to inspect, investigate and take punitive actions in case violations of the statutory provisions. The Committee coordinates the activities related to GMOs in the State with the Central Ministries. This Committee also nominates State Government representatives in the activities requiring field inspection of activities concerning GMOs.

### **District Level Committee (DLC)**

This Committee constituted at the district level is considered to be the smallest authoritative unit to monitor the safety regulations in installations engaged in the use of GMOs in research and applications. The District Collector heads the Committee who can induct representatives from State agencies to enable the smooth functioning and inspection of the installations with a view to ensure the implementation of safety guidelines while handling GMOs, under the Indian EPA.

### **Some Relevant Para of Rules 1989 on GMOs**

There are 20 para in the Rules 1989. Different aspect of the Rules. Each para can also be designated by suffixing the number of the para and by prefixing the word Rule for identifying them.

*Para 7* (can also be called as Rule 7 as explained above) of the Rules deal with approval etc. by individuals on the import, export, transport, manufacture, process, use or sell of GMOs. This para deal with use of GMOs for the purpose of researches in laboratories that are notified by the Ministry of Environment & Forests. Further, it directs that the GEAC authorize individuals and laboratories to take proper measures for the handling or discharge of GMOs in the open environment. Use of GMOs in large plants as well as in pilot plants requires a license from the GEAC. Certain experiments of lower risk could be carried out with the approval of the IBSC. This para does not specifically state what steps are to be taken for experiments conducted in the small scale under fully contained conditions. Indeed, the powers of the GEAC as embodied in para 4(4) talk about authorization of GEAC for activities involving large-scale use of GMOs in research and industrial production. There is clear cut indication of how contained small-scale research of GMIS is to be dealt with. On interpretation it appears that this is within the purview of the RCGM as per Rule 4 (2). Realizing this situation, internal working arrangements have been made to allow RCGM to handle contained small-scale research using GMOs, and these have been reflected in the latest Biosafety guidelines.

*Para 8* deals with production of GMOs where authorization for production is to be obtained from the GEAC GM microorganisms, plants and animals require authorization for commercial use in accordance with this para.

*Para 9* deals with deliberate or unintentional release of GMOs into the open environment. For this purpose all situations of use are to be authorized by the GEAC.

*Para 10* and 11 deal with approval for substances, which may contain GMOs. The use of such substances in commercial arena requires authorization from GEAC.

*Para 12* deals with procedures for applicants for obtaining approval for use of GMOs under different conditions. The applicants are required to make an application in a prescribed format.

*Para 13* deals with conditions of approval of GMOs for commercial use. It can be seen from the recital of para 13 that Government applies a precautionary principle while granting permission for marketing any GMO or products thereof. All commercial authorization is for a limited period, which requires renewal after the expiry period. Further, approvals are also given with conditions of observing and collecting information from the country on the risks if any, arising from the commercial use of GMOs and products thereof.

*Para 14* deals with a mechanism for supervising the implementation of the terms and condition under which approvals for the marketing and commercial use of GMOs and products thereof are authorized.

*Para 15* deals with penalties that can be levied/imposed on persons/institutions/companies who are responsible for non-compliance of measures required to be taken for the safe use of GMOs and products thereof.

## **Indian scenario on transgenic research**

### **Microorganisms**

Efforts are being made to construct transgenic micro organisms that code for bio active therapeutic proteins. Transformed E.Coli coding for several recombinant proteins such as interferons, interleukins, human growth hormone, bovine growth hormone, granulocyte colony stimulating factors, human pro-insulin, human epidermal growth factor, streptokinase, recombinant hepatitis B Vaccine etc. are being experimented upon in different laboratories in the country. Recombinant yeast species of *Saccharomyces cerevisiae*, *Pichia pastoris*, *Hansenula polymorpha* etc. have been modified to code for specific therapeutic proteins. Hepatitis B surface antigen gene has been coded in these yeast and the antigen has been isolated and formulated into dosage form for use as vaccines to protect human against Hepatitis B. Such vaccines have been commercially made in this country. These products have been tested for safety under the Indian EPA and these have been found to be safe. Genetically modified cholera microorganism is being evaluated for its safety as well as efficacy; a non-virulent

strain of *Vibrio cholera* was isolated from natural sources and an immunogenic gene was incorporated into to make the strain responsible for eliciting immunogenic response. Responders producing antibodies to it are expected to be protected from the disease. Genetically modified fungi belonging to *Aspergillus* spp are being experimented upon for the production of value added enzymes. All such microorganisms are also tested for environmental safety (in case of accidental release in to the open environment) as well as for human safety under the Indian EPA.

## Plants

The first transgenic plant experiment in the field was started in 1995 when *Brassica juncea* plants containing Bar gene regulated with plant specific constitutive promoters and linked with Barnase & Barstar genes regulated with floral tissue specific promoters were planted at Gurgaon (Haryana), India, under contained conditions. These studies were conducted to assess the extent of pollen escape. Subsequently, several experiments have been started in the field in different locations using transgenic plants, which are ready for green house/poly-house evaluation and some are ready for field evaluation as well. Table 1 below gives a list of major Indian developments up to the present time in transgenic plants.

**Table 1: Developments in India in transgenic research and applications**

| Institute                                       | Plants/crops used for transformation | Transgenes inserted                           | Aim of the project and progress made   |
|---|--------------------------------------|---|--|
| Central Tobacco Research Institute, Rajahmundry | Tobacco                              | Bt toxin gene Cry 1A(b) and Cry1C             | To generate plants resistant to <i>H.armigera</i> and <i>S.litura</i> . One round contained field trial completed Further evaluation under progress. |
| Bose Institute, Calcutta                        | Rice                                 | Bt toxin genes                                | To generate plant resistant to lepidopteran pests. Ready for undertaking Green House testing.  |
| Tamilnadu Agricultural Univ., Coimbatore        | Rice                                 | Reporter genes like hph or gus A and GNA gene | To study extent of transformation in the green house.  |

(Contd....)

|  |                       |  |   |
|--|-----------------------|--|---|
| Delhi University,<br>South Campus,<br>New Delhi                          | Mustard/ rape<br>seed | Bar, Barnase,<br>Barstar Marker<br>gene remover<br>(cre-lox)   | Plant transformations<br>completed and ready for<br>green house experiments.<br>Plants with marker genes<br>made.   |
|  | Rice                  | Selectable marker<br>genes (hygromycin<br>resistance and gus).<br>Abiotic stress<br>tolerant genes<br>(codA,dor47,<br>hsp1). | Transformation completed<br>with marker   |
|  | Cotton                | Cry 1 A (c) gene   | Transformation completed  |
|  | Wheat                 | Abiotic stress<br>tolerant gene<br>(hva 1)   | Transformation completed  |
|  |                       | Insect resistance<br>(Pin 11)  | Transformation completed  |
|  | Brinjal               | Abiotic stress<br>tolerant genes<br>(adc, mtl D, imt I)  | Transformation completed  |
|  |                       | Fungal resistance<br>(glucanase)   | Transformation completed  |
|  | Tomato                | CTX-B  | Transformation completed  |
| Indian<br>Agricultural<br>Research Institute<br>sub station,<br>Shillong | Rice                  | Bt toxin gene  | To impart lepidoteran<br>resistance, transformations<br>in progress   |
| Central Potato<br>Research Institute,<br>Simla                           | Potato                | Bt toxin Gene  | To generate plants<br>resistant to lepidopteran<br>pests. Ready to undertake<br>contained field trials.   |
| M/s Proagro PGS<br>(India) Ltd, Delhi                                    | Brassica/<br>Mustard  | Barstar, Barnase,<br>Bar   | To develop better hybrid<br>cultivars suitable for local<br>conditions; over 15 locatins<br>contained field trails<br>completd by the end of 2000-<br>2001 period. Further<br>contained open field research<br>trials in completed at 50<br>locations during 2001-2002.<br>Results awaited. |

|                    |             |  |   |
|--------------------|-------------|--|---|
|                    | Tomato      | Cry1 A(b)                              | To develop plants resistant to lepidopteran pests; glass house experiments and one season contained field experiment completed. Further experiments suspended temporarily.  |
|                    | Brinjal     | Cry 1 A(b)                             | To develop plants resistant to lepidopteran pests; glass house experiments completed.   |
|                    | Cauliflower | Barnase, Barstar and Bar               | To develop hybrid cultivars for local use; glass house experiments completed.   |
|                    | Cauliflower | Cry1H/Cry 9C                           | To develop resistance to pests; experiments kept in abeyance.   |
|                    | Cabbage     | Cry1H/Cry 9C                           | To develop resistance to pests; experiments kept in abeyance.   |
| M/s MAHYCO, Mumbai | Cotton      | Cry 1 Ac                               | To develop resistance against lepidopteran pests; Multi-centric field trials in over 51 locations completed by the end of 2000-2001. During 2001-2002 more than 400 locations large scale trials were conducted. Based on the results of large scale field trials, company was permitted to introduce Bt-Cotton in India under certain conditions in 2002.. |
|                    | Cotton      | Cry X (Fusion of Cry 1 Ac and Cry 1Ab) | To develop long term resistance against lepidopteran pests; limited field trials in 3 locations completed.  |

(Contd....)

|                                  |             |  |   |
|----------------------------------|-------------|--|---|
|                                  | Cotton      | Herbicide resistant (Roundup ready gene)   | To develop herbicide resistant cotton, limited field trials in 2 locations completed.   |
|                                  | Brinjal     | Cry 1 Ac   | To develop resistance against lepidopteran pests; green house studies completed.  |
| M/s Rallis India Ltd., Bangalore | Chilli      | Snowdrop (Galanthus nivalis) Lectin gene   | Resistance against lepidopteran, coleopteran & homopteran pests, transformation experiments in progress                                   |
|                                  | Bell Pepper | Snowdrop (Galanthus nivalis) Lectin gene   | Resistance against lepidopteran, coleopteran & homopteran pests, transformation experiments in progress                                   |
|                                  | Tomato      | Snowdrop (Galanthus nivalis) Lectin gene   | Resistance against lepidopteran, coleopteran & homopteran pests, transformation experiments in progress                                   |
| Jawaharlal Nehru                 | Potato      | Gene expressing for seed protein containing lysine obtained from seeds of Amaranthus plants (Ama-1 gene) | Transformation completed and transgenic potato under evaluation in the contained open environment.  |
|                                  | Tomato      | Oxalate Decorboxylase gene   | Transformation completed and transgenic tomato under evaluation in the contained open environment to assess reduction in oxalate content. |

(Contd....)

|   |            |   |  |
|---|------------|---|--|
| Indo American Hybrid Seeds, Bangalore   | Tomato     | Leaf curl virus protein genes, chitinase and alfalfa gluconase gene and combinations  | Transformation completed, green house tests completed and ready for contained open filed experiments.                              |
| International Crops Research Institute for the Semi-Aried Tropics (ICRISTAT), Hyderabad | Ground Nut | Viral resistant replicase genes of Indian peanut clump virus (IPCVcp; IPCV replicase) | Fore resistance against IPCV infection. Transformation completed, Green House studies completed and to initiate open field trials. |

### **Animals**

Work on transgenic animals carried out in India is yet at rudimentary stage. Lab experiments have been conducted to produce transgenic mice containing growth hormone genes. Certain marker genes have also been utilized. Introducing genes that code for substances that produce luminescence, produced glowing slikworms; this work only reinstated that these organisms are amenable to the strategy of genetic manipulation. Efforts have also been made to produce transgenic catfish, tilapia and Indian carps containing growth hormone genes; the objectives were to obtain transformants that mature fast. However, these experiments have not provided any significant success, and none of these works has yet come to the stage of large-scale trials.

### **Conditions for trials using Transgenic Organisms**

The RCGM monitors research on transgenic organisms in the laboratory and in the contained open environment/fields. For transgenic plants, experiments are conducted in contained green house to generate several vital safety information before decisions are taken to conduct contained open field experiments. In the field under contained conditions besides designing experiments for collecting data on environmental safety aspects, the agronomic advantages of the transgenic plants in small plots are also assessed. The RCGM looks for information on environmental safety including human and animal food safety issues for all kinds of GMOs. Food safety issues are linked with GMOs that may enter into human or animal food chain directly. The information sought from the trials of GMOs is summarized briefly in Table-2



**Table 2****Summary of the Biosafety information sought from GMO trials**

| <b>Particulars</b>   | <b>Information Sought</b>   |
|--|---|
| Rationale for the development  | Economic agronomic and other benefits, and nationale of development   |
| Details of the molecular biology of GMOs<br>(Microorganisms, plants and animals)         | <ul style="list-style-type: none"><li>● Description of the host organisms (microorganisms, cell lines, plants, animals etc)</li><li>● Source and sequence of transgene</li><li>● Sequential block diagram of all trans-nuclear acid stretches inserted</li><li>● Cloning strategy</li><li>● Characteristics of inserted genes with details of sequences</li><li>● Characteristics of promoters</li><li>● Genetic analysis including copy number of inserts, stability, level of expression of transgenes, biochemistry of expressed gene products etc.</li><li>● Transformation/cloning methods and propagation strategy.</li></ul> |
| Laboratory, Green House Trials (for plants) and contained enclosure trials (for animals) | <ul style="list-style-type: none"><li>● Back-crossing methods for plants</li><li>● Seed setting charateristics of plants</li><li>● Germination rates of seeds</li><li>● Phenotypic characteristics of transgenics</li><li>● Organisms challenge tests where ever applicable</li><li>● Effects of chemical herbicies for all herbicide resistant plants</li><li>● Growth characteristics and general health of animals, measured through specific scientific parameters</li><li>● Toxicity and allergenicity implications to human if any during handling of GMOs.</li></ul>   |
| Field trials in open environment   | <ul style="list-style-type: none"><li>● For GM Plants, comparison of germination rates and phenotypic characteristics, using non-transgenic s controls.</li><li>● Study of gene flow of plants</li><li>● Possibility of weed formation for GM plants</li><li>● Invasiveness studies of plants and animals compared to non-transgenics used as controls</li></ul>  |

|  |   |
|--|---|
|  | <ul style="list-style-type: none"> <li>● Possibility of transfer of transgenes to near relatives through out crossing./cross-fertilization</li> <li>● Implications of out crossing/cross-fertilization</li> <li>● Comparative evaluation of susceptibility to diseases and pests for plants and animals</li> <li>● For human food/animal feed, elaborate determination of composition and assessment of quality of transformed plants/fruits/seeds as well as animals as the case may be, with appropriate controls. Compositional analysis shall include near equivalence studies of all the major ingredients in GMOs so as to assess substantial equivalence with reference to non-transgenics. Change in the levels of allergenes, toxicants if any, beyond acceptable limits is a matter of food safety concern and such substances are unsuitable for commercial release.</li> <li>● Toxicity and allergenicity implications of transformed GMOs. This includes micoorganisms, plants/fruits/seeds as well as animals, lab animal studies for food/feed safety evaluation is a requisite.</li> <li>● Handling procedures for allergenic substances</li> <li>● Agronomic evaluation for GM Plants</li> <li>● Economic evaluation for GM animals</li> </ul> |
|--|---|

The genetic materials can be allowed to be imported or transferred within the country by the RCGM for research use only, based on applications submitted through the IBSC.

For conducting experiments with transgenic plants contained Green House, designs have been worked out for constructing low cost but substantially contained environment where temperature, light and humidity can be controlled to a considerable extent. Nets have been recommended that arrest the entry/exit of insects below 0.6-mm diameter. Although similar contained conditions for conducting experiments with transgenic animals have yet been published, designs are available and can sent to the investigators on request.

#### **Issues in transgenic plant experiments and methods for proceeding step by step**

The issues that are taken into consideration before authorizing field trials under contained conditions using GM plants include the potential of the transgenic plants for dissemination into the open environment such as through cross

pollination, the dispersal mechanism of the pollens as well as the seeds, the presence of wild members of the species in the eco-system and the presence of other non-transgenic planting materials in the vicinity. While designing field experiments efforts are made to maintain appropriate reproductive isolation so as to prevent the likelihood of seed setting outside the experimental plot. The transgenic plants are isolated from the gene pool represented by sexually compatible plants to prevent the escape of transgenes. Conditions are also introduced in certain cases to prevent flowering of plants. It is ensured that the genes or the genetically modified plants are not released into the environment beyond the experimental sites. Only such plants are taken into the open environment for experimentation, which have the minimum chance of unintended and uncontrolled adverse effects. The time of sowing, flowering and planting are also taken note of. Only those plants have been used in Indian trials for open field experiments under contained conditions, where the transgenes are considered to be safe or where the pollens are linked with imparting male sterility properties. Experiments have also been designed to study the potential for gene transfer and the consequence of transferring transgenic properties to weeds or other near relatives. The probability of pollen transfer and the natural mutation rate have been made conditions for computation in the experimental designs. The transgenic traits that have been looked at in such experiments in India include Bt-insect resistance, Bar resistance, Bar-bariness as well as Bar-barster systems, Bar-Bt systems, antibiotic resistance, altered nutritional properties and abiotic stress resistance properties.

As indicated earlier, data for submission by the applicants include mating systems in plants comparison of germination rate, invasiveness, toxicity and allergenicity or alterations in the anti-nutritional properties of the plants due to the transgenes including the marker genes etc. A detailed format for submitting information has been devised comprising nine chapters, and applicants are required to provide such information to the Government seeking permission for commercial release of target transgenic plants under Rules 7,8,9,10 or 11 of the above Notification.

