Asia Regional Workshop on Risk Assessment and Risk Management in Implementing the Cartagena Protocol on Biosafety

C O N T E N T S

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

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Introduction

Capacity building needs are considered to be the key milestones to be successfully crossed by the developing regions including at least some developing countries in the region to enable the confidence building exercise. In other words there should be societal acceptance of the technologies of living modified organisms (LMOs) and in the context capacity building needs become most relevant aspect in the safe use of LMOs. The capacity building element constituents are elaborated below:

Institution Building

Risk assessment includes capacity to plan, analyze and take decisions on the basis of data generated on LMOs on a case by case basis. Data are to be generated on sound scientific basis. Risks from LMOs include 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 compatibles promoters, the target transgene and the hosts need to be analysed and understood through scientific methods. Core competence include 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 of sophisticated instruments. Besides, 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. Besides, 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, right relationships among the related institutes are also to be developed in order to enable them to broaden their horizon of activities.

The first steps in the capacity building needs of institutes are 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 strategy 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 in the transformed prokaryotic hosts are to be constructed and isolated. In addition, there is a need foe 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 completed to some satisfaction, the right kinds of transformants with better agronomic benefits and traits are to be selected that concomitantly have minimum risks to the environment and to human health.

In order to carry out different experiments in molecular biology efficiently in areas of LMO plants in 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. Inspite 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 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 form 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. Unless, therefore, the critical mass is in place, it would be difficult to make inventions by developing countries on a stand-alone basis. Even it would be difficult to appreciate the complexities of the products and technologies.

There are several companies in the private sector such MAHYCO, Pro-Agro PGS, Syngenfa, Ankur Seeds, SPIC, Rasi seeds, Rallis India, Indo-American Hybrid seeds, Bejo-Sheetal etc. Which 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 Indian environment. This situation will not give India strength in the long run when one compares 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 form foreign laboratories that have competence in this area. These include training in isolating genes and polynucleotide sequences of interest, regeneration potential of transformed cells/calli and creation of stronger insfrastructure.

There can also be great wisdom in collecting economically valuable Indian germplasms and use 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 of comparison of money spent in India on a bench level researcher 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 against US Dollar 1000-2000 per person per year in average laboratories in the country, 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 environment. The scenario in other developing countries is not much different.

Risk Assessment Capacities

Besides capacity in molecular biology, most developing countries yet do not 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 have been stated as under.

Environmental risk assessment capacities include study of extent of pollen flow, implications of out crossing /cross fertilization, the aggressiveness charateristics of LMOs, susceptibility to diseases and pests, stability of the transgenic genome, germination rates, resistance to abiotic stresses etc. Food safety evaluation includes capabilities of determination of 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 the acceptance of LMOs, the scientific assessment can not be the ultimate basis of decision making, how so ever precise the scientific study may be scientific evaluation can not guarantee cent percent safety, although this statement does not any way belittle the great assurance the scientific experiments provide for. The gray area often constitute a miniscule percentage of suspected risks and the present scientific development does not allow to find precise answers 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 along with 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, the societies would have to decide on accepting or rejecting LMOs. Such decisions would have to be take on the basis of other non-scientific considerations such as cost benefit analysis, 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 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 the 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 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.

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

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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".

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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 he 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 the conduct of the risk assessment. First, 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.

Second, 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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GMOS: INDIAN LEGAL FRAMEWORK AND SCIENTIFIC PROGRESS

Introduction

It is the expectation that the Genetically Modified Organisms (GMOs) were going to play important role in the economic uplifting of India in its various facets of applications including human and animal health care system, 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 was 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 this can be unsafe too. This will depend upon the trans-genes, the host organism and the environment where the GMO is being tested. In case of GM plants, in laboratory experiment, 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 protected attack from insects but such portatoes were not safe to rodents when they 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 porteins would affect the silkworm larvae, as these are insects that are susceptible to Bt proteins. There are examples of microoganisms, 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 microogranisms 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 Committee constituted by the Department of Biotechnology of the Union Ministry of Science & Technology is to monitor on the developments in biotechnology at National 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.

The Review Committee on Genetic Manipulation (RCGM)

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

RCGM can approve application for generating research information on transgenic microoganisms. The growth of microoganisms. The growth of microorganisms under sterile conditons in a fermentation vessel under submerged conditions 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 puts conditions of contained use of the biorecactors in order to prevent the escape of genetically modified microorganisms into the open environment.

The procedures for safe handing 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 are generated under authorization of RCGM in contained green house as well as in small plots. The 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 open environment is made to seek answers to relevant and necessary questions on envirionmental 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 apporpriate systems including animals 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 and lcoing 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. All expriments using GMOs, which belong to risk category-III, and abive as elaborated in the guidelines require authorization (permit) to be issued by the Department of Biotechnology for

conducing such experiments. All such permits are issued on the basis of the recommendations of the RCGM. According to the Indian classification of risks, the Category-I risks involve routine recombinant DNA experiments in 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 up to 20 liter geometric volume can be Category-II risk experiments, if the transgenic microorganisms or cell limes use 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 human and animals. Other Category-III risk experiments involve genes/DNA of microbial, plant or animal origin, which can cause alterations in the biosphere and does not fall in Category-I & II. All open field experiments of GMOs howsoever 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 such conditions as would be required to generate long-term environmental safety data from the applicants seeking release of transgenic microorganisms, plants and animals into the open environment. RCGM can also setup expert committees to monitor the research experiments. For monitoring the contained field experiments with GM plants, the RCGM had setup a Monitoring cum-Evaluation Committee (MEC) with many agricultural experts as its members. MEC makes on the spot visits of the experimental sites and advises the RCGM about the steps to be followed in the conduct of experiments for assessing agronomic benefit, besides conducting environmental risk assessments.