A few experimental designs have been evolved and approved by the RCGM for trials using GM plants in the open environment. The designs are for studying pollen dispersal, the comparison of cross-ability of non-transgenic plants with the transgenics and evaluation of their comparative competitiveness or invasiveness potential in unmanaged and managed land. The experimental results from two studies have shown that pollen escape was a real phenomenon. The cross-ability studies conducted, for example on transgenic Indian mustard, has shown that there existed pre and post fertilization barriers and the results corroborated the classical literature, confirming that escape of transgenes from same crops like the Indian mustard crop was not favoured in nature. However,

viable F1 seeds could be produced by manual cross-pollination with related cultivated as well as wild species. This observation was consistent with similar studies made with *Brassica napus*. It was observed, while studying the Bt. Cotton plants that their pollen also traveled some distance with the help of insects. It can be stated from these observations that gene transfer shall be taking place in open environments when transgenic plants are cultivated. By appropriate management practices it might be possible to reduce the extent of pollen transfer into the open environment for all crops, but it cannot be fully contained. Therefore, the consequence of gene transfer is a real issue. The implications of this issue have not yet been satisfactorily resolved. A decision has to be taken by the Indian Government on this to decide to what extent transgene flow can be allowed and what are the consequential risks, taking also into consideration the agronomic benefits expected from the use of transgenic plants. In March, 2002, the Indian Government finalized its decision on the commercialisation of insect resistant Bt. Cotton containing *Cry I Ac* gene. Three cotton hybrids containing the gene were approved for commercial cultivation in India, subject to certain conditions. The conditions were worked out based on the experimental results of Bt.cotton, conducted in India. These have been discussed in detail later on.

In addition to these experiments, major chunks of data must be generated on food safety in accordance with the latest Indian guidelines. The information emphasizes quantitative production of transgenic proteins and their effects on as-is-where-is basis on experimental animals in the context of determining the toxicity allergenicity, and anti-nutritional properties etc.. The data generated in Indian experiments for Bt.cotton at the Industrial Toxicology Research Centre, Lucknow using goats as the ruminant model, and for transgenic Indian mustard assessed on rat, rabbit, guinea pig and hen model (at Shriram Industrial Research Centre, Delhi) as well as on goats model (at Fredrick Institute of Plant Protection and Toxicology, Tamilnadu) did not show any additional food safety risks.

The transgenic field experiments conducted in India have enabled the country to have hands on experience on several genetically modified plants. Most important among them are transgenic Bt cotton, Bar-Barnase and Bar-Barstar mustard and Bt tomato. Data generated in India has demonstrated substantial agronomic benefits from transgenic plants over the corresponding non-transgenic controls. Table 3 provides an overview of the initial findings on the performance of the GMO plants up to the period 2000-2001.

**Table 3**

| <b>Name of the plant</b>    | <b>Range of increase in productivity in % over controls</b> |
|-----------------------------|---|
| Bt Cotton                   | 23 to 60%: Average in 51 location study : nearly 40%        |
| Bar-Barnase-Barstar mustard | 5% to 43% Average in 15 location study : over 16%           |
| Bt tomato                   | About 300% : (one location study)                           |

In addition, experiments are also being conducted on insect resistant vegetables and crops such as brinjal, tobacco, potato etc., Several other plants such as rice, pigeon pea, soybean, Chiuli bell pepper and corn have been transformed with improved traits and these are soon likely to be experimented upon in open environmental conditions.

#### **Insect Resistant Bt-Cotton approved in India under conditions**

In April 2002, the Indian Government approved the commercial cultivation of three hybrids of Bt Cotton designated as Bt-MECH-12, 165 and 184 respectively for a period of three years initially under the following conditions.

1. Every field where Bt cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-Bt cotton hybrid shall be sown. The size of the refuge belt shall be such as to take at least five rows of non-Bt cotton or shall be 20% of the total sown areas whichever is more.
- ii. To facilitate this, each packet of seeds of the approved hybrids shall also contain a separate packet of seeds of the same non-Bt cotton hybrid, which is sufficient for planting in the refuge defined above.
- iii. Each packet shall be appropriately labeled indicating the contents and the description of the Bt hybrid including the names of the transgenes, the GEAC approval number physical and genetic purity of the seeds, the directions for use including sowing pattern, waste management methods, suitability of agro-climatic conditions etc., in vernacular language.
- iv. The company shall enter into agreements with its dealers/agents that will specify the requirement from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions wher Bt cotton is sown.
- v. The company shall prepare annual reports by 31st March each year on the use of Bt cotton hybrids by leaders, acreage, locality (state and region) and submit the information in electronic from the GEAC if asked for.

- vi. The company shall develop plants for Bt based integrated Pest Management and include this information in the seed packet.
- vii. The company shall monitor annually the susceptibility of bollworm to Bt gene vis-à-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC.
- viii. Monitoring of susceptibility of bollworm to the Bt gene will also be undertaken by an agency identified by the Ministry of Environment and Forests at the applicant's cost
- ix. The company shall undertake an awareness and education program, ineralia through development and distribution of educational material on Bt cotton for farmers, dealers and others.
- x. The company shall also continue to undertake studies on possbile impacts on non-target insects and crops, and report back to the GEAC annually.
- xi. The label on each packet of seeds, and the instruction manual inside each packet shall contain all the relevant information.
- xii. The company shall deposit 100g seed each of approved hybrids as well as their parental lines with National Bureau of Plant Genetic Resources (NBPGR).
- xiii. The company shall develop and deposit with the NBPGR the DNA fingerprints of the approved hybrids.
- xiv. The company shall also provide to the NBPGR the testing procedures for identifying transgenic traits in the approved hybrids by DNA and protein methods.
- xv. The period of validity of the approval is for three years from April 2002 to March 2004.

After receiving the approval, the company has taken steps to ensure that all the conditions stipulated by the government are fulfilled. In accordance with the above approval of the government, the company may, in the first year, i.e. 2002-3 period, start selling the seeds soon in the states of Maharashtra, Andhra Pradesh, Karnataka, Madhya Pradesh, Gujarat and Tamil Nadu. The seed delivery is expected from May 2002 onwards. The Bt MECH 162 is expected to be the most popular. The company is expected to provide detailed spraying instructions to manage the attachment of bollworm. For the spraying for control of bollworm, one spray will be applied if the number of larvae per plant exceeds one in a sample of 20 plants. Scouting would be required in the morning hours

at least twice a week in order to establish the number of bollworm present per plant. Concurrently, for the management of sucking pest such as whitefly, aphids, thrips, jassids and mites, the Economic Threshold Limits (ETL) are to be worked out during scouting. Earlier in a paper the details about the cotton pests were discussed by the author. The company will provide planting plans for the refuge in the leaflet/literature that will accompany the packet of seeds sold. All seeds would be sold through recognised sources. A package of practices to be followed by each farmer will be detailed in Vernacular languages. The distributor and the dealer of the company will be required to provide the details about the sale of seeds, the acreage cultivated and the regions/ states where Bt cotton is sown. The company will work with the Project Directorate for Biological Control (PDBC), Bangalore to conduct a baseline susceptibility study of bollworm to Br Cry 1 Ac gene every year and submit the data to the government. In order to undertake an awareness and education program, the company has appointed more than 500 persons including Field Executives, Field Assistants and dealers. It is anticipated that the company will then be adequately prepared to ensure that all the conditions will be satisfied. Concomitantly, the government infrastructure, as well as the intent to ensure the fulfillment of all these conditions may have to be further integrated involving the State Government officials as well as the institutions to the maximum extent.

## **Conclusions**

The Indian Government created the rules and procedures for dealing with GMOs in 1989 under the Indian EPA in August 1997, M/s Shantha Biotechnics, Hyderabad introduced genetically modified hepatitis B surface antigen protein, produced in recombinant *Pichia Pastoris*. They developed the product indigenously. Later on, after Shantha, three more companies have come into production of this vaccine. By 2002, three more recombinant products, namely Erythropoietin, Granulocyte colony stimulating factor and interferon alpha are being produced in India utilizing GMOs under contained conditions.

In GM plants, the first transgenic plant experiment in the field was started in 1995. Since then, the country has acquired substantial experience in understanding the issues related to the handling of GMOs. In April 2002, transgenic Bt cotton was approved for cultivation. The impact of the use of this planting material will be known within a couple of years. With regard to actual risks, there are issues on the flow of trans-genes into the open environment, which are indeed real. Transgenic traits would spread into the natural environment over the years. Such spread of traits has not yet been found to create environmental problems that cannot be contained. Hence for each case of

GM plants a decision has to be taken by the government for its release or otherwise based on the considerations of gene flow, the genetic bio-diversity, the presence of non transgenic near relatives of GM plants in the Indian environment, the potential environmental or other risks from the use of GM plants and the real agronomic benefits emanating from them.

Experiments in transgenic animals including fish are yet to reach the development stage and the country has to go a long way before such products are developed for commercial applications.

It can be seen from the above that India has developed a considerable experience in handling GMOs, which include microorganisms and plants. With time, as the scientific development takes place, the legal framework will also require changes concomitant with the assessment of risks and management thereof and emanating from the use of different kinds of GMOs and products thereof. Eventually, a case-by-case approach on a precautionary mode would be beneficial to society, to the regulators and to the scientific community at large.

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## **INDONESIA**

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### **Introduction**

The Indonesian archipelago, situated in the tropics with total land area of 1.919 million square kilometers and comprising 17508 islands, represents one of the megadiversity countries together with Brazil and Zaire. Indonesia is a party of the Convention of Biological Diversity as stated in Indonesian Law no 5/1994 for the ratification of UN Convention on Biological Diversity. Indonesia now is the world's fourth largest country in population and the value of agriculture as % of GDP is 13%. Agriculture plays a substantial role in Indonesian economy, involving more than 55% of the population, 19% of the gross domestic product (GDP) and more than 60% of the value of non-oil exports. Over the last two decades annual agricultural output has grown by 4%. Rice production accounts for more than 40% of agricultural output, land use and employment (Dart et al., 2002). Production increased from 12 million t in 1969 to 44 million t in 1991 then decreased to 39.9 million t in 2001 (Indonesian statistics) mainly due to the land conversion. A similarly dramatic increase occurred in livestock production including fish and eggs, from 2.2 million t in 1974 to 4.3 million t in 1987, a 52% increase.

As one of the mega biodiversity countries, Indonesia would like to utilize the diversity of our natural resources in a sustainable manner as one of the modalities and comparative advantages in the development of biotechnology. Indonesia has placed a high priority on the development of biotechnology since 1985 to address the need for sufficient food production in a more sustainable agricultural system. A national committee for biotechnology was established in the same year at the State Ministry for Science and Technology (Sasson, 1993) to prepare and formulate policies and programs for the national development for biotechnology. In order to implement the research priorities and policies, the State Ministry of Science and Technology has designated four national centers, which are the two centers of excellence for agriculture and two other centers for industrial and medical biotechnology.

The major players of agriculture related biotechnology research in Indonesia are research centers under the Ministry of Agriculture, non-ministerial governmental research organizations coordinated by the State Ministry of Research and Technology, and universities. Plant transformation programs are now being carried out at public and semi public research institutes, a public university and

an industrial laboratory. RCBt, RIFCB (Research Center for Food Crop Biotechnology-CRIFC, Bogor Agricultural University (BAU), are public research institutes or universities located in Bogor and have programs on plant transformation. The two semi public research institutes working in this area are BRUEC (Biotechnology Unit for Estate Crops) also located in Bogor and ISRI (Indonesian Sugar Research Institute) located in Pasuruan, East Java. Appendix 2 shows an overview of the research status of the transformation program in Indonesia. The only industrial research institute carrying out research in this aspect is the Indah Kiat research center in Pekanbaru-Riau which focuses on forestry plants (Slamet-Loedin et al., 2000). Animal transformation project has been initiated this year in RCBt-LIPI.

After the economic crisis in 1998, the focus of biotechnology research has been redirected to immediate application of existing biotechnology techniques for product(s) manufacture aimed to respond to the needs of the people, especially in food production, production of traditional medicine and adding value to agricultural products for export production as the first priority. As a long term priority, strategic research and capacity building were aimed at responding to the rapid global development of biotechnology to improve national capabilities in this field.

Immediate application of existing technology in agricultural biotechnology was elucidated as the application of cattle embryo transfer to increase and improve cattle populations in response to the demand for meat and milk, improvement of the production of staple foods including rice and soybean, production of raw material for drug and traditional medicine, embryo transfer and diagnostics kits for animal diseases, biofertilizer and biopesticides.

Strategic research is aimed at achieving a competitive position for Indonesia in the global market. Strategic research programs should be based on the competitive advantages of the country in biological diversity. Drug discovery projects, genomics, conservation of germ plasm, genetic improvement of agriculture commodities (food crops, horticulture, fruits, animal husbandry etc.), marine biotechnology and environmental biotechnology (bio-remediation) are projects planned to be undertaken in this field.

### **Biosafety Status and National Biosafety Framework**

Indonesia has signed and is a member of Cartagena protocol. The focal point of the Protocol is the Ministry of Environment, while Competent National authorities are the Department of Agriculture and Food and Drug Agency. The Indonesian Institute of Sciences was assigned as the focal point for Biosafety Clearing House. Indonesia is the first country in Southeast Asia to venture into the environmental release of a genetically engineered crop, that is the Monsanto Bt cotton, after having done the risk assessment in the form of glass house trial, limited field release and multi location trials prior to release. The release was limited for one year for seven districts in South Sulawesi and has been extended for the second year based on the results of environmental risk analysis in the field.

In August 1993, the State Ministry on research and Technology released a guideline on genetic engineering research. The emphasis of this guideline is for the control of research of genetically modified organisms. Indonesian biosafety regulations for release of GMO were put in place in 1997. The Minister of Agriculture released a Ministerial Decree for Genetically Engineered Agricultural Biotechnology Product in 1997. To implement the decree, a Biosafety Commission was formed in 1997 with a mandate to advise the government on the safe release of agricultural biotechnology products for human health and/or environment. A biosafety technical team, consisting of experts in agricultural biotechnology and representing different national institutes and universities, was formed to assist the commission to evaluate the application and carry out technical studies and tests of the genetically engineered biotechnology product in a biosafety containment or confined field. This technical team formulated a series of guidelines for release of genetically engineered organism. The guidelines include general guidelines for plant, cattle, fish and microbes and specific guidelines for each item.

The 1997 decree did not cover food safety. To fulfill this need, another decree was released in 1999 as a collective decree of four ministries (Ministry of Agriculture, Ministry of Estate crop and forestry, Ministry of Food, Ministry of Health) for biosafety and food safety of Genetically Engineered Agricultural Biotechnology Product (Herman, 2000). The committee members and technical team members were also expanded representing different parties. The guidelines of food safety of GMO products have been drafted. After applications are reviewed and accepted by the National Biosafety Committee for contained and limited field trial and pass the biosafety status then they have to go to the Plant Variety Release Committee for multi location field trials with monitoring by the Biosafety Committee.

At present the government is preparing an improved national biosafety framework in the form of presidential decree or law. According to the food safety law (UU no.7, 1996) and the regulations, labeling of genetically engineered food has been mandatory since 1999, but due to several reasons it has not been implemented yet.

Indonesia has commercially released Bt cotton from Monsanto, although this has been limited to certain areas in southern Sulawesi for the second period of one year. The second year extension was given based on the results of an environmental risk analysis including a study on non-target insects, impacts to soil microbes and gene flow. Several applications have been reviewed by the technical team and the Biosafety Commission. These include the Monsanto Roundup ready soybean, Roundup ready and Bt cotton, Roundup ready and Bt Corn, and Pioneer Bt. Confined field trials have been done for the transgenic RR and Bt cotton, RR soybean and RR and Bt corn from Monsanto.

### **National Agricultural Research System/Institutes**

Agricultural biotechnology research and development in Indonesia are largely financed and undertaken by the public sector. The Ministry of Agriculture, State Ministry of Research and Technology, non-ministerial government organizations and universities are the major actors in agricultural research.

The Ministry of Agriculture has several research institutions involved in research and development under its Agency for Agricultural Research and Development (AARD). There are at least 8 research institutes under AARD related to biotechnology. Those are the Central Research Institute for plantation (estate) Crops, Bogor and Marihat Medan, Central Research Institute Industrial Crops, Bogor, Indonesian Sugar Research Institute, Pasuruan, Research Institute for Animal Production, Ciawi, Bogor, Research Institute for Animal Diseases (Balitvet), Bogor, Central Research Institute for Freshwater Fisheries, Jakarta (Gumbira Said, 2001).

In 1985 the state Minister of research and technology designated four national centers of excellence for agricultural, industrial and medical biotechnology. The centers of excellence on Agricultural Biotechnology I and II are the Central Research Institute for Food Crop Biotechnology-AARD and Research Center for Biotechnology-Indonesian Institute of Sciences/ of LIPI (formerly R&D Center for Biotechnology) and both are located in Bogor. The other centers of excellence are the Medical faculty, University of Indonesia in Jakarta and Eijkmann Institute for medical biotechnology in Jakarta and Agency for Technology Assessment and Application (BPPT) for industrial biotechnology in Jakarta. The later one also

conducts activities related to agriculture biotechnology. The Indonesian Institute of Sciences and the Agency for Technology Assessment and Application (BPPT) are both non-ministerial government bodies responsible to the Head of Government, but their activities are coordinated by the Ministry of Science and Technology.