The RCGM had 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 enviroment; they are also designed to create reasonably effective barrier to prevent the escapte 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. Furhter 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 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 limied 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 hepatatitis B Vaccine etc. are being experimented upon in different laboratories in the country. Recombinant yeast species of Saccharomyces cerevisae, Pichia pastoris, Hanseneulla 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 dosages 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 micorroganism 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 elicing 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 enviroment) 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 osme 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.

Indian Developments in transgenic research and applications

Institute	**Plants/crops used for transformation**	**Transgenes inserted**	**Aim of the project and progress made**
Central Tobacco Research Institute, Rajahmundri	Tobacco	Bt toxin gene Cry 1A(b) and Cry1C	To generate plants resistant to H.armigera and S.litura. 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.
Delhi University, South Campus, New Delhi	Mustard/ rape seed	Bar, Barnase, Barstar Marker gene remover (cre-lox)	Plant transformations completed and ready for green house experiments. Plants with marker genes made.
	Rice	Selectable marker genes	Transformation completed with marker

Institute	Plants/crops used for transformation	Transgenes inserted	Aim of the project and progress made
		(hygromycin resistance and gus). Abiotic stress tolerant genes (codA,dor47, hsp1).	
	Cotton	Cry 1 A © gene	Transformation completed
	Wheat	Abiotic stress tolerant gene (hva 1)	Transformation completed
		Insect resistance (Pin 11)	Transformation completed
	Brinjal	Abiotic stress tolerant genes (adc, mtl D, imt I)	Transformation completed
		Fungal resistance (glucanase)	Transformation completed
	Tomato	CTX-B	Transformation completed
Indian Agricultural Research Institute sub station, Shillong	Rice	Bt toxin gene	To impart lepidoteran resistance, transformations in progress
Central Potato Research Institute, Simla	Potato	Bt toxin Gene	To generate plants resistant to lepidopteran pests. Ready to undertake contained field trials.
M/s Proagro PGS (India) Ltd, Delhi	Brassica/Mustard	Barstar, Barnase, Bar	To develop better hybrid cultivars suitable for local conditions; over 15 locatins contained field trails complted by the end of 2000-2001 period. Further contained open field research trials in completed at 50 locations during 2001-2002. 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;

Institute	Plants/crops used for transformation	Transgenes inserted	Aim of the project and progress made
			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 ovr 51 locations completed by the end of 2000-2001. During 2001-2002 more than 400 locations large scale trials were conducted. Based on the resoutls of large scale field trails, company ws 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 tern resistance against lepidopteran pests; limited field trials in 3 locations completed.
	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	Resistance against lepidopteran, coleopteran

Institute	Plants/crops used for transformation	Transgenes inserted	Aim of the project and progress made
		nivalis) Lectin gene	& 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.
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

Particulars	**Information Sought**
Rationale for the development	Economic agronomic and other benefits, and nationale of development
Details of the molecular biology of GMOs (Microorganisms, plants and animals)	• Description of the host organisms (microorganisms, cell lines, plants, animals etc) • Source and sequence of transgene • Sequential block diagram of all trans-nuclear acid stretches inserted • Cloning strategy • Characteristics of inserted genes with details of sequences • Characteristics of promoters • Genetic analysis including copy number of inserts, stability, level of expression of transgenes, biochemistry of expressed gene products etc. • Transformation/cloning methods and propagation strategy.
Laboratory, Green House Trials (for plants) and contained enclosure trials (for animals)	• Back-crossing methods for plants • Seed setting charateristics of plants • Germination rates of seeds • Phenotypic characteristics of transgenics • Organisms challenge tests where ever applicable • Effects of chemical herbicies for all herbicide resistant plants • Growth characteristics and general health of animals, measured through specific scientific parameters • Toxicity and allergenicity implications to human if any during handling of

Particulars	Information Sought
	GMOs.
Field trials in open environment	• For GM Plants, comparison of germination rates and phenotypic characteristics, using non-transgenic s controls. • Study of gene flow of plants • Possibility of weed formation for GM plants • Invasiveness studies of plants and animals compared to non-transgenics used as controls • Possibility of transfer of transgenes to near relatives through out crossing./cross-fertilization • Implications of out crossing/cross-fertilization • Comparative evaluation of susceptibility to diseases and pests for plants and animals • 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. • Toxicity and allergenicity implications of transformed GMOs. This include micoorganisms, plants/fruits/seeds as well as animals, lab animal studies for food/feed safety evaluation is a requisite. • Handling procedures for allergenic substances • Agronomic evaluation for GM Plants • Economic evaluation for GM animals

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 likely-hood of seed setting outside the experimental plot. The transgenic plants are isolated ffrom thegene 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 affects. 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-barness as well as Bar-barster systems, Bar-Bt systems, antibiotic resistance, altered nutritional properties and abiotic stress resistance properties.