In addition, the government of Indonesia established Inter University Centers in Bogor Agricultural University, Bandung Institute of Technology and Gajah Mada University in Jogjakarta focusing on agricultural biotechnology, industrial and medical biotechnology respectively. These centers are attached to the universities as part of university network for the development of education. At present however, they have become research centers under different names and they also play an important role in the development of agricultural biotechnology in Indonesia in their respective area. The Department of Forestry also has research centers working in forest biotechnology.

The funding for research comes from internal and external resources. The government has launched several funding schemes, such as the Integrated Supreme Research (RUT) grant program in 1992, Joint Supreme Research (RUK), Competitive grant for universities (Hibah bersaing) and the International integrated competitive joint research (RUTI) in 2002, to accelerate the development of biotechnology. The priorities of research are formulated by the National Research Council, while the selection of the proposals are conducted by a panel experts set by NRC and universities in the case of competitive grant. The panel of experts will advice the National Planning Board and Ministry of Finance to fund recommended proposals. External Funding such as funding from Agricultural Research Management/ ARM (World Bank Loan), USAID, The Rockefeller Foundation, Winrock International, ACIAR, INCO-European projects, Japan International Cooperation Agency have played an important role in the development of agricultural research, although mainly in the initial development of biotechnology such as building infra-structure and man power development.

### **Capacity development**

From 1989-1997, the number of researcher has almost tripled, with MSc and BSc holders increasing from 75 to 247, while the number of researchers holding a PhD degree doubled from 50 to 102 (Falconi, 1999) and has further increased. However, researchers in the field of plant molecular biology are still scattered in different institutions. This group of professionals has become the basis for the development of agriculture biotechnology advances in the future, and 96% of

them are working in the public sector. About 60% of the researchers are located in three research organizations, which belong to the public sector: RIFCB, RCB-IIS.

The details capacity related to biosafety is summarized in Table 1.

**Table 1 Capacities in Indonesia in Biosafety**

|                     | <b>Existing Capacities</b>   | <b>Capacities needed</b>  |
|---------------------|--|---|
| Risk Assessment*    | <ul style="list-style-type: none"> <li>● Capacity to analyze application data related to molecular biology, entomology and breeding are available, but knowledge can be improved.</li> <li>● The expertise is stronger in plant science compared with animal science.</li> <li>● Capacity for food safety assessment are not sufficient</li> </ul> | <ul style="list-style-type: none"> <li>● Ecologists aware of this topic and related aspects are needed.</li> <li>● Number of trained entomologist capable of handling this topic needs to be increased.</li> <li>● Information on risk assessment strategy in similar regions is required (not only summary of risk assessment as minimally required in the protocol)</li> <li>● Food safety assessment knowledge needs to be improved</li> </ul> |
| Risk Management     | <ul style="list-style-type: none"> <li>● Very little</li> </ul>  | <ul style="list-style-type: none"> <li>● Knowledge needs to be improved</li> <li>● Strategy needs to formulated</li> </ul>  |
| Legal issue         | <ul style="list-style-type: none"> <li>● Moderate</li> </ul>   | <ul style="list-style-type: none"> <li>● Knowledge improvement in liability issues is required</li> </ul>   |
| Communication issue | <ul style="list-style-type: none"> <li>● A small number of scientists deal with this matter</li> <li>● Information in the media is imbalanced between the pros and cons</li> </ul>   | <ul style="list-style-type: none"> <li>● Public awareness and risk communication techniques needs to be improved</li> <li>● Capacity to convey issues of risk management to the farmers is needed</li> </ul>  |

## **Capacity Building**

Man-power development to build a critical mass for different aspects of biotechnology and launching a more structured public awareness programs to increase public knowledge in risk and benefit of biotechnology, improvement of institutions and coordination framework and the creation of a conducive scientific environment have been recommended to improve and promote development of biotechnology in Indonesia in the 2001 draft for policy strategies. Promoting involvement of the private sector through development of industrial areas for biotechnology (bio-island concept), establishment of incubator technology and a special investment policy are also recommended.

Specific training in risk assessment and management for technical persons is required. General training has been carried out several times, but more is needed inspecific training in carrying out the risk assessment on several biosafety issues. Quarantine people need training to handle the importation of GMO.

Indonesia has already a legal framework for biosafety in the form of Ministrial decrees, but this needs to be improved to include participation of all stakeholders and to form more legally binding regulations in the form of law or at the least precedential decree. The proposal on development of the national biosafety framework has just been accepted by the UNEP-GEF project and will be implemented in the next 18 months. ICCP/COP-MOP can form complete guidelines for risk assessment and management and publish them as books.

## **Regional Cooperation mechanism and recommendations**

There are various areas where regional cooperation is needed. Among these areas or the topics where regional cooperation needs to be sthreinghened are the following:

- Sharing information for risk assessment in similar ecological regions would be very useful for countries to carry out their own risk assessment. This sharing of information can be done through the national biosafety clearing house.
- Disseminating information of biotechnology products and breakthroughs in research and development
- Regional effort on capacity building for risk assessment and management in specific topic of environmental and food safety issues in the form of training, modules and publications

- Regional effort on capacity building for data management and biosafety website development
- Regional effort on capacity building for developing a national biosafety framework
- Regional effort on capacity building for quarantine people
- Strategy formulation for risk management for specific GM crops
- Harmonization of the biosafety regulations in the form of dialogue at the policy level
- Public awareness approach to strengthen public confidence in biotechnology
- Cooperation in research and development in various areas of biotechnology, particularly genomics, transcriptomics and proteomics for global competitiveness.
- Cooperation in carrying out R&D related to environmental impact and food safety issues of genetically engineered agricultural products and foods.

At a national level, formulation of a balanced and legally binding national biosafety framework is very important. Capacity building for biotechnology in general and risk assessment and management issues is needed. Formulation of a national strategy on biotechnology is very important. Responsibilities at a national level include: human resource development to build a critical mass for different aspects of biotechnology and launching more structured public awareness programs to increase public knowledge in the risks and benefits of biotechnology; improvement of institutions and a coordination framework; creation of a conducive scientific environment.

At sub- regional and regional level a joint effort in capacity building in various aspects mentioned above can be conducted. Cooperation in R&D in various aspects of biotechnology including risk assessment and management strategies would be very beneficial. Development of the internet as a basis for information sharing inside the region regarding regulatory matters, risk assessment and analysis and research development would be needed. This would assist countries in the same regions to make decision on environmental release of GM organism and products and to counteract misinformation by providing scientifically based information and to assist country to develop assessment methods, detection methods and risk management and monitoring strategies.



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**Appendix 1. List of Agricultural Biotechnology Research Institutes in Indonesia**

| <b>Name, Address</b>  | <b>Status</b> | <b>Areas of Activity</b>   |
|---|---------------|--|
| Centre for the Assessment and Application and Agricultural Biotechnology-BPPT<br>BPP Teknologi Building 10th Floor<br>Jl.M.H.Thamrin 8<br>Jakarta Pusat,Indonesia | Public        | Agricultural Biotechnology<br>Animal Biotechnology<br>Forestry Biotechnology<br>Industrial Biotechnology |
| Research Institute for Food Crops Biotechnology<br>Jl. Tentara Pelajar 3A<br>Bogor 16111, Indonesia   | Public        | Agricultural Biotechnology   |
| Research Centre for Biotechnology Indonesian Institute of Sciences (RCBt) -LIPI<br>Jl. Raya Bogor Km 46<br>. Cibinong 16911.                                      | Public        | Agricultural Biotechnology<br>Animal Biotechnology<br>Forestry Biotechnology<br>Industrial Biotechnology |
| Research Institute for Animal Production<br>Balai Penelitian Ternak<br>P.O.Box 221  | Public        | Agricultural Biotechnology<br>Animal Biotechnology<br>Industrial Biotechnology<br>Bogor 16002, Indonesia |
| Research Institute for Veterinary Science<br>P.O.Box 52 Bogor 16114<br>Indonesia  | Public        | Veterinary Biotechnology<br>Jl. R.E. Martadinata 30  |
| Biotechnology Research Unit for Estate Crops<br>Jl. Taman Kencana No.1<br>Bogor 16151, Indonesia  | Public        | Agricultural Biotechnology   |
| Inter University Centre (IUC) on Biotechnology<br>Institut Teknologi Bandung<br>Jl. Ganesha 10<br>Bandung 40132, Indonesia  | Public        | Industrial Biotechnology   |

(contd....)

|  |                   |   |
|--|-------------------|---|
| Faculty of Animal Science<br>Diponegoro University<br>Jl. Hayam Wuruk 4-A<br>Semarang, Indonesia   | Public University | Animal Biotechnology  |
| Laboratory of Biotechnology<br>Department of Biotechnology<br>Faculty of Science and Mathematics<br>Diponegoro University<br>Faculty of Science and Mathematics<br>University of Diponegoro<br>Tembalang Campus<br>Semarang, Indonesia | Public University | Agricultural Biotechnology<br>Industrial Biotechnology  |
| Faculty of Agriculture<br>Sebelas Maret University<br>Jl. Ir. Sutami no. 36A<br>Ketingan, Surakarta, Indonesia   | Public University | Agricultural Biotechnology  |
| Faculty of Biotechnology<br>Jendral Soedirman University<br>P.O.Box 30<br>Purwokerto, Indonesia  | Public University | Industrial Biotechnology  |
| Faculty of Agriculture<br>Gajah Mada University<br>Sekip Unit I, P.O.Box I<br>Yogyakarta 55281, Indonesia  | Public University | Agricultural Biotechnology  |
| Faculty of Biology<br>Gajah Mada University<br>Jl. Teknik Selatan,<br>Bulak Sumur,<br>Yogyakarta, Indonesia  | Public University | Agricultural Biotechnology<br>Animal Biotechnology<br>Medical Biotechnology                             |
| Food and Nutrition Development<br>and Research Centre (FANDARC)<br>Teknika Utara, Berek Yogyakarta<br>Indonesia  | Public            | Agricultural Biotechnology<br>Animal Biotechnology<br>Industrial Biotechnology                          |
| Inter University Centre for<br>Biotechnology (IUC-Biotechnology)<br>Gajah Mada University<br>Jl. Teknik Utara, Berek<br>Yogyakarta, Indonesia  | Public University | Agricultural Biotechnology<br>Animal Biotechnology<br>Industrial Biotechnology<br>Medical Biotechnology |

(contd....)

|  |                   |   |
|--|-------------------|---|
| Faculty of Pharmacy<br>University of Airlangga<br>Jl. Darmawangsa Dalam<br>Surabaya 60286, Indonesia   | Public University | Agricultural Biotechnology<br>Animal Biotechnology<br>Medical Biotechnology |
| Institute of Teacher Training<br>and Education<br>Kampus IKIP Ketintang<br>Surabaya, Indonesia   | Public University | Agricultural Biotechnology  |
| Faculty of Animal Husbandry<br>Brawijaya University<br>Industrial Biotechnology<br>Jl. Majen Haryuono 169<br>Malang 65415, Indonesia           | Public University | Animal Biotechnology  |
| Industrial Technology Study<br>ProgramAgricultural Technology<br>Division Brawijaya University<br>Jl. Urip Sumohardjo F-3<br>Malang, Indonesia | Public University | Agricultural Biotechnology<br>Industrial Biotechnology                      |
| Research Institute for Tobacco<br>And Fibre Crops (RITFC)<br>Jl. Raya Karangploso<br>Malang, Indonesia   | Public            | Agricultural Biotechnology  |
| P.T. Fitotek Unggul<br>Jl. Jampang- karihkil Km 7<br>Parung, Indonesia   | Private           | Agricultural Biotechnology  |
| P.T. Monfori Nusantara<br>Jl. Jampang- karihkil Km 4<br>Parung, Indonesia  | Private           | Forestry Biotechnology  |
| P.T. Indah Kiat Pulp & Paper<br>Coorporation<br>Jl. Raya Minas-Perawang Km 26<br>Desa Pinang Sebatang Bengkalis<br>Riau Indonesia              | Private           | Forestry Biotechnology  |
| Yogyakarta Plantation Institute<br>Jl. Urip Sumoharjo 100<br>Yogyakarta 552222, Indonesia  | Private           | Agricultural Biotechnology  |
| P.T. Foodtech Utama International<br>Jl. Ancol I, no 4-5 Ancol Barat<br>Jakarta 14430  | Private           | Agricultural Biotechnology<br>Industrial Biotechnology                      |

(contd.)

## Appendix 2. Status of Transgenic Research in Indonesia

| Crop                      | Institute                 | Target trait                         | Gene  |
|---------------------------|---------------------------|--------------------------------------|---|
| Rice                      | RCBt                      | Resistance to rice stem borer        | cry and/or snowdrop lectin  |
| Rice                      | RCBt                      | Blast and drought                    | chitinase , other anti fungal genes and newly explored regulatory genes |
| Paraserianthes falcataria | RCBt                      | Resistance to stem borer             | pin   |
| Cassava                   | RCBt                      | Starch composition                   | Candidate genes   |
| Rice                      | RIFCB                     | Resistance to rice stem borer        | cry   |
| Corn                      | RIFCB                     | Resistance to Asian corn borer       | pin and cry   |
| Sweet potato              | RIFCB                     | Sweet potato feathery mottle virus   | coat protein and pin  |
| Soya bean                 | RIFCB                     | Pod borer                            | cry   |
| Peanut                    | BAU                       | Resistance to peanut stripe virus    | coat protein  |
| Chili pepper              | BAU                       | Resistance to potato Virus Y         | coat protein  |
| Potato                    | BAU                       | Resistance to potato Virus Y         | coat protein  |
| Coffee (Arabica)          | BRUEC                     | Tolerance to rust                    | chitinase   |
| Cacao                     | BRUEC                     | Stem borer                           | cry   |
| Sugarcane                 | BRUEC, ISRI & Jember Uni. | Drought tolerance                    | Candidate genes   |
| Sugarcane                 | ISRI                      | Stem borer                           | cry   |
| Forestry plants           | INDAH KIAT                | Insect resistance, agronomic quality | n.k   |
| Papaya                    | RIVC & RIFCB              | Virus resistance<br>Delayed ripening | Coat protein, anti-sense  |

*Note: The abbreviations can be consulted in Appendix 1*

## **LAO PDR**

**Sourioudong Sundara**  
**Science Technology and Environment Agency**

### **Present status**

Lao PDR do not undertake research, development and commercialization of GMO products. The Biosafety regulation will be prepared under the National Biosafety Framework.

### **Cartagena Protocol on biosafety**

Lao PDR is a member of the Convention on Biological Diversity and ratification of the Cartagena Protocol on biosafety is in progress.

The Convention on Biological Diversity was signed in 1996. As a signatory to this convention the Government of Lao PDR agrees to:

- (a) develop a national strategy for the conservation and sustainable use of the nation's biological diversity;
- (b) develop regulatory provisions and economically and socially sound measures for protecting threatened species, populations and ecosystems;
- (c) integrate conservation and sustainable use of biological resources into national decision-making and planning processes;
- (d) conduct environmental assessment (EA) of proposed development projects with a view to minimizing negative impacts on biological diversity;
- (e) take measures to ensure that the sharing of benefits arising from the use of traditional knowledge and genetic resources is sustainable and equitable; and
- (f) promote and encourage the understanding of the importance of biological diversity.

### **National Biosafety Framework**

Participation in the programme for developing a "National Biosafety Framework" initiated by UNEP-GEF is vital and appropriate to help Lao PDR in developing a regulatory system. The Research Institute of Science, STEA was designated as a single entity to fulfil the functions of both focal point and competent national authority for the Cartagena Protocol on Biosafety.

- a. Inventories of the following:
  - i Current use of modern biotechnology as defined in the Cartagena Protocol on Biosafety (including those techniques that are covered in the Protocol but excluded from the Advanced Informed Agreement procedure e.g contained use, veterinary use and possibly human pharmaceuticals);
  - ii Existing legislation or legal instruments related to biotechnology/ biosafety, etc.;
  - iii Active or planned National Projects for capacity building related to the safe use of biotechnology.
- b. A report on existing sub-regional biosafety frameworks and mechanisms for harmonization of risk assessment/management.
- c. Rosters of relevant experts within the country, identifying their experience and expertise so that adequate coverage in all areas of expertise is obtained and potential gaps can be identified.

Phase Two of the national project (Months 7-12), which includes the necessary analysis for the preparation of the NBF, will be expected to produce the following outputs:

- d. Access to relevant information for all stakeholders in accordance with the requirements of the Cartagena Protocol on Biosafety.
- e. Development of National Biosafety Database and linkages to the Biosafety Clearing House.
- f. Mechanisms for adequate involvement of all stakeholders, including public and private sectors, on issues related to biosafety.
- g. Identification of the components of the national Biosafety Framework, in consultation with all relevant stakeholders.

Phase Three of the national project, (Months 13-18), during which the draft NBF will be prepared, will be expected to produce the following outputs:

- h. Draft of legal instruments, including guidelines, as appropriate.
- i Systems for risk assessment and management, including audit, which take into account national and sub-regional/regional needs.
- j Administrative system for compliance with the Cartagena Protocol on Biosafety



- k Mechanisms for public consultation in decision-making processes regarding LMOs.
- l Mechanisms for sharing of scientific assessments at sub-regional levels, whilst allowing for decision-making at the national level.
- m Identification of country needs and mechanisms for participation in the Biosafety Clearing House.
- n Publication of inventories, reports of national meetings, draft and/or final National Biosafety Framework, relevant regulations and guidelines.

#### **Follow-up action**

Subject to guidance provided to the GEF by ICCP and in future by the Meetings of the Parties of the Cartagena Protocol on Biosafety, the country may be eligible for further assistance to implement its National Biosafety Framework. The follow-up activities will benefit from the experience gained in assisting pilot countries to implement their respective biosafety frameworks. This further development was set out in the GEF initial strategy on Biosafety adopted by the November 2000 GEF Council meeting.

#### **Conclusions**

Lao-PRD recognises its limited capacities dealing with issues of biosafety. As a Party to CBD, Lao PDR attaches importance for the ratification of the Cartagena Protocol. Technical and financial capacities are needed for implementation of any activity. It is in this regard Lao PDR recognises the need for regional cooperation and collaboration.

## **PHILIPPINES**

**Amparo C Ampil and Merle C PalacPac**  
**Department of Agriculture**

### **Background**

The Philippines ratified the Convention on Biodiversity (CBD) in December 1993. The focal point of the CBD is the Department of Foreign Affairs.

Earlier in September 1992, Philippine President Fidel Ramos signed E.O. No. 15, created the Philippine Council on Sustainable Development (PCSD), under the Office of the President, and adopted a national policy framework on the biological diversity conservation as well as a national strategy to ensure the preservation of the variability of the country's living organisms at the generic, species and ecosystem level. The PCSD formulated a National Biodiversity Strategy and Action Plan (NBSAP) in response to an Executive Memorandum dated 4 June 1995. In July 14, 1997, President Ramos issued a memorandum to all government agencies to integrate the National Biodiversity Strategy and Action Plan (NBSAP) into their sectoral plans, programs and projects.

The National Economic and Development Authority serves as the Secretariat of the PCSD. The Sub-committee on Biodiversity is a sub-group of the PCSD consisting of national government agencies and non-government organizations and is chaired by the Department of Environment and Natural Resources - Protected Areas and Wildlife Bureau. The government member agencies include the Departments of Science and Technology (Philippine Council for Agriculture Resources Research and Development), Health, Agriculture, Local Government, Tourism, Foreign Affairs and the National Economic Development Authority. The Sub-committee on Biodiversity serves as a forum for discussions of the NBSAP, the CBD, and the Biosafety Protocol, among others.

### **Status of the Implementation of Article 19 of the Convention on Biodiversity**

#### ***Legislative, Administrative or Policy Measures***

#### ***On Article 19, Handling of Biotechnology and Distribution of Benefits***

It was fortunate that as early as 1990, the country recognized the importance of ensuring the safe application of modern biotechnology while recognizing its distinct benefits, i.e., preventing and treating disease, enhancing food productivity, and protecting and sustainably managing the environment. Executive Order 430. "Constituting the National Biosafety Committee of the

Philippines ((NCBP) and For Other Purposes”, was signed by President Corazon Aquino, in October 15, 1990, signaling the start of a regulatory regime that will ensure biosafety.

In May 1995, another significant law was signed by President Fidel Ramos, Executive Order 247 “Prescribing Guidelines and Establishing A Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, For Scientific and Commercial Purposes, and For Other Purposes.” E.O. 247 regulates the research, collection and use of species, genes and their by-products, and recognizes the rights of Philippines communities to their traditional knowledge and practices. E.O. 247 was a direct response to Article 16 of the CBD “Access and Transfer of Technology”, which covers biotechnology.

#### **Mandates and Agencies involved:**

Both EO 430 and EO 247 are implemented through the creation of committees using the inter-agency approach.

#### ***EO 430 “Creation of the National Biosafety Committee”***

Per E.O. 430, the NCBP mandate is broad and covers the following areas: (a) Identification of the potential hazards involved in initiating genetic engineering experiments or the introduction of GMOs and recommendation of measures to minimize risks; (b) Formulation, review and amendment of national policies on biosafety and guidelines on risk assessment, (c) Development of working arrangements with its government member agencies; (d) Development of technical expertise, facilities and resources, and (e) Deliberations of its work and public consultations.

EO 430 brings together four government agencies into the NCBP. The chair is the Undersecretary of the Department of Science and Technology and member-representatives come from each of three other agencies which have concerns on biosafety namely: Department of Agriculture (Plant Quarantine Service), Department of Health (Bureau of Food and Drugs), and Department of Environment and Natural Resources (Ecosystems Research and Development Bureau). Other members include distinguished experts, i.e., a biological scientist, an environmental scientist, a physical scientist, a social scientist; and two respected members of the community.

### ***E.O. 247 “The Bio-prospecting Law”***

The main mechanism set forth in EO247 for an application is the consent of communities for both the academic and commercial research agreement. In addition, the EO sets the minimum requirements/terms for such researches.

EO 247 is implemented through an Inter-agency Committee on Biological and Genetic Resources attached to the Department of Environment and Natural Resources, with members from the Departments of Science and Technology, Agriculture, Health, Foreign Affairs, National Museum, representatives of non-government organizations and people’s organization that includes indigenous cultural communities.

The inter-agency committee processes research agreements and recommends the application for approval of the concerned Secretary of either DENR, DOH, DA and DOST, and ensures that conditions in the agreements are strictly observed.

### ***Other Legislative Measures***

Agriculture and Fisheries Modernization Act (Republic Act No. 8435) signed in September 1997

The AFMA sets the policy framework for modernization and transformation of the agriculture and fisheries sector using technology as a base. Modern biotechnology, representing the most recent technology for use in the agriculture sector, is considered as one of the tools among many, to achieve modernization. The AFMA Implementing Rules and Regulations dated June 10, 1998, also provide that 20% of the DA research budget be allotted for modern biotechnology. Legislative measures are currently being undertaken to extend the funding of the AFMA.

### ***Further Policy Pronouncements***

President Joseph Estrada, during his administration, approved a national policy to use biotechnology as a strategy to improve agricultural production, modernize Philippine agriculture and enhance rural development. Likewise, he extended support to initiatives that will foster the development and application of biotechnology. Such approval was contained in a Memorandum dated January 17, 2000 from Senior Deputy Executive Secretary Ramon B. Cardenas to the then Secretary of Science and Technology Filemon Uriate and Dr. William D. Dar, Presidential Adviser on Rural Development as a response to their proposal entitled “Institutionalization of A National Policy To Use Biotechnology as One Strategy To Increase Agricultural Productivity and Enhance Rural Development” dated 7 January 2000.

When President Gloria Macapagal Arroyo assumed the Presidency in January 2001, her Executive Secretary Alberto Romulo likewise issued a Memorandum dated 16 July 2001, to the Secretaries of Agriculture, Science and Technology, Health, Environment and Natural resources, and Trade and Industry, informing them of the President's approval of a Policy Statement on Modern Biotechnology. The Policy Statement promoted the safe and responsible use of modern biotechnology for food security, equitable access to health, sustainable and safe environment, and industry development. The Policy Statement contained a directive to the Departments to address the prevailing issues on biotechnology and formulate regulations to address such issues

### ***Philippines and Biosafety Protocol***

In May 2000, the Philippines became one of the signatories of the Cartagena Protocol on Biosafety.

Internal discussions on the Cartagena Protocol on Biosafety including that of the process of ratification, is currently lodged with the Sub-committee on Biodiversity chaired by the DENR-PAWB. The Department of Foreign Affairs, as the focal point of the CBD, continues to function as the focal point for the Biosafety Protocol. There is no agreement, as yet, among the agencies regarding competent authorities for the Protocol. However, the Department of Agriculture, having the legal mandate to issue permits (mainly for SPS, importation of plants and plant products through the Bureau of Plant industry), had, as early as 1998, initiated discussions leading to the formulation of rules and regulations covering importation of plant and plant products derived from the use of modern biotechnology. DA released Administrative Order No. 8, series of 2002, last April 13 (Item B.5). The DA has also taken initiatives to participate in the proceedings of the Intergovernmental Committee on the Cartagena Protocol.

### ***Rule and Regulations for Commercialization of Biotech Plant and Plant Products***

After over three years of work, the Department of Agriculture released the Department of Agriculture Administrative Order No. 8, "Rules and Regulations on the Importation and Release Into The Environment of Plant and Plant Products Derived From the Use of Modern Biotechnology", on April 3, 2002. AO 8 sets into place a process by which the DA will conduct a formal determination of the safety of plants and plant products derived from the use of modern biotechnology. Under AO 8, all biotech plants and plant products for release into the environment (field testing and propagation) or for importation for direct use as food, feed or for processing shall undergo the required safety

tests. The permits that will be granted under AO 8 include; (a) permit for field testing; (b) permit for propagation (or commercial planting); (c) permit for importation for direct use as food, feed, and processing; and (d) permit for the delisting of the regulated article(s).

AO 8 identifies all the information that needs to be provided by the applicant to the regulatory agencies to facilitate the conduct of a risk assessment.

The main regulatory agency for DA AO 8 is the Bureau of Plant Industry which has the mandate over plants and plant products, whether derived using modern biotechnology or not. The BPI will be assisted by other DA regulatory agencies, i.e, Bureau of Animal Industry, Bureau of Agriculture and Fisheries Products Standards, and the Fertilizer and Pesticide Authority who will give advisory opinions in accordance with their respective mandates/responsibilities and the nature of the product.

The BPI is aided by a Scientific and Technical Review Panel (STRP), an independent body, i.e. non-DA, of scientists who will conduct risk assessments.

## **Risk Assessment and Management**

### ***NCBP Risk Assessment Guidelines***

As there is a need for risk assessment in the various stages of development of a GM plant, the NCBP formulated risk assessment guidelines for applications for contained use and field tests.

The NCBP published the Philippine Biosafety Guidelines, in 1991, for the purpose of regulating importation, transfer and use of genetically modified organisms for contained use and field releases. The biosafety guidelines originated from a 1987 report of the joint ad-hoc committee on biosafety constituted by the University of the Philippines at Los Banos, the International Rice Research Institute and the Department of Agriculture. The Guidelines include a description of the NCBP and the Institutional Biosafety Committees; procedures and guidelines on the introduction, movement and field releases of regulated materials; and physico-chemical and biological containment procedures and facilities.

The primary responsibility of enforcing the rules and regulations on biosafety tests rests in the member agencies and institutions. The NCBP Guidelines were intended to help each institution.

In 1998, the NCBP released a second edition of the Guidelines with three monographs: (1) Biosafety Guidelines for Small-Scale Laboratory Work; (2) Biosafety Guidelines for Large-Scale Contained Work and Greenhouse Trials and (3) Biosafety Guidelines for Planned Release of Genetically Modified Organisms (GMOs), which serves as the official guide to risk assessment for field testing.

### ***Risk Assessment and Management under DA-AO 8***

In its regulations (Administrative Order 8), the Department of Agriculture, introduces risk assessment as an additional measure to the usual SPS measures, i.e., quarantine and standards, currently observed DA regulatory agencies responsible for the regulation of plant and plant products used as planting materials/seeds, or for direct use as food, feed, processing. As a basic policy, Section 3 of the AO provides that “no regulated article shall be allowed to be imported or released into the environment without the conduct of a risk assessment performed in accordance with the Order”. Further, AO 8 provides that the NCBP guidelines be followed.

As a signatory to the Cartagena Protocol on Biosafety, the DA had endeavored to harmonize the risk assessment principles of AO 8 to be consistent with Annex III of the Protocol, some principles of which are found in other countries’ national measures and some of which have reached international consensus. Section 3 of AO 8 adopts the five principles of risk assessment of the Cartagena Protocol, with some modifications:

- (a) The risk assessment shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of, and guidelines developed by, relevant international organizations and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment.
- (b) Lack of knowledge or scientific consensus shall not be interpreted as indicating a particular risk, an absence of risk or an acceptable risk.
- (c) The identified characteristics of the regulated article and its use, which have the potential to pose significant risks to human health and environment, shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions.
- (d) Risk assessment shall be carried out case by case and on the basis of the transformation event.

- (e) New information on the regulated article and its effects on human health and the environment will be used to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

These principles on risk assessment currently guide the Department regulatory agencies in their ongoing work/preparation of protocols and guidelines for risk assessment for environment, food and feed safety.

## **Capacity Development**

### **Need for National Biosafety Framework and other Domestic Regulations**

The establishment and formulation of biosafety regulations in the Departments of Science and Technology and Agriculture partially fulfills the directive set by the President Gloria Macapagal in the Policy Statement on Modern Biotechnology. Eventually, the Department of Environment and Natural Resources may need to formulate regulations regarding the use of biotechnology products for the environment as requests for such activities (i.e. bioremediation) come up.

In this regard, the DENR, as the country's focal point has expressed interest to partake of the UNEP-GEF-funded National Biosafety Framework. The NBF will be built on existing regulations of the departments on biosafety. The Department of Agriculture has formally requested its inclusion in the project in the light of AO 8, and to avail of training on risk assessment and management. Likewise, the DA has recommended the participation of the National Committee on Biosafety of the Philippines into the NBF Project. A proposal is being put together with inputs from concerned agencies.

Following AO 8, DA regulatory agencies are also formulating their agency protocols for their new role in regulating plants and products of modern biotechnology and are building on the NCBP risk assessment guidelines and expert advice of international organizations engaged in biotechnology/biosafety. The training needs required by regulators include basic training course on modern biotechnology and development of protocols and training for the evaluation of GMO products for food, feed, processing and release into the environment. The regulatory agencies would also need to come up with monitoring protocols.

An area of policy that needs to be looked into jointly by Departments is the policy on labeling of GM plant products, as it has been consistently raised as an issue by stakeholders. The Secretary of Agriculture had in 2001 has taken the



initiative to discuss this issue with the Secretaries of Health, Trade and Industry, and Science and Technology.

### **Regional Cooperation**

The Philippines welcomes the setting up of a regional website for use of the regulators within the region.

Likewise, the Philippines will appreciate participating in a regional training on risk assessment for release into the environment, food and feed safety and regional discussions on the same, for policymakers and regulators.

We also look forward to the possibility of the sharing data to arrive at or collect socio-economic studies on the use of GM crops for the region.

### **National Needs**

The Philippines fully agrees to the capacity building needs identified at the discussions of the Inter-governmental Committee on the Cartagena Protocol (ICCP) 1 on capacity building and adopted as areas for engaging the services of the roster of experts at the ICCP 3.

There is also a need to intensify national efforts to educate stakeholders on biotechnology and government regulations. This is being done at the moment by several institutions in the Philippines including the Department of Agriculture, Science and Technology, and the National Academy of Science and Technology, among others.

### **Institutions Involved in Biotechnology Work**

#### **Government Regulatory Agencies**

1. National Committee on Biosafety of the Philippines  
Department of Science and Technology
2. Department of Agriculture  
Bureau of Plant Industry  
Bureau of Animal Industry  
Bureau of agriculture and Fisheries Product Standards  
Fertilizer and Pesticide Authority

**Others Agencies (Policy)**

3. Department of Agriculture - Office for the Assistant Secretary for Policy, Planning, Research and Regulations
4. Department of Health - Bureau of Food and Drugs
5. Department of Trade and Industry
6. Department of Environment and Natural Resources

**Others Institutions**

1. Institute(s) of Molecular Biology and Biotechnology  
University of the Philippines Los Banos, Diliman, and Manila
2. Institute of Plant Breeding  
University of the Philippines. Los Banos, Laguna

**Conclusions**

Philippines is constantly striving to achieve capacities as well as set up regulatory measures to deal with issues of biosafety. It also considers sharing of information and experiences in the region a critical for successful implementation of not only the Cartagena Protocol but also national biosafety frameworks.

## **SRI LANKA**

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**Ministry of Environment and Natural Resources**

### **Introduction**

Sri Lanka has a high number of flora and fauna per unit area, distributed among a wide range of different terrestrial and aquatic ecosystems and habitats. Many of these species are endemic to the country. These biological resources are being rapidly lost due to high population density, poverty and unemployment, leading to habitat destruction, over - exploitation, introduction of exotic species etc. Rich ecosystems are converted to various other uses, which yield higher financial returns and there are inadequacies in institutional capacities.

Sri Lanka has been named as one of the 25 biodiversity hotspots of the world, especially the South Western region of Sri Lanka. Therefore, conservation of biological diversity in Sri Lanka is of national interest and of global relevance. The Convention on Biological Diversity was signed and ratified by Sri Lanka in July 1992 and March 1994 respectively. The Ministry responsible for the subject of Environment has the duty to ensure that the provisions of the Convention are adhered to.

Due to inadequate infra-structural development, including human resources and poor investment in the field of biotechnology and a lack of legal instruments and institutional frameworks to control and regulate importation of LMOs/GMOs and their products, Sri Lanka's native biodiversity is at risk and will suffer adverse impacts in the trade of LMOs/GMOs in an open economy. There have also been reports that products containing LMOs have been imported for release into the local market for household clearing purposes, waste management, agriculture purposes, etc.

Sri Lanka signed the Biosafety Protocol on 24 May 2000 and is planning to ratify it as early as possible. Before the ratification Sri Lanka should establish domestic legal measures and build capacity in the area of biosafety.

The Ministry of Environment is the National Focal Point and is obliged to implement the articles of the protocol.

## **Present Status**

### **Implementation of Article 19 of the CBD**

- (i) “Take measures to provide for the effective participation in biotechnological research activities by those contracting parties which provide the genetic resources for such research” - no measures have been taken with regard to this provision so far.
- (ii) “Take all practicable measures to promote and advance priority access on a fair and equitable basis by contracting parties to the results and benefits arising from biotechnologies based upon genetic resources provided by those contracting parties” - some measures are in place.

### **Application of Biotechnology**

The following areas of priority have been identified for development in Sri Lanka within the framework of safety for human health and the environment.