As indicated ealier, data for submission by the appliants 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 conducting 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 transgencis and evaluation of their comparative competitiveness or invasiveness potential in unmanaged and managed land. The experimental result from two studies has shown that the pollen escape was real phenomenon. The cross-ability studies conducted for example on transgenic Indian mustard has shown that their 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, which observation was consistent with similar studies made with Brassica napus. It was observed, while studying the Bt. Cotton plants that their pollen also traveled to some distance with the help of insects. It can be stated from these that gene transfer shall be taking place in open environment 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 an issue, which is real. The implications of this issue have not yet been satisfactory 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 commericialisation of insect resistant Bt. Cotton containing Cry 1 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 are required to 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 allergencity and anit-nutritional properties etc., The data generated in Indian experiments for Bt.cotton at Industrial Toxicology Research Centre, Lucknow using goat as the ruminant modes, and for transgenic Indian mustard assessed on rat, rabbit, guinea pig and hen model (at Shriram Industrial Research, Delhi) as well as on goats model (at Fredrick Institute of Plant Protection and Tocicology, Tamilnadu) did not show any additional food safety risks.

The transgenic field experiments conducted in Inda 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

Name of the plant	**Range of increase in productivity in % over controls**
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 convened 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.

i. 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 where 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 date 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 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 possible 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 al the conditions stipulated by the government are fulfilled. In accordance with the above approval of the government, the company would in the first year, i.e. 2002-3 period may 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 one. The company is expected to provide detailed spraying instructions to manage the attach of bollworm. For the spraying for the control of bollworm, one spray will be applied if larvae per plant exceed 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, aphinds, thrips, jassids and mites, the Economic Threshhold Limits (ETL) are to be worked out during scounting. 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 than will be accompanying 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 with these preparedness from the company , all the conditions would 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 surgace 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, Granulocite 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 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 at development stage and the country has to go a long way before such products are developed for commercial appliations.

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

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Assessing and Managing Risks: Biotechnology and Biosafety

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Introduction

The evolution of human civilization has been reliant on diversity. Domestication and modification of life forms around us – be it for food, feed or material needs led to intensive use of living organisms for millions of years. Food formed an important and often significant link in identification of human culture. Safety and acceptability of such actions are based more on culture and tradition than on objective safety aspect alone.

Introduction of new traits into plants and animals are nothing new for humans. Plant breeding, selection and recombination form the basis of our very survival today. Breeders and farmers were engaged in producing novel crops and breeding for specific uses for a long time now but such breeding has been a time-tested process where the genotype versus environment interaction played a crucial role as a natural risk assessment tool. Novel combinations were rejected by nature if they did not fit into the web of life. These gave much confidence for people so that they accepted the technology and supported the same. However, such confidence was only built over time and testing.

Modern biotechnology began with similar intention as above. However, with the pace and advent of techniques and often successes, we were able to attempt new genetic recombination never thought of as possible even three to four decades ago. Since biotechnology – in its modern form – is technology intensive, quicker and attempted inter-generic transfer of characters, it caught the consumers unaware. Very few people were able to understand the technology, mechanism and impacts. Also, little time was spent on addressing the issue of acceptability both by consumers and environment before novel combinations of genes were released into environment. This created a sense of apprehension which was also fuelled by misinformation and emotional rejection.

UNDP Human Development Report 2001

The 2001 Human Development Report commissioned by UNDP concludes that many countries might reap great benefits from genetically modified foods, crops and other organisms. The report acknowledges that there are health and environmental risks that needs attention. The report urges increases in public investment in research and development in biotechnology and argues that it is only the public funded activities that will cater to developing country needs.

The report also cites poor policies, inadequate regulation and lack of transparency as reasons for problems with biotechnology becoming popular. The report also points to Argentina and Egypt as examples of developing countries that are moving forward in creating national guidelines, approval procedures and research institutions to evaluate GMO risks. The Report concludes that while developing countries face the challenges of scarce funding and expertise it mentions that "the voices of people in poor countries – who stand to gain or lose the most from these new technologies – have not yet been heard".

Source: UNDP Human Development Report 2001

Societies respond to uncertainties by seeking to maximise the benefits and minimise the risks of technological change. Doing so is complex as well as controversial. Advent of green revolution, nuclear technology are classical examples of these. Adoption of new technologies are needed provided we weigh the potential benefits, costs of inertia versus costs of change and means of managing risks. Yet reasons for change comes from the dilemma many countries have to embrace new technology and capacity needs they have. From this perspective developing countries have both advantages and disadvantages. Advantages because they need not risk new technologies but can instead observe the risks. It is a disadvantage because societal and global pressure requires them to embrace the new technologies sometimes faster than needed. In the event of having good regulatory standards these risks or uncertainties can be avoided.

Some of the perceived risks associated with genetically modified organisms are that transformed organisms could displace existing species and change the ecosystem, gene flow among plants could transfer the novel gene into related species making super weeds and novel genes could have unintended harmful effects on non-target organisms. Risk assessments are essential to study this situation and must be conducted hand-in-hand with expected benefits also. The example of chronic failure of cotton crop due to lepidopteran pest attack in India and the desperation of resource poor farmers to protect their crop led to movements by farmers to let government consider commercialisation of Bt cotton in India. The precautionary approach taken by India in this particular case is encouraging.

It is crucial that proponents of new technologies must consider alternatives that are safe and productive while opponents must not ignore the harms of the *status quo*. Public choices and consumers often influence these decisions. For developed countries the need is for more nutritious crop and not adequate food while for developing countries it is more quantitative increases of food production that is the need of the hour. Hence the choices of risk and assessment of risk *versus* benefits would be looked from a different angle.

Decision on safety or agreement to usage is dependant on public trust in the technology and confidence vested in developers of such technology. The imbalance of voices and influence that make decisions need to be rectified and corrected.

Using the precautionary principle is one of the options provided under Cartagena Protocol (Article 10,11, 26). This is often interpreted as the rule that a country can or should reject the products of new technologies when full scientific certainty that such product will not cause harm is lacking. In fact the precautionary principle is a fairly new concept with different formulations none of them being clear. They range from the soft formulations to strong formulations. The principle is still evolving and countries need to make different choices.

“Use the precautionary principle” But which one?

A variety of precautionary principles are in use, ranging from soft to strong formutaions.. A relatively soft formulation appears in the 1992 Rio Declarations on Environment and Development, where it says that “to protect the environment, the precautionary approach shall be widely applied by states according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation". That is, regulators can take cost-effective steps to prevent serious or irreversible harm even when there is no certainty that such harm will occur.

A strong formulation is set out in the 1990 Third Ministerial Declaration on the North Sea, which requires governments to “apply the precautionary principle, that is to take action to avoid potentially damaging impacts of (toxic) substances… even where there is no scientific evidence to prove a casual link between emissions and effects". This formulation requires governments take action without considering offsetting factors and without scientific evidence of harm.

Between these two declarations lie a wide range of positions. For example, the 2000 Cartagena Protocol on Biosafety states that ‘lack of scientific certainty due to insufficient knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question .. to avoid or minimize such potential adverse effects.” This formulation drops the requirement that prevention be cost effective and shifts the burden of proof for safety onto exporting countries. At the same time, refusing import is optional, not obligatory, and countries can decide to accept the risks on the basis of other factors that they consider relevant, such as potential benefits and the risks inherent in the technologies that would be replaced.

Source: UNDP – HDR, 2001

Precautionary principle applied to deliberate release Of GMOs

Research and development of genetically modified organism (GMOs) is seen to contribute to sustainable development, increased food production, environmental hygiene and economic prosperity. On the other hand the amount of information available to us on the environmental impacts of GMOs is scare and time is not yet ripe to categorically provide judgements on safety. The basic information with regard to mechanisms governing the environmental interactions of GMOs is insufficient. Ecosystems and ecological processes are too complicated for us to quickly predict the impacts – either shot term or long term. Furthermore, the socio-economic and biodiversity aspects of GMO usage are ambiguous and other unpredictable. Hence applying the precautionary principle should be an important basis for initiation of risk associated research as well as for elaboration of more satisfactory risk assessment methods and procedures.

Article 10 of the Cartagena Protocol specifically calls for countries to apply the precautionary principle to their permitting decisions dealing with LMOs intended for import to be introduced into the environment. Article 11 applies the precautionary principle to the introduction of LMOs for direct use as food, feed or for processing. Article 26 identifies additional factors that need to be considered relevant to the ultimate decision. It is also requests countries to take socio-economic consideration into effect when deciding on import of LMOs.

The Protocol clearly states that lack of scientific certainity or insufficient scientific evidence regarding potential adverse effects shall not be used as a reason to delay action to control or protect against such effects.

Safe use of new technologies is ensured by creating a systematic approach to risk assessment and management. This calls for regulatory policies and procedures that are clear and logical. The following principles can be considered for an effective safe use biotechnology:

- Use scientific information to turning uncertainty to risk
- Ensure public participation through risk communication
- Create flexible institutions and diverse technologies (UNDP - HDR, 2001)

The Cartagena Protocol on Biosafety

Under the Convention on Biological Diversity (CBD) one of the significant developments has been the adoption of a Protocol on Biosafety - The Cartagena Protocol on Biosafety with a record number of signatories on the opening day during CoP-5. Countries are set to see the protocol in implement. Under the Protocol Article 15 and 16 specifically deal with issues of risk assessment and risk management.

Article 15 - Risk Assessment

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence on order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

(Source:Cartagena Protocol on Biosafety)

The difficulty of Protocol coming into force so far has been the issues of capacities countries have to implement the Protocol, preventing countries from ratifying the Protocol. Repeated voices from countries point to the fact that there is inadequate capacities, unclear guidelines and experiences on risk management and assessment as seen through the difficulties in negotiations of issues like compliance, liability, redress and labelling.

Training, building of institutional and personal capacities are much needed specifically in areas like risk assessment and management coupled with regional cooperation to enable countries ratify the protocol with confidence.

Article 16 – Risk Assessment

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.
3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.
5. Parties shall co-operate with a view to:
   a) Identifying living modified organisms or specific traits of living modified organisms that may have effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
   b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

(Source: Cartagena Protocol on Biosafety)

Issues of Safety

The goal of safety assessments is often not to establish on absolute level of safety but rather the relative safety of new products. This can ensure a reasonable certainity that no harm will result from intended use. More important is also the issue of processing. Many plants consumed by people are toxic but appropriate processing eliminates the toxicity (eg; Cassava)

The FAO/WHO joint expert consultation on foods from biotechnology (FAO/WHO 2000) concluded that application of the substantial equivalence concept contributes to a robust safety assessment framework. One example of this can be the genetically modified potatoes that expresses coat Protein from Potato virus Y (PVY) and thus displays virus resistance. In non-transformed potatoes, the presence of viral coat proteins is due to natural viral infection and thus a common occurrence (hence safe). Plant viral coat proteins have never been associated with toxicity or cases of allergic reaction. Given this, transgenic potatoes expressing PVY can be considered to be substantially equivalent to non-transformed potatoes (Agbios, 2001).