1. Agricultural biotechnology
2. Medical biotechnology
3. Industrial biotechnology
4. Biosafety
5. Bioinformatics
6. Human resource development & capacity building
7. Management

### **Present Status of Biotechnological Research**

Until the early 1990's, biotechnology in Sri Lanka was mainly concerned with plant tissue culture with the exception of the molecular biology work done by a few medical research groups. Hence, the development of facilities and resource allocations were directed towards micropropagation, without much concern for the future potentials of new biotechnologies. However, an upsurge of interest on the new biotechnologies has taken place in the new millennium, and at present, many universities, research institutes and government departments carry out research in biotechnology. The number of personnel skilled in biotechnological operations is still low. Table 1 shows the involvement of the scientists in biotechnological research and development in the country as at present (2000).

The National Science Foundation (NSF), The Council for Agricultural Research Policy (CARP) and the National Research Council (NRC) provide funds for research in biotechnology and thereby maintains a limited sort of management.

**Table 1. Research and Development in Biotechnology**

| R & D  | Current status       | Future |
|--|----------------------|--------|
|  | % personnel involved |        |
| Genetic engineering and DNA markers in crop breeding | 18                   | 28     |
| DNA/Immuno diagnostics                               | 63                   | 68     |
| Vaccines   | 03                   | 06     |
| Gene therapy   | 00                   | 03     |
| Environmental biotechnology                          | 05                   | 12     |
| Industrial biotechnology                             | 04                   | 07     |
| Food biotechnology                                   | 04                   | 08     |

| Activities                              | Investigators (%) |
|---|-------------------|
| DNA/RNA/Protein extraction              | 80                |
| Culture of microorganisms/tissue        | 69                |
| Use of EMOs/GMOs                        | 34                |
| Using pathogens/vectors/animals         | 53                |
| Using cloning vectors/host systems      | 41                |
| Production of recombinant molecules     | 39                |
| Radiolabelling of biomolecules          | 39                |
| PCR assaya/DNA sequencing               | 79                |
| Production of monoclonal antibodies     | 09                |
| ELISA assays                            | 38                |
| Production of transgenic animals/plants | 11                |
| Use of fermentor                        | 11                |

(National Science Foundation, 2001)

The data shows that there are only two main areas of research at present viz. disease diagnosis (63%) and crop improvement (18%) which can be further strengthened and developed as they are at present in the early stages.

There are other very important areas in biotechnology such as food biotechnology, industrial biotechnology and environmental biotechnology that need to be identified, programmes prioritised and assisted. They will be benefited immensely by the application of the new technologies.

A significant feature arising from this information is the lack of partnership and interest by the industrial sector.

### **Actions and measures adopted**

After 1998, the formation of various biotechnology fora and committees by research governing bodies such as The Specialists Group of Agricultural Biotechnologist of CARP (Council for Agricultural Research Policy), The Biotechnology Working Group (committee) of the NSF (National Science Foundation) and The Biotechnology Panel of NRC (National Research Council) can be considered as a step forward for planning and managing the use of biotechnology for the benefit of the country. The CARP committee has identified national priorities for agricultural biotechnology, whilst the NSF and NRC have listed important areas for research and development in biotechnology.

The universities have developed their curricula to include biotechnology at undergraduate and postgraduate levels. New departments to deal with biotechnology have been created.

The Asian Development Bank (ADB) has provided loan facilities to develop biotechnology at both undergraduate and postgraduate levels in several universities, as well as in some institutes. Through this loan facility, the University of Peradeniya has established two buildings with equipment for developing biotechnology capabilities at undergraduate level (Biotechnology Laboratory, Faculty of Science) and postgraduate level (Agricultural Biotechnology Centre, Faculty of Agriculture). Moreover, scholarships for local training of up to 50 M.Sc. students and 10 Ph.D. students, as well as for upgrading the faculty staff, and for consultancies and workshops were also available through this programme. Funds were also available for upgrading and developing biotechnology at the University of Colombo.

Some institutions involved in biotechnology

- Research Institutes: Institute of Fundamental Studies, Industrial Technology Institute, Coconut Research Institute, Rubber Research Institute, Rice Research Institute, Veterinary Research Institute, Sugar Research Institute, Tea Research Institute, Plant Genetic Resources Center, etc.
- Universities: University of Colombo, Eastern, Kelaniya, Peradeniya, Rajarata, Ruhuna, Sabaragamuwa, Sri Jayawardenapura, etc.
- Private sector: Distilleries

Institutions involved in the use, implementation and monitoring of biosafety include Ministries relevant to Science and Technology, Health, Fisheries and aquatic resources, etc. National Science Foundation, Department of Agriculture, Animal Production and Health, Customs, Wild life Conservation, Forest, National Aquatic Resources Agency, Central Environment Authority, etc.

### **Capacity Development**

#### **Biosafety Regulations/Guidelines**

Sri Lanka is at present establishing regulations for biosafety that includes guidelines for laboratory-based experiments, for testing in the green house and for small and large scale field trials of genetically modified plants and organisms and for their commercialisation and release into the environment or food chain. These regulations are taking into consideration the Cartagena Protocol on Biosafety which advocates a global system for assessing the impact of GMOs on biodiversity as well as the “precautionary approach” described in the 1992 Rio Declaration on Environment and Development. Sri Lanka is at present considering the introduction of guidelines or mandatory measures for labelling GMFs.

The National Science Foundation has drafted the guidelines for the safe use of recombinant DNA technology in the laboratory. The guidelines are applicable to all laboratory research and other laboratory activities involving rDNA (recombinant DNA) molecules in Sri Lanka. The guidelines are for the safe use of rDNA technology in the laboratory. The safety considerations are presented under three main areas of research viz. (i) genetic manipulation of microorganisms, including animal and plant viruses and viral vectors (ii) genetic manipulation of plants and plant pathogens and (iii) genetic manipulation of animals. The procedure to be followed by the investigator/s undertaking rDNA work is briefly outlines in the beginning of the document for his/her convenience.

As prescribed in the guidelines, the investigator/s undertaking the rDNA work and the institution/s where the work is to be performed must establish procedures for the safe conduct of all rDNA research activities.

An institutional mechanism for implementation of guidelines is also described. The guidelines prescribe specific action required to establish safe procedures for rDNA research. The investigator/s and the institution/s would be responsible for the compliance of these guidelines and the safe conduct of rDNA work, to ensure protection of health and the environment. An Institutional Biosafety Committee (IBSC) would serve as the advisory body to all rDNA work conducted within an institute. All institutions conducting rDNA work should establish IBSCs. At national level, a rDNA Advisory Committee (RAC) will serve as the focal point on rDNA activities in the country and provide advice and guidance to all institutions and their IBSCs and investigators. The investigator's/s' role and responsibilities, the structure and composition of advisory and implementation bodies, their scope, responsibilities and functions are proposed in the guidelines.

The overall, comprehensive, national biosafety guidelines, including guidelines for field research and release, are being finalized by the Ministry of Environment.

At present collaborative research is carried out by individuals and various academic institutions. The current trend in the use of genetic resources for the production of LMOs/ GMOs indicates a timely need for a comprehensively drawn set of National Biosafety Guidelines in accordance with the Biosafety protocol. The National Experts Committee on Biological Diversity of the Ministry of Environment and Natural Resources propose to develop National Biosafety Guidelines. In this regard, a sub committee, The National Technical Committee on Biosafety Guidelines was established in 1999.

### **National Technical Committee on Biosafety Guidelines**

The committee has developed a draft of the National Biosafety Guidelines. The Fifth draft of the National Guidelines for import and planned release of genetically modified organisms and products thereof have been reviewed.

This includes the following.

- Objective, scope and general principles
- Implementation procedure - submission of a proposal, evaluation and public participation, accidental release and emergency measures, responsibility for compliance



- Institutional arrangements - mechanism of implementation, safety at institutional level, placing on the market, final provisions
- Summary of procedures
- Annexes - information on GMO and its release, additional information on transgenic plants, organisms for biological control, organisms for bioremediation, risk analysis, IBC assessment of a planned release proposal, information sheet for purposes of public notification, and IBC report on planned release after its completion.

### **Legal Measures**

Before the ratification of the Protocol, Sri Lanka should establish domestic legal measures and build capacity in the area of biosafety. A committee on Domestic Legal Measures on Biosafety has been established to discuss and clarify important matters relating to the existing legal framework, to handle legal matters, to identify legal gaps, etc. related to biosafety and biotechnology.

#### **Committee on Domestic Legal Measures on Biosafety**

The committee includes the following members.

- Secretary to the Ministry of Environment
- Government Institutions involved with biosafety matters: Agriculture, Health, Trade, Forests, Wildlife, Livestock, Fisheries and Aquatic Resources, Customs, Food and Drug, etc.
- Experts on Biosafety related areas
- Legal Officers
- Representatives from NGOs
- Representatives from private sector

The committee has met several times and reviewed the relevant national legislation on importation of genetically modified organisms and relevant measures have been carried out. Some of existing legal instruments include:

- Fauna and Flora Protection Ordinance
- Plant Protection Act
- Fisheries and Aquatic Resources Act
- Forest Ordinance
- National Heritage Wilderness Areas Act

- Food Act
- National Environmental Act
- Diseases of Animals Act
- Code of Intellectual Property Act

### **Code of Ethics**

A technical committee has been set up by the Ministry of Environment and Natural Resources to formulate a Code of Ethics for research.

A draft Code of Ethics for research on Biological Diversity involving Access to Genetic Resources has been prepared.

### **Ban of Genetically Modified Foods (GMFs)**

Ban of GMFs comprising 21 food items by the Food (Genetically Modified Foods) Regulations-2000 under the Food Act was deferred, but is expected to be re-imposed considering the World Trade Organization (WTO) regulations.

### **Capacity building**

#### **National Biosafety Frame Work**

Sri Lanka is identified as a potentially eligible country to participate in the UNEP-GEF Biosafety Project in the Asia-Pacific region. Sri Lanka is in the process of preparation of the National Project Document (Budget and the work plan) and hopes to begin implementing the project in the latter part of 2002.

#### **Risk Assessment and Management**

No mechanism is in place to evaluate the potential risks and management of the range of Genetically Modified Organisms and/or their products.

#### **Biosafety Clearing House**

Establishment of Biosafety Clearing House at Biodiversity Secretariat in Ministry of Environment and Natural Resources, strengthening existing biodiversity and biosafety information exchange mechanisms and facilitating information exchange through electronic and print media and implementation of biosafety clearing house through the UNEP/GEF Biosafety Project should be carried out.

Sri Lanka is in the process of developing databases on all biosafety aspects.

## VIETNAM

**Le Thi Thu Hien, Le Thanh Binh  
Nong Van Hai and Le Tran Binh  
Ministry of Science, Technology and Environment**

### **Biotechnological Research and Development in Vietnam**

Biotechnology has made a significant contribution to the economy of Vietnam. In a national social economic strategy, it has been identified as an essential and important prerequisite for achievement of national goals. For the period 1995-2010, the government's first priority for scientific research is in biotechnology. Four major focus areas have been identified for the application of biotechnology in agriculture:

- \* Development of large-scale micropropagation technology for economical important plants;
- \* Application of genetic engineering and cell technology to plant and animal breeding programs, with emphasis on rice, vegetables and root crops;
- \* Research and technology transfer for improving crop and animal varieties and processing agricultural products;
- \* Development of biotechnology related to environmental protection and reforestation.

Considered as a national priority, biotechnological research and development has received funding from the government, which has increased considerably (Table 1). Government support for capital construction is also provided. For example, by the years 2001-2003 the government approved to fund IBT three millions USD (\$US 3,000 000.00) for setting up National Key Laboratory for Gene Technology.

Table 1. Capital investment from Vietnam Government for Science and Technology from 1996 to 2000 (billions Vietnamese dong)

Data source: MOSTE and General Statistical Office

|   | 1996 | 1997 | 1998 | 1999    | 2000    |
|---|------|------|------|---------|---------|
| National budget for Science and Technology              | 734  | 905  | 1110 | 1,039.6 | 1,876.5 |
| Percentage in comparison with total national budget (%) | 1.08 | 1.15 | 1.37 | 1.33    | 1.99    |

The biotechnology research activities in Vietnam are concentrated in several ministries and agencies:

- \* Ministry of Agriculture and Rural Development (MARD): Within MARD biotechnology research is conducted by several national programs in many Research Institutes including Agricultural Genetics Institute (AGI), Cuu Long Delta Rice Research Institute (CLRRI), Vietnam Agricultural Science Institute (VASI), and Food Crops Research Institute (FCRI), etc. At province level, many plant tissue culture laboratories have been set up.
- \* The National Center for Natural Science and Technology (NCST): Under NCST, the Institute of Biotechnology (IBT) has been established as a leading biotechnology research institution of Vietnam. IBT focuses on fundamental and applied research in the field of biotechnology and related subjects.
- \* The Universities: Within the Universities, several Biotechnology Centers have been created.
- \* Other sectors

Modern biotechnology has been developed at IBT and several national institutes of MARD such as AGI and VASI. These Institutes implement national research programs in biotechnology and focus on the development of genetically modified organisms (GMOs). Presently, GMOs for agriculture could be produced at least at four national research institutions as follows: IBT, AGI, Institute of Tropical Biology (ITB), and CLRRI.

Agronomically important genes have been introduced into many important crops such as rice, papaya, potatoes, sugarcane, and tomato. These genes include Xa21 (bacterial blight resistance); cryIA(a,b,c,d) (insect resistance); chitinase gene (fungi disease resistance); P5CS, OAT, Tps, Nha, HAL (salt and drought tolerance); CgS, SAT (amino acids content enhancement); CP (PRSV resistance); ACC antisense (delayed ripening), etc. At IBT, many industrial genes are using for research and development (Table 2) and transformation experiments of rice, sweet potato, papaya, potato, cotton and maize have been attempted and several small-scale tests of transgenics at laboratory and field trial levels have been conducted.

**Table 2. Industrial genes used for research and development at IBT**

| <b>Gene</b>                           | <b>Purpose(s)</b>               | <b>Progress</b>          |
|---------------------------------------|---------------------------------|--------------------------|
| Amylase recombinant bacterial strains | production of industrial enzyme | already has              |
| ectinase                              | production of industrial enzyme | at gene expression level |
| RIPs                                  | drug-products                   | gene expression          |
| Lipase                                | industrial enzyme               | recombinant strain       |
| Fab                                   | production of antibody          | recombinant strain       |
| DNA polymerase                        | molecular biology               | on screening             |
| HbsAg                                 | recombinant vaccine             | gene expression          |

At IBT and some other Institutes, well-equipped laboratories for molecular biology and genetic engineering have been set up. Main facilities and equipment included Automated DNA Sequencers, Oligonucleotide Synthesizer, Thermocyclers, Ultracentrifuges, Micromanipulator, Biolistic Particle Delivery System, Fermentors (5-85L), Continuous Centrifuge, Spray Dryer, Freeze Dryer, FPLC System, UV Spectrophotometer, Automated Amino Acid Analyzer, Electrophoresis Systems, Green House and Experiment Fields, Animal House, Bio-informatic Unit, Research Library, etc. With all these essential research facilities, the research works have achieved some impressive results. However, up to now no GM crop has been released in Vietnam.

### **Current status of Bio-safety in Vietnam**

#### **● National level**

The Convention on Biological Diversity (CBD), which entered into effect on December 29, 1993, establishes important principles regarding all aspects of biological diversity. Under this convention, the Cartagena Protocol was adopted as a guiding framework for activities on safety in biotechnology.

Vietnam became a party of CBD in 1994 but has not yet signed the Cartagena Protocol on bio-safety. However, Vietnam recognizes the ecological and economic importance of an effective bio-safety regulation in biotechnology development. It also recognizes the need to have in place an appropriate safety regulation before large-scale field trials of GMOs are conducted and released to the environment. At present, Vietnam is in a process of designing and developing a safety regulation and has brought into the government consideration for rectification and approval of Cartagena Protocol.

Responsibility for drafting the National Regulation on Safe Management of Living Modified Organisms and their products (the Regulation) lies with the National Environment Agency (NEA) under Ministry of Science, Technology and Environment (MOSTE) and AGI of MARD. However, many experts from biotechnology research institutes and governmental agencies are strongly contributing to and involved in drafting and incorporating the Regulation in National Laws. The draft Regulation has been passed and endorsed by the Committee, which was led by the MOSTE, and is now under consideration by the Government. So far, Vietnam has not had in place the Regulation or the monitoring procedures for implementing it. This is one of the reasons for the delay in further GMOs product development.

#### ● **Institutional level**

There are risks associated with either the use or the non-use of GM crops. To minimize the risk of genetic recombination even further, institutional bio-safety guidelines for laboratories and research work have been prepared and implemented in a few biotechnology research institutes without setting up institutional bio-safety committees.

Particularly, at IBT bio-safety is of an important issue and therefore has received much attention. Its own bio-safety guideline has been implemented in a professional manner. Followings are some activities on bio-safety that have been carried out:

- (i) training all students, visiting fellows and junior researchers on bio-safety before employment in specific research laboratories; and
- (ii) co-organizing with the International Service for the Acquisition of Agri-biotech Applications (ISAAA) a workshop on biotechnology awareness addressing many aspects of bio-safety issues. Biotechnologists, ecologists, regulatory bodies are benefitting greatly from this event.
- (iii) conducting biotechnology programs including an associated project on risk assessment leading by Dr. Le Tran Binh.

However, the existing regulatory institution is not adequate for oversight of biotechnology products since there is no national legislation to address all aspects of bio-safety issues so far.

- **Overview of the National Regulation on Safe Management of Living Modified Organisms and their Products**

Basically, the criteria for bio-safety in Cartagena protocol have been adopted. In general, the Regulation:

- aims at ensuring that the use of biotechnology products will not be detrimental to the environment and human health.
- addresses issues associated with the conduct of containment trials, field tests and the transport of GMOs within Vietnam as well as trans-boundary movement of GMOs.

Article 2 of this Regulation states that: The Regulation shall apply to all domestic and foreign organizations and individuals whose activities undertaken on the territory of Vietnam are related to biological safety, including the research, deployment and development, management, handling, transport, use, transfer and release of GMOs and their products.

### **Challenges and Constraints**

Although in most industrialized countries, bio-safety regulations have been implemented since the mid 1980s, Vietnam now is still in the process of developing and implementing safety regulation in harmony with the ASEAN framework. Therefore, as a new practice, drafting and implementing of the Regulation has posed challenges and constraints. These challenges are:

- Lack of understanding on biosafety among scientists and media
- Lack of well -trained personnel who are involved in developing and implementing bio-safety regulatory mechanisms.
- Insufficiency of monetary and enforcement systems.
- Lack of experience in the regulatory process and in analyzing the environmental risks of small and large scale field releases and commercial use of transgenic crops.
- Lack of facilities for analyzing the risk assessment.
- Inadequate institutional capacity.

### **Future plans**

It is very important to develop National Projects, which focus on the preparation of a National Bio-safety Framework including regulatory, administration and decision-making systems, and mechanisms for public participation and information. Here are some of the activities:

- Gathering necessary information concerning the use of modern biotechnology, existing legislation on biotechnology and/or bio-safety;
- Establishing Committees such as: National/Institutional Bio-safety Committees, GM Advisory Committee, Review Committee, and GMO Approval Committee to enforce the Regulation;
- Training Bio-safety Committees at both institutional and national levels to conduct scientifically sound bio-safety reviews, etc;
- Developing National Bio-safety Database and linkages to the Bio-safety Clearing House;
- Drafting legal instruments as Guidelines for implementing the Regulation;
- Sharing of experience on the organization and risk analysis with other countries, which are in a more advanced stage of drafting and enforcing bio-safety regulations;
- Cooperating with other countries and international organizations in developing relevant educational, public awareness programs and intensive workshops on bio-safety.

#### **Main contacts and addresses**

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Draft version of Vietnamese Regulation on Safe Management of Living Organisms and their Products.

## **BT-Crops: Biosafety Assessment and Risk Management**

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**Monsanto Research Centre, India**

### **Introduction**

Transgenic plants expressing insecticidal proteins derived from the soil bacterium, *Bacillus thuringiensis* (herein referred to as Bt), have been found to provide an environmentally safe and effective method of insect pest control. The year 1996 may be considered as a turning point in the history of crop protection as three insect resistant Bt-crops were commercialised in the USA: Bt-Corn for control of the European corn borer; Bt-potato against the Colorado potato beetle; and Bt-cotton against the cotton bollworm complex. In subsequent years, these were introduced into other countries also like Argentina, Australia, Canada, China, France, Indonesia, Mexico, Portugal, Romania, South Africa, Spain and Ukraine. On a global basis, the area under Bt-crops has grown from 4.0 million hectares in 1997 to 11.54 m ha in 2000. Such a large-scale adoption of a new technology is unprecedented in agriculture and clearly reflects the outstanding performance and benefits from these products leading to grower satisfaction. In India, Bt-cotton hybrids, developed by MAHYCO (Maharashtra Hybrid Seed Company) incorporated with Monsanto's patented 'Bollgard' Bt-gene (Cry 1Ac), is the first transgenic crop approved (on March 26, 2002) by the Govt. of India for commercial cultivation.

Bt-crops, like any other GMO's were subjected to extensive regulatory trials in their respective countries to satisfy biosafety requirements and risk management before they were approved for commercial cultivation. Some of the critical studies included, safety of cry proteins to non-target organisms, feed safety, gene transfer, fate of protein in the soil, environmental impact of Cry proteins and insect resistance management.

### **Bt Insecticidal (Cry) Proteins**

The cry (acronym for crystal) proteins expressed in the commercialised Bt-crops include cry 1Ab or cry 1Ac in Bt-corn, cry 1 Ac in Bt-cotton and cry 3A in Bt-potato. Cry proteins are highly specific in their action, requiring certain conditions present only in the target organisms, for their mode of action. The cry 1 class of cry proteins require alkaline pH values of 10 or above for effective processing and also require specific receptors (on the brush-border membrane of mid-gut epithelium cells of target insect) for binding and activity which finally leads to the death of the caterpillar. Safety assessment studies revealed that such

specific conditions are lacking in non-target organisms and that Bt-crops are safe to humans, animals and the environment. Mammalian toxicology and digestive fate studies which have been conducted with the proteins produced in the currently approved Bt-crops have confirmed that these Cry proteins are non-toxic to humans and pose no significant concern for allergenicity. Food and feed derived from Bt-crops that have been fully approved by regulatory agencies have been shown to be substantially equivalent to the food and feed derived from conventional crops. Non-target organisms exposed to high levels of cry proteins are virtually unaffected, except for certain insects that are closely related to the target pests. The cry proteins produced in Bt-crops have been shown to rapidly degrade when crop residue is incorporated into the soil. Thus the environmental impact of these crop is negligible. The human and environmental safety of Bt-crops is negligible. This is further strongly supported by the long history of safe use of Bt microbial spray formulations on horticultural crops and forestry around the world for more than 40 years.

### **Gene flow and Weediness**

The movement of transgenes from the Bt-plant into related weeds (through pollen flow) has been a major concern for regulatory authorities due to the possibility of weeds gaining a selective advantage in the environment from the newly gained insecticidal activity of its tissue. This concern has been addressed for each Bt-crop that has been approved and it has been experimentally demonstrated that there is no significant risk of capture and expression of any Bt cry gene by wild or weedy relatives of corn, cotton, or potato. The low risk has been ascribed to sexual incompatibility (differences in chromosome number), crop phenology (i.e., periodicity or timing of events within an organism's life cycle as related to climate, e.g., flowering time) and habitat.

The potential for horizontal gene transfer from Bt-crops and its risk was also considered and evaluated. Various sub-species of Bt are generally common in soil and therefore various cry genes have been available for long periods of time for horizontal transfer from Bt to other soil species. Thus Bt crops in no way will be adding to the already existing flux of cry genes among the soil micro-organisms. Also, there is no evidence that horizontal gene transfer occurs from plants to microbes.

### **Fate of Bt proteins in soil**

It is feared that soil micro flora and other organisms may be affected on being exposed to cry proteins being leached from roots of Bt-crops or from incorporation of above-ground plant tissues into the soil after harvest, or by pollen deposited on the soil. Exposure may occur by breeding on living or dead Bt roots or, theoretically by ingestion or absorption after secretion of cry protein into the soil. Experiments addressing the amount and persistence of cry protein in the soil have been conducted by the registrants and the data has been reviewed by the regulatory authorities. Bt insecticidal proteins, unlike inorganic chemicals, do not have the potential to bio-accumulate causing delayed effects. An accumulation through the food chain is therefore not expected to take place, and there are no data to support this possibility for proteinaceous substances. The basic biological properties of proteins also make Bt cry proteins readily susceptible to metabolic, microbial and abiotic degradation once they are ingested and excreted into the environment. Although there are reports of soil binding under certain circumstances, the bound cry proteins are also reported to be rapidly degraded by microbes upon elution from soil.

### **Environmental Implications**

The U.S. Environmental Protection Agency (EPA) has concluded “that toxicity and infectivity risks of cry proteins to non-target organisms like avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasitoids, honey bees, annelids, and mammalian wildlife will be minimal to non-existent at the label use-rates of registered *B. thuringiensis* active ingredients.” This provides strong evidence that cry proteins produced in Bt-crops, approved for commercial cultivation, will pose low risk to non-target organisms. Published data of toxicity of un-naturally high doses of Bt protein to monarch butterfly caterpillars in the laboratory do not hold good for the natural situation where such high levels on plants are highly improbable.

### **Insect Resistance Management**

Pest populations exposed to Bt-crops continuously for several years have the potential to develop resistance to cry proteins. Resistance is not unique to Bt-crops. In view of this proactive insect resistance management strategies have been developed and are in place. A key element of these plans is that growers should plant sufficient acreage of non-Bt crops to serve as a refuge for producing Bt-sensitive insects. The refuge strategy is designed to ensure that Bt-sensitive insects will be available to mate with Bt-resistance insects, should they arise. The offspring of these matings will be Bt-sensitive, thus mitigating the spread of

resistance in the population. Gene pyramiding, optimum dose and deployment of Bt-crops as one of the components of integrated pest management are the other options for IRM.

Growing refuge has been made as one of the conditions while giving approval for Bt-cotton in India. In India, *helioverpa armigera*, besides cotton, has a large number of alternative hosts like chickpea, pigeonpea, tomato, sunflower, maize and sorghum which are grown in the same area at the same time as cotton. These may serve as natural refugia, thereby helping IRM.

All the above aspects related to bio-safety assessment and risk management will be discussed in detail.

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## **Capacity Building needs and its relevance to implementation of Cartagena Protocol on Biosafety**

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### **Introduction**

Capacity building needs are considered the key milestones need to be crossed by the developing countries including at least some developing countries in the region. In other words there should be societal acceptance of the technologies of living modified organisms (LMOs) and, in the context capacity building needs, this becomes a most relevant aspect in the safe use of LMOs. Elements of capacity building are elaborated below:

### **Institution Building**

Risk assessment includes capacity to plan, analyze and make decisions on the basis of data generated on LMOs on a case by case basis. Data are to be generated on a sound scientific basis. Assessment of risks from LMOs requires a deeper understanding of the behaviour of transgenic microorganisms, plants and animals. In all LMOs, the three factors, namely the transgenic nucleotide sequences including the host compatible promoters, the target transgene and the hosts, need to be analysed and understood through scientific methods. Core competence includes abilities to construct and identify sequences, analyze sequences base pairs and optimize conditions for the best expression of the genes in the hosts. Multidisciplinary expertise is required to develop competence, starting from molecular biology to skills in handling sophisticated instruments. In addition, knowledge in microbiology, plant sciences as well as animal sciences are also required. The relationships between the symbiotic or antagonistic activities among different forms of life are to be understood in greater detail. Additionally, expertise is also required for building competence in quantitatively estimating the transgenic traits expressed by LMOs, and their implications on the environment and on food security issues. Though developing countries may have several institutes specializing in some of these disciplines, the need for capacitating them with more sophisticated instruments and methodologies for quantitative analysis of different analytes can not be belittled. Moreover, relationships among the related institutes are also to be developed in order to enable them to broaden their horizon of activities.

The first step in capacity building in institutes is to have proficiency in the isolation of genes, preparation of construct along with development of the right cloning strategies. Transformation and isolation of fit transformants are other related areas of expertise building. After the selection of the fit transformants, the backcrossing and breeding strategies are to be adopted. The techniques in molecular biology require capacities to discover genes by the production of DNA libraries, bio-informatics (for easing sequence studies and authentication) along with capabilities to sequence natural polymeric DNA pieces. Further, there is a need for amplifying and understanding gene functioning where the transformed prokaryotic hosts are to be constructed and isolated. In addition, there is a need for molecular and bio-chemical assay of the genes and gene products. For studying the expression in plants, initially constitutive promoters are to be procured, which include ubiquitin promoter, CMV-35S promoter etc. Strategies are also to be developed for over-expression. Thereafter, target specific utilization of genes by use of tissue specific promoters and terminators are to be made. In order to isolate the target constructs, proper marker genes are also to be incorporated into the constructs. Once a transformation is complete to satisfaction, the right kinds of transformants with better agronomic benefits and traits that concomitantly have minimum risks to the environment and to human health are to be selected.

In order to carry out different experiments in molecular biology efficiently in areas of LMO plants in the Indian context, there are presently close to 25 institutes that carry out at least some components of the above work. These institutes include Indian Agricultural Research Institute; South Campus Delhi University; International Center for Genetic Engineering and Biotechnology; Jawaharlal Nehru University, National Center for Plant Genetic Resources; National Botanical Research Institute; Central Institute of Medicinal and Aromatic Plants, Central Institute of Cotton Research; Bhaba Atomic Research Center; Bose Institute; Calcutta University; Madurai Kamraj University; Tamil Nadu Agricultural University; Hyderabad University; Osmania University; Directorate to Rice Research, Indian Institute of Science; University of Agricultural Sciences; Indian Institute of Technology - Kharagpur; National Chemical Laboratory; Indian Institute of Horticulture Research; GB Plant University for Agriculture; Punjab Agriculture University; Hissar Agriculture University; Central Potato Research Institute, and the Central Tobacco Research Institute. In spite of such an impressive infrastructure, most of these institutes are unable to discover genes and transform plants into transgenic cultivars of agronomic value. Moreover, most of these institutes that have the capabilities are working on imported polynucleotide constructs including promoters, genes, terminator sequences, plasmids etc. The Indian institutes have not yet been able

to develop local materials of considerable economic value. One of the main reasons for this is that, although many of these institutes are equipped with instruments and equipment, they do not have an adequate number of trained people to carry out such a developmental work. Trained manpower in this context means a minimum number of people that have complete capabilities from gene isolation to preparation of the desirable constructs, abilities to transform the hosts efficiently, competence in transforming the transformed materials into plants, and abilities to assess at each stage the extent of transgenic traits. These call for considerable training in multidisciplinary facts of molecular biology. Therefore, unless the critical mass is in place, it would be difficult for developing countries to make inventions on a stand-alone basis. It would even be difficult to appreciate the complexities of the products and technologies.

There are several companies in the private sector such MAHYCO, Pro-Agro PGS, Syngenta, Ankur Seeds, SPIC, Rasi seeds, Rallis India, Indo-American Hybrid seeds, Bejo-Sheetal etc. that are working with Indian cultivars but are utilizing transgenic materials from foreign sources. The research carried out is primarily in the form of back-crossing and selection for isolating the most economic cultivars that are agronomically suitable in the Indian environment. This situation will not give India strength in the long run compared with the situation of developed countries where the technology in its full context is developed there.

There is therefore a need to train people, especially in the public sector, institutions to learn the process in great detail from foreign laboratories that have competence in this area. This includes training in isolating genes and polynucleotide sequences of interest, regeneration potential of transformed cells/calli and creation of stronger infrastructure.

There can also be great wisdom in collecting economically valuable Indian germplasms and using them as source materials for isolating and discovering polynucleotide sequence of economic value. This can be done if scientists from Indian Public funded institutions could visit able Research Universities and Government Institutions in developed countries and bring the transformed material back to their country and use them in agriculture. The intellectual properties developed through such process could be shared on mutually agreed terms, consistent with the IPR Laws prevalent in those countries.

In addition there is a need to spend more money in consumables per researcher per year in developing countries including India. As an example using comparisons of money spent in India on a bench level researchers in molecular biology, it is stated that, while India spends on consumables in top class



laboratories close to US Dollar 4000 per person per year, in average laboratories, spending on consumables is US Dollar 1000-2000 per person per year. The expenditure per person per year in international public funded laboratories is close to US Dollar 20,000, and about US Dollar 30,000 or more per year in private foreign industries. These expenditures reflect the amount of expensive materials the researchers have access to and are indicators of opportunities of development in different environments. The scenario in other developing countries is not much different.

### **Risk Assessment Capacities**

Besides capacity in molecular biology, most developing countries do not yet have adequate expertise in assessing the environmental risk from GM plants both on a short term basis as well as on a long term basis. Here also, there is a need to increase the capacity by creating infrastructure, protocols and trained manpower in different agricultural universities in the public domain as is stated below.

Environmental risk assessment capacities include study of the extent of pollen flow, implications of out crossing /cross fertilization, the aggressiveness characteristics of LMOs, susceptibility to diseases and pests, stability of the transgenic genome, germination rates, resistance to abiotic stresses etc. Food safety evaluation includes capabilities to determine composition and assessment of the quality of LMOs, compositional analysis and near equivalent studies of major ingredients to assess substantial equivalence, toxicity and allergenicity implications of LMOs handling procedures for allergenic substances etc. For environmental risk assessment and evaluation of food safety, a series of protocols are to be developed to address specific safety issues.

### **Involvement of Stakeholders**

The Stakeholders for the successful use of LMOs include non-governmental organizations (NGOs,) local communities, private sector units, LMO-procedures and the non-vocal local community, LMO-consultants etc. For acceptance of LMOs, scientific assessment can not be the ultimate basis for decision making, how so ever precise the scientific study may be. Scientific evaluation can not guarantee 100 percent safety, although this statement does not any way belittle the great assurance the scientific experiments provide. The gray area often constitutes a miniscule percentage of suspected risks and present scientific development does not allow precise answers to be found to such risks because of inadequate precision assessment and management tools. Consequently, while the major concerns would be adequately addressed on the basis of sound scientific experiments, there would be gray areas where the present knowledge in science

would not provide a definite answer. For example, the effects of cross-pollination by transgenic pollen to its near relatives can not be accurately predicted. The question of transfer of marker genes, including antibiotic resistant genes, from LMO plants to microorganisms and further to higher life forms, as well as the effect of such transfer can not be quantitatively resolved. In such cases, having assessed the probabilities of risks through scientific experiments and taking cognizance of the limitations of such studies, societies would have to decide on accepting or rejecting LMOs. Such decisions would have to be made on the basis of other non-scientific considerations such as cost benefit analysis and the relevance of LMOs to societal needs in relation to addressing the problems of hunger or meeting the nutritional requirements etc. In such instances the public, including NGOs, would have to play an important role in making a choice. Therefore the process for community consultation as well as NGO consultation prior to decisions will go a long way in the implementation of the Protocol.