However, there are certain limitations to this issue of substantial equivalence. This is with particular reference to amount of analytical data available or generated comparisons are possible. Only if there is a well documented history of use like the PVY case or in case like Canola and Soybeans with modified oil composition where care is taken to ensure that the modification are purposefully designed to be comparable with composition and nutritional quality of their traditional counterparts. (FAO/WHO 2000), equivalence issues can be accepted.

Apart from these, some new products that were intentionally altered for nutritional profiles can be challenging. For example, the genetically engineered low – glutelin rice produced for low glutelin levels was associated with unexpected increase in levels of prolamines. Increased levels of prolamines may not affect industrial use of rice but may affect nutritional quality of rice and may increase the allergic potential of modified rice.

A second example can be cited of 'golden rice' which was engineered to express high levels of beta-carotene- a precursor to vitamin A. It was found that this genetic modification was associated with increased levels of Xanthophylls. Such unexpected biochemical charges can occur in the modifications. It cannot however be said that genetic engineering always caused such surprising unintended expressions. To nullify all possibilities of such situations it is important to take a precautionary approach and develop better methods to assess the risks.

Safety Considerations and Risk Assessment

Safety Considerations

The goal of the risk assessment process for genetically engineered foods is to examine the intentional and unintentional consequences of the specific modification on food components, including toxicants, in comparison with a counterpart food that has a history of safe use. Within this general framework, "case-by-case" variations must be considered.

International discussion between OECD countries, and within the United Nations FAO/WHO expert consultations, have resulted in a consensus on the specific safety issues that should be considered when evaluating a novel food (OECD 2000). They include:

- a description of the host organism that has been modified, including information on nutrient composition, known antinutrients, toxicants and allergenic potential, and any significant changes in these that may result from normal processing;

- a description of the donor organism, including any known associated toxicities and allergenicities, and the introduced gene(s);

- molecular characterization of the genetic modification, including a description of the modification process and the stability of the introduced trait;

- identification of the primary and secondary gene products, including a description of the characteristics of the inserted gene;

- evaluation of the safety of expected novel substances in the food, including an evaluation of any toxins produced directly by the modification

- assessment of the novel food's potential allergenicity; and

- evaluation of unintended effects on food composition, including

  (a) assessment of changes in the concentration of nutrients or naturally occurring toxicants,
  (b) identification of antinutrient compounds that are significantly altered in novel foods, and
  (c) evaluation of the safety of compounds that show a significantly altered concentration.

  In evaluating these safety issues, due consideration should be given to the processed version of the food, if the food normally undergoes manufacturing or processing, and food consumption issues, including:
  - identification of the potential human population consuming the genetically engineered foods and the amount they are expected to consume, and
  - assessment of any effects that may occur if intake of the modified food differs from intake of its conventional counterpart.

Risk Assessment

One of the prerequisites for beginning any risk assessment is the provision/availability of information. Several examples of checklists and information requirements are available for people to use. These include;

- Biosafety Protocol - Annexes 1, II and III
- EC Directory 2001/18/EC
- USDA Molecular Genetic Charaterisation Data
- US and Canada Reviewer's checklists

Risk assessment is a scientific process that make use of the best up-to-date scientific knowledge and experience. Although details of risk assessment may vary from case to case, there are a few logical steps that need to be followed. These are:

1. Identification of potential adverse effects on human health and/or environment.
2. An estimation of likelihood of these adverse effects being realised.
3. An evaluation of the identified risks.
4. Considerations of appropriate risk management strategies.
5. Assessment of the overall potential environmental impact, including a consideration of the potential impacts that may be beneficial to human health or the environment.

In addressing these issues it is important to consider the following characteristics carefully:

- the recipient organism
- the donor organism
- the modification method
- the stability of introduced trait
- the expressed material
- the receiving environment.

The Initial Steps

The first steps of a risk assessment scene will be to detail the characteristics of ;

- the recipient organism
- the donor
- the modification method
- the stability of introduced trait
- the resulting expressed material

Details are these are briefly presented to help better understanding of the steps and issues including a 'real life' example (Agbios, 2001).

The Recipient Organism

The usefulness of the concept of substantial equivalence as a starting point for assessing the risks of genetically engineered organism(s) is dependent on a thorough knowledge of non-modified host or recipient organism. Such information/knowledge is important especially when food safety assessments are carried out.

The MON 810 Case Study

History and characters of recipient organism

Maize is a member of the tribe Maydae and is included in the sub family Panicoidae of grass family Graminae. The genus Zea includes two subgenera: Luxuriantes and Zea. Maize (*Zea mays* L.) is a separate species within the sub genus Zea along three sub species.

Maize is one of the few major crop species indigenous to Western Hemisphere and is grown all over the world (Hallauer et al 1988). Maize is widely used as human food source and several products based on semi or fully processed maize are consumed. Maize is also used as animal feed because of its high starch-low fibre content. Maize also does not contain any endogenous toxins or significant levels of antinutritional factors (Watson 1988).

There are reported cased of allergens in maize, especially in maize pollen. However, the protein(s) responsible for causing the allergy have not been identified.

The recipient material in this event is the derivative of A188 and B73 inbred lines of maize. These lines are publicly available and widely grown.

The food products of genetically engineered maize in this event are maize and its derived products. Animal feed uses of this modified maize include maize grain, protein rich fractions, feed and forage. It is expected that the modified maize will represent some fraction of total maize products. The total consumption pattern of maize or its products is not expected to change because of this introduction.

The Donor Organism

Information about the natural history of the donor organism is required, particularly if the donor or other members of its genus normally exhibit characteristics of pathogenecity or environmental toxicity, or have other traits that affect human health.

Example of MON 810

The donor genes: MON 810 contains DNA sequences derived from *Bacillus thurigiensis* (Bt) Cry1Ab gene, Cauliflower mosaic virus (CaMv) enhanced 355 promoter, an intron from maize hsp 70 gene and the 3' untranslated regions of Nopaline Synthase gene (NOS 3') from the Ti plasmid of *A. tumefaciens*. None of the inserted sequences are known to have any pathogenic or harmful characteristics. In addition 4 markers genes are present on the plasmid used in transformation but were NOT integrated into MON 810 genome.

Bacillus thurigiensis (Bt) is the donor organism in this event that is naturally found in soils and is known to produce delta endotoxins that rupture the intestinal walls triggered by specific receptors in the mid-gut of lepidopteran pests like cotton bollworm. Numerous scientific studies have proved that Bt endotoxins are specific to lepidopterans and does not target other organisms. (Siegel & Shadduck 1989) Hence use of Bt in genetic modification has been considered safe and in USA the modification involving Bt are exempt from risk assessment studies. However, it may be useful to treat this transformation with precautions in other countries with appropriate risk assessment studies before release into environment.

The Modification Method

The method by which the novel traits are introduced into the host plant determines, partly, the information requirements for the assessment of the molecular biology of the plant.

There are two principal methods of transformation that are widely used: The agrobacterium mediated transformation and particle bombardment or biolistic transformation.

Agrobacterium mediated transformation results in a low transgene copy number, minimal rearrangements and higher transformation efficiency than direct DNA delivery (particle bombardment) techniques. However, such transformations are often associated with extra genome from the bacterium getting integrated, multiple copies of inserted genes occurring and silencing of genes. (Birch 1997; Kononov et.al 1997).

Microprojectile or particle bombardment is a technique that is used to deliver the DNA to the host genome directly. This is used in tissues that are not amenable to agrobacterium mediated transformation but is often inefficient in producing stably transformed cells.

This technique often caused extensive rearrangements to transformed sequences. (Pawlows. and Somers 1996; 1998)

In the MON 810 study the derivative of A188 and B73 inbred lines was transformed using plasmid DNA by particle bombardment method. The MON 810 was produced by transforming maize genome Hi-II with a DNA solution containing two plasmid vectors . One of the plasmid vectors contained the Cry 1Ab gene from Bt under the control of CaMv 355 promoter alone with other promoters and makers.

Molecular Characterisation

Characterisation of a transgenic plant at the molecular level is used to provide information about the composition and integrity of the inserted DNA, the number of copies of inserted DNA, the number of sites of insertion and the level of expression of novel protein(s) over time and in different tissues.

The molecular characterisation of transgenic plants often receive less attention from regulators since the data is difficult to interpret. However, they can provide some useful information but not all. There is largely a misconception that molecular characterisation alone can answer questions on risk assessment and safety of transgenics which is completely misinformed.

While information on integrity and number of copies of inserted DNA are generally required by regulatory authorities, there is no evidence to suggest that transgenic crops containing multiple copies of inserted genes are less safe that those containing single copy. A detailed molecular characterisation may be able to address issues on positional effects, pleiotropic effects and gene silencing. However, in the absence of other empirical data, such analyses are unlikely to predict unforeseen effects on the concentration of key nutrients, antinutrients or endogenous toxins.

Molecular characterisation of MON 810 revealed that MON 810 was produced by particle bombardment with one copy of Cry 1 Ab gene a promoter and an intron.

Genetic Stability of Introduced Trait

The inheritance and stability of each introduced trait that is functional in the transformed plant must be determined. For each novel trait, the pattern and stability of inheritance must be demonstrated as well as the level of expression of the trait. Serological tests like ELISA, western blotting, radiommunoassay assay are used for this purpose.

If the new trait is one that does not result in the expression of a new or modified protein, then its inheritance will have to be determined by examining the DNA insert directly or by measuring RNA transcript production.

In MON 810 case the stability of insertion of Cry 1Ab was demonstrated through seven generations of crossing.

Expressed Material

Hazard identification requires knowledge of which introduced genes are expressed, the characteristics, concentration and localization of expressed products, and the consequences of expression.

Where the result of the modification is the expression of a novel protein, or polypeptide, this material must be characterized with respect to: identity; functionality; and, where appropriate, similarity to products from traditional sources.

The concentration of novel protein expressed in transgenic plant tissues can be very low, often times much less than 0.1% on a dry weight basis. Studies, such as acute toxicity testing, that require relatively large amounts of material are often not feasible using the protein purified from plant tissue. Instead, these studies normally make use of protein purified from bacterial expression systems. In such cases, it is necessary to demonstrate the functional equivalence (i.e., equivalent physicochemical properties and biological activities) of proteins purified from the two sources. When equivalence is demonstrated based on serological cross-reactivity, it is important to use antisera (either polyclonal or monoclonal) that have been well characterized with respect to their specificity. The possibility of post-transnational modification (e.g., glycosylation) in eukaryotic systems should also be taken into account, as this may affect allergenic potential.