Capacity Building Efforts - Indian expertise and experience that can be shared in the Regional Biodiversity Programme, Asia

The three top areas in which India has expertise and experience to share with other developing countries are elaborated below:

#### **Development and strengthening of legal and regulatory structures**

India has already a comprehensive legal and regulatory structure to deal with LMOs. This structure oversees the developments of LMOs from the research stage to contained use followed by large scale commercial use. All LMO plants require evaluation in the open environment. Guidelines have been developed for such field evaluation. Food safety issues are also addressed in the guidelines. There are detailed procedures for involving the state government authorities as well as scientists from state and central government institutions. The regulations adequately bring closer the scientific personnel, the government officials as well as the legal system while considering the evaluation of LMOs for introduction in the environment.

#### **Skills in Biotechnology process and applications**

India has a well developed scientific man-power who are trained in various aspects of molecular biology, immunology, microbiology, virology, plant pathology, agronomic evaluation etc. There are several R&D institutions and infra structure for the conduct of research in this area. India has also established its agricultural universities and institutional network. This infrastructure has

contributed to the development of stable, disease free cultivars that have contributed to increased food production. In many of these institutes, people can be trained in specific areas.

### **Human resources strengthening and development**

There is a strong need to have adequate trained manpower in biosafety for all aspects of biosafety protocol development, evaluation and maintenance for risk assessment and risk management. Over the years India has developed expertise in scientific, managerial and legal skills to handle LMOs. A large number of locally developed scientific protocols have been utilised to assess risks of LMOs. There is a need to involve a large group of scientists and managers to co-ordinate risk assessment programs. Here also India has gained experience through the conduct of several field experiments through out the country. Many training programs have been organised to expose the people to the nitty-gritty of risk assessment and risk management. Several countries have also consulted Indian experts in order to frame their domestic regulations. In this area also in specific aspects, India can provide training to scientists of developing countries.

## **Pest Risk Analysis for shipping wheat from Karnal bunt (*Tilletia indica*) infected areas to disease free destinations**

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### **Introduction**

The Karnal bunt (*Tilletia indica* (Mitra)) is native to South Asia. It was identified in 1931 (Mitra, 1931,1935) from Punjab and it is generally felt that the pathogen was there much earlier. The disease always existed, causing concern here and there but, unlike the cereal rusts, it never caused serious yield reduction. However, due to unexplainable reasons, this cosmetic disease of wheat that had very limited world wide distribution (Nagarajan et al., 1997) became a quarantine concern interfering with free and fair grain trade. The wide public attention that KB received when it was reported from the USA to be sneaking through the stringent quarantine precaution created panic in the grain trade circles. Europe, Canada, Australia and many of the wheat exporters saw a need for zero tolerance to KB to arrest the spread of this obscure pathogen to new areas. Inadequate access to the epidemiological knowledge made many believe that the pathogen would spread to wheat growing areas with a temperate climate if the flowering stage of the crop coincided with the weather conditions that are congenial for infection. The trade complications that followed this unfounded fear made it necessary to develop a scientifically sound, data based and transparent Pest Risk Analysis so that the KB prevalent wheat exporting nations and the importers were not forced into unnecessary negotiations.

Pest Risk Assessment (PRA) in the SPS Agreement is defined as ‘The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of a member according to the sanitary and phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human and animal health arising from the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or foodstuffs’ (Devorshak, 2000). The FAO’s IPPC (International Plant Protection Convention) uses the PRA to define the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measure taken against it.

The KB pathogen *Tilletia indica*, survives in soil as teliospores and spreads to new areas along with contaminated seed and/or infected grain. Long and stout promycelium (germ tube) germinates from teliospore under field conditions particularly under optimum temperatures (20 - 25oC). The promycelium bears a bunch of primary or filiform sporidia (macrosporidia) on the tip. Further secondary or allantoid sporidia (microsporidia) are formed when the field temperature fall to 10 - 15oC through the process of budding/ germination / transformation of primary sporidia. These secondary sporidia are transferred from the soil surface along with water splashes and land on the lower leaves where they multiply by self budding. Enroute infection site (the spikelet), allantoid spores perform monkey jumps to reach boot leaf from where, with the help of rain/dew drops, they flow down into the spike emerging out of the boot. Successful penetration of florets and ovaries by allantoidal germ tubes needs a low temperature of 10 - 12oC and saturated humidity (100% or free water) in the spike, which is provided by rain or dew at the time of flowering. This basic knowledge of disease epidemiology can be pooled together with temporal facets of crop growth, as well as cultural inputs, to develop a flexible model of PRA for establishment of KB in non-traditional areas. Wind and water normally do not spread the teliospores or the microconidia for more than a distance of a few kilometer. Therefore, the PRA requirement is confined to commodity movement or trade and seed / grain is the primary pathway for the pathogen to spread to new areas. Entry point quarantine and post shipment certification systems will reduce the risk of pest spread during commodity trade.

#### **KB risk assessments - Utility of comparing weather at infection time:**

Environmental conditions dictate where *T. indica* can survive and cause damage. A comparison of meteorological information from KB infested to non-infested regions of the world would show that KB has little potential for long-term establishment in the cold temperate climates of the world. The potential for *T. indica* to survive and infect wheat is restricted less by physical requirements for survival of the teliospore than by synchronization of wheat heading with climatic conditions favorable for teliospore germination, secondary sporidial multiplication, penetration and infection.

The spread of KB to different ecological zones on the Indian subcontinent and its appearance in other geographical areas of the world has been the logic behind the argument (Zhang et al., 1984) that the pathogen possesses great adaptability to different climatic conditions. But in fact, in India KB is confined to the places

where it was earlier known to occur in the 1970s and has simply not spread to the wheat areas south of Narmada river or to places above the snow line in the Himalayas or to the arid desert of western Rajasthan .

### **Post harvest handling of grain: Indian system**

The states of Punjab and Haryana, parts of Western Uttar Pradesh and terai areas of Uttarakhand in NWPZ and parts of Central Zone (e.g. Malwa region) are some of the important grain surplus exporting regions of India. Normal sown, irrigated, well-fertilized wheat is harvested by the third week of April in NWPZ and by mid March in the CZ. Nearly 50% of the area in NWPZ is combine harvested and, where hand harvesting is done, bundles remain in the field for 4-5 days to dry and then threshing is done by machine. The entire process may last for 7-10 days and is exposed to the vagaries of weather. The harvested grain is moved to the procurement centers/ grain mandis (grain markets) in tractor trolleys or trucks. Here, the trader cleans and grades the produce and the grain may remain in the open for another 4-5 days. Following this, the commission agents store the grain in gunny bags, pile them up and keep it covered by black LDPE sheets (CAP storage). From here, depending on the destination, the grain is transported in trucks or railway wagons to various parts of the country. The time taken for surface movement of the grain from Ludhiana (Punjab) to southern destinations may take about 7 to 10 days.

### **Geo-phytopathology in relation to KB**

In India, North West Plain Zone is endemic to KB and, despite a continuous free movement of grain from this place to destinations with different weather conditions, the disease has not spread to all the 25 million hectares sown to wheat. On the basis of several years of disease occurrence data wheat, growing areas have been delineated as high-risk, medium and low risk zones. The KB incidence in these tracts may vary year to year, depending on the climatic factors and the availability of inoculum. In the case of certain regions/ states, the disease does not occur every year and it is only once in several years that the disease makes its appearance. This occurs only under certain specific environmental conditions and these regions are termed as low risk zones. The wheat growing areas in the Himalaya above the snow line can be termed as 'no-risk zone' since the disease never occurs here despite being close to the endemic belt.

Data on disease (KB) incidence collected over the years has been tabulated in Table 1. From this data, it is clear that in the states of Punjab, Haryana, Western Uttar Pradesh including the foothills of the newly created state of Uttranchal, plains of Himachal Pradesh, Jammu and Kashmir and Delhi are high-risk areas. The second group of states or regions is northern Rajasthan, central and east Uttar Pradesh, Bihar, north and Madhya Pradesh where the disease has been recorded occasionally are medium risk areas. In Gujarat, few grains of KB were recorded only three times out of 13 years. During 1990's, only once, during 1993, did the KB incidence reach a maximum of 0.16% at few locations. After 1993, KB has so far not been recorded from Gujarat in the various grain surveys. Wheat growing areas of Maharashtra, Chattisgarh and Karnataka are free from KB.

In India, the KB endemic zone lies within 28-33° N latitude whereas, the low risk zone extends up to the Tropic of Cancer (23 1/2° N) and further south is the 'no risk zone'. By coincidence, the KB reported areas of North America are also between the tropic of Cancer (23 1/2° N) and 33° N. The West Asian countries where KB is known to occur are also between these latitudes. If we consider the KB report from South Africa to be authentic, then there, also, the wheat belt is between the Tropic of Capricorn (23 1/2 ° S) and about 33° S.

#### **A rapid KB risk estimation based on geo-agronomic input: a computer software developed under ICAR - USDA collaboration**

The computer software developed to evaluate the probability of risk of KB consists of two parts. The first part "GEOKB" was designed by assigning probability values for KB occurrence at locations in different latitudes and agronomic conditions according to the wheat growing at the particular location. A metric system was followed to assign the probability of risk to KB. Only in exceptional cases, where there was a feeling that the increase or decrease of associated risk is not in a logarithmic manner, different values were assigned. The second part of the software 'KBRISK' utilized the climatic data and production models to evaluate the probability of KB occurring/ establishing.

Table 1

The Kb Situation During 1977-78 To 1999-2000 Crop Season (State-Wise)  
In India.

| S. No. | State                    | No. of Years            |                    | No. of Times infection monitored |            |     |     |     | Highest level | No. of times during 1991-2000 | %   | No. of times during 1991-2000 | Remarks (Risk Zones) |
|--------|--------------------------|-------------------------|--------------------|----------------------------------|------------|-----|-----|-----|---------------|-------------------------------|-----|-------------------------------|----------------------|
|        |                          | No. of Yrs of infection | Total No. of years | %                                | Zero Level | <1% | <2% | <5% | >5%           |                               |     |                               |                      |
| 1      | Punjab                   | 18                      | 18                 | 100                              | 0          | 0   | 0   | 0   | 18            | 5/5                           | 100 | 8/8                           | HRZ                  |
| 2      | J & K (Foot hills)       | 16                      | 16                 | 100                              | 0          | 0   | 0   | 0   | 16            | 5/5                           | 100 | 9/9                           | "                    |
| 3      | Haryana                  | 18                      | 18                 | 100                              | 0          | 0   | 0   | 0   | 13            | 5/5                           | 100 | 9/9                           | "                    |
| 4      | H.P (Lower parts)        | 14                      | 14                 | 100                              | 0          | 0   | 0   | 0   | 14            | 2/2                           | 100 | 8/8                           | "                    |
| 5      | Delhi                    | 11                      | 11                 | 100                              | 1          | 1   | 2   | 5   | 5             | -                             | -   | 4/4                           | "                    |
| 6      | U.P. (West)              | 17                      | 17                 | 100                              | 0          | 0   | 0   | 2   | 15            | 5/5                           | 100 | 8/8                           | "                    |
| 7      | Rajasthan (East & North) | 11                      | 15                 | 73.3                             | 4          | 2   | 5   | 7   | 4             | 3/5                           | 60  | 5/8                           | LRZ                  |
| 8      | Bihar                    | 4                       | 15                 | 26.6                             | 9          | 0   | 1   | 2   | 4             | 1/3                           | 33  | 1/5                           | 7.7% in 1993 LRZ     |
| 9      | Gujarat                  | 3                       | 13                 | 23.1                             | 10         | 2   | 0   | 0   | 1             | 0/5                           | 0   | 1/8                           | 0.16% in 1993 LRZ    |
| 10     | M.P.*                    | 8                       | 17                 | 47.0                             | 9          | 5   | 6   | 7   | 1             | 1/5                           | 20  | 3/9                           | 0.7% in 2000 LRZ     |
| 11     | Maharashtra              | 0                       | 15                 | 0.0                              | 15         | 0   | 0   | 0   | 0             | 0/5                           | 0   | 0/9                           | NRZ                  |
| 12     | Karnataka                | 0                       | 11                 | 0.0                              | 11         | 0   | 0   | 0   | 0             | -                             | 0   | 0/4                           | "                    |



\*Commercial samples from Mandies are mostly free, only rarely, some samples are infected. However, seed production forms having seed of wheat varieties from endemic areas coupled with sprinkler irrigation show KB in low level.

Abv. HRZ = High Risk Zone; LRZ = Low Risk Zone; NRZ = No Risk zone

Source : Various AICWIP/DWR annual reports.

### **Geographic weightage: the backbone of GEOKB**

The diverse wheat growing mega environments in India have several micro niches and, due to the associated minor climatic variations, the frequency of occurrence and severity of KB varies even within a zone. The wheat disease survey has been conducted for the last 30 years and detailed field data are available. On the strength of these data some KB probability values were assigned for the micro niche in different wheat growing environments.

The mountainous NHZ covers the lower Himalayas (<1000 m), the middle Himalayas (~2000 m) and the Higher Himalayas (> 3000 m). The climatic conditions vary widely with the elevation even though the physical distance between each may be just a few kilometers. The KB probability therefore is rated as 1.0; 0.01 and 0.001 for the three elevations.

The NWPZ can be divided into three situations as the foothill plains, river or canal plains, and desert vicinity and the probability of KB occurring in these locations was rated as 1.0; 0.5 and 0.01, respectively. Similarly in the NEPZ the Himalayan tarai, area around the Ganges system, and the non-irrigated tracts were assigned a KB probability value of 0.5; 0.2 and 0.001, respectively.

The All India Coordinated Wheat Improvement Project (AICWIP) organizes centrally distributed yield trials that involve growing wheat at different sites all over the country with many sites in each zone. The AICWIP completed its 40th year recently. KB has not been wide spread in CZ and is not known to occur in the PZ even though there are more than a dozen locations where these trials are conducted each year. Based on an educated guess on the probability of KB occurring in an area, certain values were assigned. The highland of CZ where sprinkler irrigation is popular was assigned a KB probability value of 0.01 and the surface irrigated or rainfed wheat was given a value of 0.001. In the PZ, KB does not occur either under 120 or in 95 days crop and so was given a value of 0.01 and 0.001. The Wellington, Nilgiris in the Southern Hill Zone receives wheat-breeding materials from different parts of the country for generation advancement, screening against rusts and to make corrective crosses. The summer nursery facility has been in operation for more than 40 years, yet KB

has never been intercepted in the SHZ. This only implies that the environment in SHZ is a major limitation as both vulnerable hosts and some infected seeds get planted by mistake every year. The KB risk probability here was rated as 0.0001.

The probability of KB appearing in Ludhiana, Karnal, Jodhpur, Indore, Pune, Dharwar, Katrain and Meshobra was calculated using the GEOKB software. Except for Ludhiana and Karnal the probability of KB occurring turned out to be very low indicating that the risk involved is negligible since the probability predicted by GEOKB is nearly zero. This can be used as rapid probability appraisal, to estimate the potential risk of KB establishing in a location upon introduction.

Assigning probability values for agronomic details: modulates the assessments of GEOKB

Choice of a variety of a particular duration is important as this decides if the flowering will coincide with the possible KB prone weather or not. Varieties that are of long duration, for a given zone, will invariably be sown in time with adequate fertilizer application and proper irrigation scheduling. Very little experimental data is available on the effect of irrigation, weed control, fertilizer dose etc. on KB occurrence. Most of the available experimental data on these agronomic parameters are based on single treatment and response methods. The response curve generated by such studies has served as the basis for assigning certain probability values.

The date of sowing of wheat varies considerably between the zones and is dependent on the favorable wheat-growing period. Wheat sown between November 1-15 is the most vulnerable to KB in the endemic areas. Both very early sown and very late sown wheat has a tendency to escape KB infection as the probability of congenial weather and adequate inoculum coinciding with the vulnerable period is less. The probability values were ascribed to different sowing dates in the various wheat growing environments accordingly.

Simulation model 'KBRISK': pools together the facts of the disease cycle, pathogen's life cycle, weather and crop phenology

Based on the number of favorable and unfavorable days during the post harvest over summering period, teliospore germination, macro conidia production, micro conidia multiplication cycles, micro conidia infection, teliospore initiation or sorus development the risk probability was calculated. Mathematical models (linear / quadratic) were developed using the data reported in literature. The temperature range under which the model is functional and the probability value assigned beyond this range has also been indicated. The models fitted had very

high R<sup>2</sup> value and from these models the p (probability) value for KB was calculated separately for maximum temperature, minimum temperature, relative humidity and rainfall (wherever applicable). All were then integrated to get one probability, say for teliospore survival for the period of concern.