In cases where the modification results in the expression of a novel non-translatable RNA transcript, the sensitivity and specificity of the desired action should be established. Examples of this include the production of antisense mRNA or other RNA species resulting in the reduced production of an endogenous protein (e.g., transgenic plants containing inserted antisense sequences). The altered regulation or expression of non target host genes should be investigated in the course of assessing the safety of the modified plant.

In MON 810 case the field trials were conducted at major maize growing regions of the world – USA, Italy and France. The identity and levels of expression of Cry1Ab from plant tissue examples from these sites were determined by ELISA method.

Results in all trials showed that Cry 1 Ab protein in MON 810 plants is similar when plants are grown in different geographies and when the gene is present in different genetic backgrounds. The level of expression was consistently high to provide season long control of target insect pests.

Nutritional Data

Nutritional analysis is a must for any plant breeding material developed whether GM on non-GM. Unintended charges in level of nutrients and expression of other biochemicals can occur in many ways including through insertion of genetic material. Food safety assessments should consider the potential for any charge in nutritional composition. For genetically engineered plants that were developed to have intentionally altered nutritional value, the aim of nutritional evaluation is to demonstrate that there has been no unintentional charges in the levels of key nutrients, natural toxicants or antinutrients or the bioavailability of nutrients.

Analysis of the compositional data of MON 810 Maize grain and forage indicated that there were few significant differences in the levels of major constituents, nutrients, antinutritional factors or natural toxicants between MON 810 and control Maize lines.

Feed safety studies of MON 810 lines conducted on Catfish did not show any considerable differences with those of control.

Toxicity

The main toxicological assessment of GM crops deal with the protein expression studies of inserted gene(s). The inserted genetic material itself is not of concern with respect to ingestion of genetically modified plants or their products since DNA is the same in all living organisms and would not differ from what is already ingested from the diet. The amount of dietary DNA ingested by humans is in the range of 0.1 to 1.0 gm per day. GM DNA intake will be about 1/250,000 of total DNA consumed and hence may be insignificant.

However, genetic material from microorganisms that were not present in normal diet is of concern. Appropriate assessment is needed for such proteins. Another issue of concern is the issue of expression of novel proteins in host organisms due to genetic modification. *Invitro* and *invivo* studies are needed to assess the toxicity levels of GM products.

The MON 810 line when subjected to toxicity tests using molecular weight, immunoreactivity and insecticidal activity. Tests revealed that the Cry1 Ab protein in MON 810 was non-toxic.

Allergenicity

Food allergies are adverse reaction of human bodies to proteins (allergens) expressed in human bodies at the trigger of immunological responses. True food allergies include cell mediated reactions which involve sensitized tissue – bound lymphocytes rather than antibodies. (Anderson 1996).

The Codex Alimentarious Commission of FAO established a list of most common allergenic foods and not so severe foods. Sensitivity to glutelins in cereals is a concern and also is common.

In genetically modified plants the common criteria to make decision regarding allergenicity can include:

a) caution must be exercised if the source of genetic material is known to contain allergens.
b) assessment of amino acid sequence of allergens.
c) immunoreactivity assessment.
d) effect of PH and/or digestion since most allergens are resistant to gastric acidity and to digestive proteases
e) heat or processing liability studies

If the genetically modified products contain genes from sources with no history of allergenicity, the studies rely on amino acid sequence homology between modified plants and known allergens followed by studies an digestibility and processing.

In the case of MON 810 case amino acid sequence homology, degradation simulated by gastric fluids, safe exposure studies provided data that support the conclusion that the modified maize does not cause allergic reactions in humans and animals.

Ecological Effects and Studies

The preceeding sections describe some of the risk assessment procedures commonly followed with explanation on why they are important. However, risk assessment of genetic modification must be undertaken on a case-by-case basis and there can be no one method or model to follow. Experience of dealing with situations helps in decision making.

In this section we will consider broader issues of risk assessment including the potential adverse effects, likelihood of these risks becoming a reality, consideration of risk management strategies and assessment of overall potential environmental impact (Anonymous 2001).

Identification of Potential Adverse Effects

Risk assessment starts with a careful look at the effect of inserted gene(s) and their impacts on genotype and phenotype of transformed organism. In addition to the kinds of assessments that need to be carried out as described earlier, we need to address other issues like the following:

- Impact or effect of transformed or recipient plant to become more persistent in agricultural habitats. These might have related potential impacts on weed management, changes in natural populations, survival of species and dispersal.

- To assess these it is important to have a clear understanding of the biology as well as ecology of host organism and scientific assessment of agronomy and dispersal.

Examples of research data on impact of genetically modified cereals like maize becoming a weed, genetic contamination of GM crops with native population (the Mexico case) are revealing to ensure that biological assessments are needed more thoroughly.

Any classic case of adverse impact of GM crop originates from the fact that the GM crops have more biological take over compared to native or unmodified crops/organisms. Assessments on range of issues described in the earlier section are established procedures and decisions can be made based on empirical data and on a time bound mode. However, the ecological and environmental impacts are trickier to assess and might take anything between few months to more than a decade.

The other concern is the issue of outcrossing between GM organisms and pathogens. The impacts may be adverse if the resulting scenario emanates as increased dissemination of infection, diseases and/or situation creating new reservoirs or vectors.