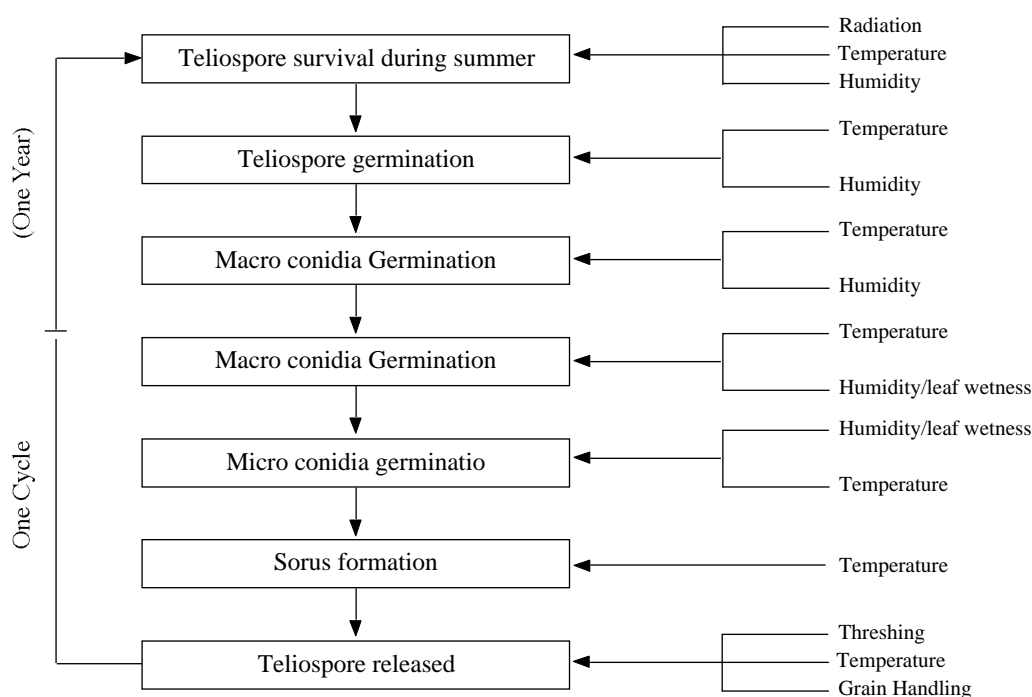
Subsequent to infection, the mycelium of *T.indica* moves systematically to adjacent kernels within a spikelet or even to adjacent spikelets. The pathogen converts the grain into a sorus by producing a mass of teliospores and this becomes visible only after the dough stage, when, due to the prevalence of high temperatures, the grain gradually hardens. In fact, there is no experimental data to show the effect of temperature on sorus development. Many workers have taken it for granted that infection is equivalent to symptom expression, as though 'latency' does not occur in this disease. To overcome this, based on our years of observation we have attributed some values for the role of temperature on sorus development.

Similarly the computer programme calculated the p value for all the stages of the life cycle mentioned in Figure 1. Whenever the conditions are beyond the range of the weather parameter, the KBRISK terminates the operation and a computer out-put is given showing the stage when life cycle is interrupted and that KB will not occur. Only when the conditions needed for the various life cycle stages are complete, the KBRISK produces the probability of the disease getting established in the new area.

**Figure 1**

**Flow diagram on the life cycle process of *T.indica*, and major weather parameter that influence it.**

**Table 1**



### Grey areas of knowledge

The study indicated how the data base in KB is often fragile. Since pieces of information generated by various discrete groups form the foundation of the analysis, there is further scope to improve this PRA by establishing a globally coordinated research trial to augment the data base and make the simulator much more robust.

The literature is totally silent on 'latency'. It is quite likely that infection by micro conidia may occur but conditions may not lead to sorus development. It has been presumed that once infections occur symptoms must appear and that there is no latency. However this presumption that infection is equivalent to disease symptom expression and that there is no latency needs experimental verification. So also the viability of teliospore under dry summer desiccation or heating and showing needs critical examination.

This therefore leads to the need for a strong 'floor coordination' in data generation and usage by those who are badly hit by KB.

The present attempt has put in place a more reliable PRA for KB and it is expected that Indian wheat grain movement will be facilitated as several concerns can be answered in a more scientific and transparent manner.

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## **4. RECOMMENDATIONS FROM GROUP DISCUSSIONS**



## **RECOMMENDATIONS FROM GROUP DISCUSSIONS**

### ***GROUP 1: IDENTIFICATION OF CAPACITY-BUILDING ELEMENTS***

Terms of Reference:

The group discussed the following ideas and options in addition to others as decided by the group members:

- a. What are the capacity needs to address issues of risk assessment and management - Technical, scientific, policy, legal participatory and information
- b. What are the existing capacities in the region - specific or non-specific
- c. What needs to be done to either create or strengthen such capacities
- d. Who will be doing this and how will it be done - eg. Training programmes, development of information documents and materials, networks, exchange of experts, regional collaboration
- e. How will these issues be taken up at either ICCP 4 or CoP - MOP

#### **Recommendations:**

The participants considered that the capacity building elements could be classified into the following areas:

- Assessment of environmental safety by scientific methods
- Assessment of food safety of LMOs
- Capacity in handling LMOs legally through a sound administrative structure
- Capacity to exchange information within and outside the territory of Parties

#### **1. ASSESSMENT OF ENVIRONMENTAL SAFETY BY SCIENTIFIC METHODS**

The participants identified that the following elements should be sharply focused for building scientific capacity:

- a. There is a need to examine the rationality of the transgenic constructs including the elements of nucleic acids introduced. These include examination of the promoter sequences, the genes, the terminator sequences, the enhancers, the markers, and other coding and non-coding transgenic elements.



- b. It is essential stability of the LMOs in the field conditions. This requires at least two seasons or two generations of trials in open environments for large LMOs like plants and animals, and several generations for micro-organisms. Capacities to write required protocols for conducting above studies should be in place.
- c. Different kinds of LMOs require generation of different kinds of data. For all kinds of Bt insect-resistant plant-LMOs, baseline data of generation of susceptibility for each target pest under a set of conditions. Different environmental conditions may require generation of data de-novo. Capacity-building includes production of transgenic micro-organisms like E-coli where the expression needs to be maximized and the micro-organisms may be multiplied for producing large quantities of target proteins. Without adequate quantities of the target protein in hand, it will be difficult to generate the baseline data. Capacity also requires setting up of insect-rearing facilities and bioassays.
- d. Gene flow for plant materials that are often cross-pollinated requires to be determined for those LMOs that have near relatives in the wild environment in a given geographic location. For self-pollinated plants, adequate data need to be generated to ensure cultivating practices that prevent the escape of pollens into the open environment. Capacity building needs are to develop protocols to address issues. Simple and sound analytical methods for tracing the transgenic traits in the open should be in hand.
- e. Analytical methods to detect the transgenic traits in terms of nucleic acids and proteins should be in place for assessing all kinds of LMOs. Generally, PCR methods are to be established for detecting and quantitatively assessing the nucleic acids. Proteins are assessed by ELISA method. There can also be other biochemical tests. Capacity-building efforts include either in-house proficiency in the above analytical methods or access to testing formats from purchased sources.
- f. Since the effects of several LMOs to non-target organisms are not yet fully known, there is a need to devise experiments to address specific issues to find out the effects of LMOs on non-target species. These include effects on soil micro-organisms, beneficial and other insects, neighbouring plants, and animals. The effects should be measured based on direct ingestion or through indirect exposure. Capacities include understanding the problem scientifically and the associated infrastructure for conducting the experiments.

- g. The aggressiveness studies for LMOs compared to their non-LMO counterparts also need to be carried out to determine if the LMOs are different in terms of fitness properties.

## **2. ASSESSMENT OF FOOD SAFETY OF LMOs**

LMOs entering into human or animal food chains can become toxic or allergenic. This will depend upon the inserted trait and the degree of expression of the inserted trait. Experiments are therefore to be mounted to conduct appropriate animal model studies under lab conditions. Protocols are to be written for conducting such studies. Usually, adult lab animals can be utilized for such studies. In-vitro lab studies to conduct antigen-antibody binding assays, RAST studies, etc. can be conducted to get initial indications about allergenicity. A comparison of the sequence of 6 to 8 amino acids continuously appearing in a protein being examined for allergenicity can be made from the already available databank.

## **3. CAPACITY IN HANDLING LMOs LEGALLY THROUGH A SOUND ADMINISTRATIVE STRUCTURE**

- a. The availability of a sound legal framework is the first step for a country to implement the Cartagena Protocol on Biosafety on a legal footing. The legal framework of the country should be consistent with the Biosafety Protocol but can be more stringent. The legal framework should adequately address the issues related to illegal entry or use of LMOs into the territory of Parties. The administrative structure should be simple, implementable, and should have access to scientific bodies in order to generate scientific information or verify the transgenic traits in substances that are under scrutiny. The legal structure can also draw from the capabilities of neighboring countries wherever possible.
- b. There should be possibilities for exchange of experts from within the country as well as among neighboring countries in order to complement the efforts in administering the Biosafety Protocol within the legal framework.
- c. Public awareness is recognized as one of the crucial elements for accepting LMOs. Mechanisms are therefore to be built to create linkages for public awareness through media, arranging seminars, etc.

#### **4. CAPACITY TO EXCHANGE INFORMATION WITHIN AND OUTSIDE THE TERRITORY OF PARTIES**

- a. The participants recognized the need for creating inter-linkages within the different administrative bodies of the country through electronic networking. Computer-friendly software can be devised for this purpose.
- b. There was also a need to develop electronic linkages among the countries so that information can be exchanged fast. Participants felt that having such networking in place would enable the countries to obtain information from neighboring countries much easier.
- c. Participants felt that every country should have a Biosafety Clearing House focal point and a site where country information can be submitted.

#### ***GROUP 2: REGIONAL COOPERATION***

Terms of Reference:

The purpose of this group discussion was to come up with some clear ideas and options for regional cooperation on issues of risk assessment, management, capacity building and exchange of information and experiences. Some pertinent questions in this regard include:

- a. Who are the regional players in this area
- b. What expertise they have and what they can offer
- c. What are the kinds of issues on which regional collaboration would work the best
- d. What are the mechanisms that should be put in place to enhance regional cooperation - institutional, information, exchange of expertise, roles of regional activities, regional institutions etc.
- e. Once these are identified how will the cooperation be ensured - roles and responsibilities
- f. When should such mechanisms be supported and how

#### **Recommendations:**

Considering the need for enhanced regional and sub-regional cooperation to address issues of safety in biotechnology, in general, and risk assessment and risk management, in particular:

The group recommends:

- Regional Cooperation should not only happen between governments but also between the following: Private sector; NGOs; Universities; Government Research Institutes/ Agencies; Farmers Organisation; Funding Agencies; Regional and International Institutions; Consumers Association; Ministries and Others
- Regional cooperation is needed in information sharing, learning from successes and failures, developing best practices, planning projects, scientific areas like testing, evaluation.
- The areas cooperation and exchange of information and expertise include those of
  - a. Initial establishment of regulations and procedures
  - b. Testing and evaluation of safety at laboratory and experimental stages
  - c. Training and technical issues
  - d. Public education, awareness raising
  - e. Scientific Assessments on impacts to environment and biodiversity
- Cooperation between countries need to be enhanced through:
  - a. Establishment of regional 'Body' to help exchange of information, expertise, undertake enabling activities in biosafety. Where available such bodies should be strengthened (eg. ASEAN Secretariat, IUCN Regional Biodiversity Programme, Asia).
  - b. Establishment of an information center on Biosafety at ASEAN and SARRC levels
  - c. Creating networks at sub regional and regional levels through focal points to facilitate regional collaboration.
  - d. Funding for Regional level activities including training, exchange of scientists, conducting assessments and exchange of information.
  - e. Expanding the scope of trust funds under Cartagena Protocol to include using services of experts other than those existing in roster of experts.
  - f. Strengthening the roster of experts under BCH and increasing their numbers and areas of expertise considering the need of additional and varied expertise needed to implement the protocol.

- g. Providing Funding option/opportunities for regional/subregional exchange of information and expertise at all levels. ( eg. through provisions in country projects where countries are preparing NBF projects and demonstrations projects. The proposals can incorporate this element).
- Legal issues pertaining to multilateral agreements such as under the WTO are going to impact implementation of biosafety protocol. Foreseeing this trend, workshops on legal issues pertaining to biosafety should be conducted. These should target policy makers, legal experts and technical persons. Additionally, national and regional training programmes may be needed on issues like.
  - a. Monitoring of LMO's at field level
  - b. Exchange of experience in developing public awareness programmes
  - c. Communication
  - d. Publication of regional newsletter or appropriate information exchange mechanism is also recommended

### **GROUP 3: SOCIO-ECONOMIC AND LEGAL CONSIDERATIONS**

Terms of Reference:

The purpose of this group discussion was to identify the need for socio-economic assessments and to address issues of legal mechanisms. Some of the questions considered include:

- a. What should be the basic socio- economic considerations that need be considered before deciding on introduction of technology(ies)
- b. How will the socio-economic assessments be carried out - indicators etc.
- c. How will legal issues be addressed while developing and developing national biosafety frameworks

How will be the legal capacities built and institutionalised - capacities, needs, mechanisms

#### **Recommendations:**

The group discussed issues of socio-economic and legal assessments needed at regional and country levels to enhance the usefulness of modern biotechnology so that rural livelihoods and traditional practices are not threatened by the advent of modern biotechnology.

The following issues and respective considerations were put forward to be a prelude to countries embarking on large-scale commercial use of LMO's.

## **1. SOCIOECONOMIC CONSIDERATIONS**

Considering the impacts of biotechnology on rural poor and traditional practices the following issues need priority attention:

- i) Feasibility studies on uptake of new techniques by
  - Economic feasibility vis-a-vis cost effectiveness
  - Choices for farmers;
  - Acceptance levels at local community level
- ii) Public awareness should be enhanced to discuss benefits and disadvantages of adoption of the technology. The target group should include: farmers, general public and all stakeholders
- iii) The degree of acceptability of new technology by all stakeholders should be gauged using appropriate indicators.
- iv) Traditional and indigenous practices should be conserved and protected
- v) The nexus between the technology and local socio-cultural practices should be assessed and measures taken to support protection of such practices.
- vi) Marketing potential should be assessed in comparison with available options.
- vii) The biggest social concern whether the technology marginalise already marginalized small farmers and landless labour should be duly addressed
- viii) Among the ecological concerns, the following issue needs to be understood before venturing into the new technology:
  - Studies related to threats to wild races
  - Impacts of LMO's on conservation of biodiversity
  - Options to preserve native germplasm of traditional varieties in vogue
  - The possibilities of LMO's turning into Invasive alien species
- ix) The technology should address national priority issues in the fields of Agriculture and Health care

## **2. INDICATORS FOR SOCIO-ECONOMIC ASSESSMENT**

To assess the socio-economic issues, the following indicators need to be developed, used and monitored at local, national and regional scale:

- i) It is recommended to initiate studies that addresses the demand for the technology through primary market surveys
- ii) a) Before adopting the new technology, the following indicators relevant to agriculture sector needs to be developed
  - yield variations
  - stability analysis
  - quality of life of farmers
  - Human Development Index
  - Health indicators (eg; pesticide residue content)
  - Environmental indicators
- b) Amongst other parameters, it is recommended to look at the Target Disease Incidence Index (TDII) for the use of technology in fields of medicine and pharmacology.
- iii) It is recommend to draw feedback through public awareness programmes; structured and semi-structured questionnaires; focus group discussions for assessing the level of acceptance of the new technology.
- iv) Sector-wise contribution of the technology to the country's GDP should be assessed.
- v) A network of countries proposing the technology should share the experiences, lessons learnt for enabling the respective governments to allocate sufficient funds for Research and Development, commercialisation of the product and capacity building.

## **3. LEGAL ISSUES IN DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS**

The major issues for development of legal frame work for implementing the biosafety protocol includes:

- i) Promoting participatory approach at the level of policy makers and implementers of the biosafety law especially in risk assessment exercises

- ii) Issues of transparency
  - iii) Ensuring flexibility of biosafety framework for periodic review
  - iv) Developing legal capacities for implementation of National Biosafety Framework
  - v) Protecting farmers' rights and safeguard IPR
  - vi) Promoting documentation and information dissemination on all aspects of legal framework
  - vii) Adopting a case-by-case approach for assessment and approval of the technology
  - viii) Addressing issues of stopping biopiracy
  - ix) Promoting the 'Precautionary approach' with respect to dealings with LMO's (as stated in Cartagena Protocol)
  - x) Ensuring that the National laws are compatible with multilateral agreements
  - xi) Assigning responsibilities and share rights with all stakeholders involved.
  - xii) Developing a balance between trade and environmental issues
  - xiii) Facilitating risk assessment and risk management.
- Implementation mechanisms should be clearly defined including penalty for offenders
  - It is necessary to establish dispute redressal committees at the local level to address outstanding issues
  - Adequate provisions and budget should be made available to the legal body implementing the biosafety protocol for monitoring research and development in areas of genetic engineering

#### **4. LEGAL CAPACITY BUILDING AND INSTITUTIONALISATION**

Considering the lack of awareness of biosafety protocol in the legal circles, it is recommended to institutionalise the activity and build capacity at various levels of the country's judiciary.

Amongst the others parameters, the following issues need to be addressed on a priority basis.



- i) It is recommended to sensitize stakeholders including policy makers, legislators, Legal academics and all others concerned
- ii) Action oriented awareness programmes concerning biosafety legal framework for school, college and university students should be organised
- iii) The implementers of the biosafety framework should be familiarised with all technical aspects of the subject.
- iv) It is suggested that the national biosafety framework should be institutionalised by forming a National Biosafety Board and members of this board should be selected from the roster of experts maintained at the national level.
- v) It is advised to develop and manage databases for all LMOs related activities and should be made available to all interested by hosting it in respective country Biosafety Clearing House websites.

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