Assessments of such situation should be based on a clear understanding of a etiology and phytopathology coupled with advance level of screening and control. Studies on habitat changes and adaptational patterns of vectors and disease causing organisms are essential in this case.

Another adverse impact of modified organisms can be the negative effect on population of non target organisms, including indirect effects on population levels of predators, competitors, herbivores, symbionts, parasites and pathogens. The case of impact of pollen from Bt transformed plants on monarch butterflies is an example for this (Sears et.al 2001).

Apart from these, other impacts include unintended effect of modified organisms on target organisms (eg; changes in soil biota – especially introduction of modified soil microbes and/or plants like nitrogen fixers with modified rhizobia)

There can also be some indirect effect that can cause negative results through an unintended spread of modified organisms due to natural disasters, accidental crossing over to wild relatives of crop plants. It is in these circumstances that experience from past, scientific studies are important to consider.

Estimation of Likelihood

After the identification of potential adverse effect follows a stage in which an estimation is made of the likelihood that the identified potential adverse effect will actually occur. It is important to estimate the chances of each of potential effect for assessment purposes.

The likelihood of certain potential adverse effects occurring can be influenced by many factors like;

- Characteristics of the inserted gene.
- Characteristics of the recipient organism
- Characteristics of the size and scale of application.

This is where a precautionary approach is useful.

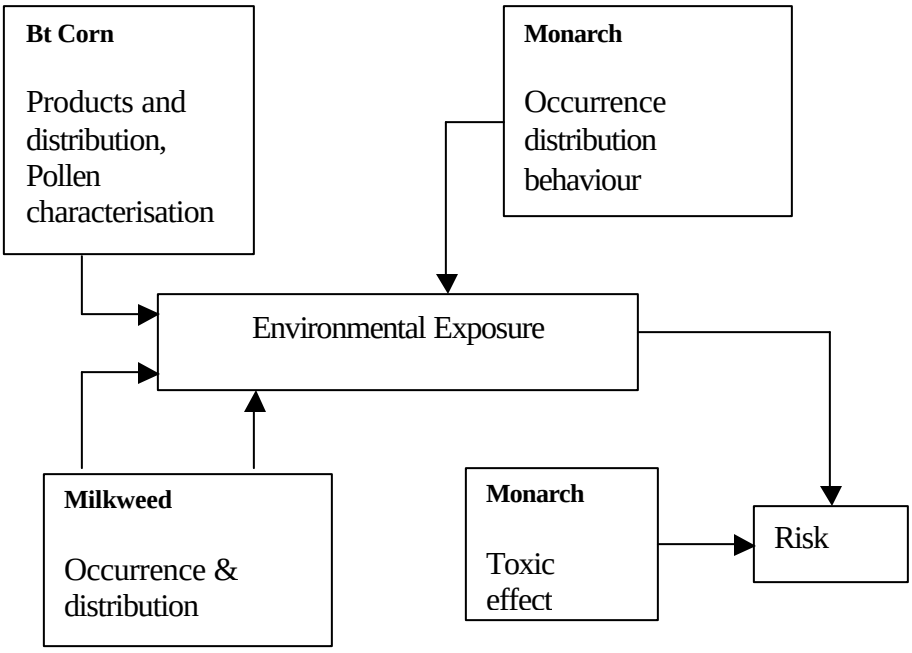

Figure 1 : Risk Assessment of Bt corn (modified after Sears 2001)

Conceptual Model For Risk Assessment: Testing of Bt corn against monarch Butterflies

Risk assessment requires knowledge of four essential components: (I) hazard identification, (ii) nature of dose response to a toxin, (iii) probability of exposure to an effective dose, and (iv) characterisation of risk. Components of a risk assessment approach as applied to the case of Bt corn and monarch butterfly are depicted in Fig. 1, Bt proteins expressed in corn plant tissues can bring about specific reactions in the gut of lepidopteran larvae, including nontarget larvae that consume Bt corn pollen. The magnitude of the reaction will depend on the type of protein produced by various transgenic events of hybrid Bt corn, the amount of protein expressed in pollen grains from different events, the amount of pollen consumed by larvae of different developmental stages, and the susceptibility of larvae to the Bt protein. Chatacterisation of toxic effects is necessary to establish the first component of risk. Laboratory and field assays of lethal and sublethal toxicity resulting from exposure to doses of Bt pollen are required to establish toxicity thresholds for comparison against the dose encountered within the environment. These toxicity thresholds will vary based on expression levels for individual Bt corn events in conjunction with environmental factors determining ecological exposure.

Consideration of risk as a function of exposure and effect requires that lines of evidence be established in four areas of inquiry: (I) Is there some density of Bt pollen on milkweed leaves that represents a lethal or sublethal threat to monarch larvae or later stages of development? (ii) What proportion of Bt pollen deposited on milkweed leaves in and around cornfields exceeds the toxicity threshold for larvae of monarch? (iii) What proportion of monarch populations use milkweed in an near cornfields? (iv) What is the degree of overlap between the phenological stages of monarch larvae and corn anthesis over the shared range of these species?

Source: Sears 2001

Evaluation of Identified risks

When an adverse impact/effect has been identified and the estimation of likelihood leads to the conclusion that it is not negligible, we move into assessing the effect as a potential risk In the case of proposed field trial with reproductive isolation (safe distance), assessment need to be done for possible consequences of the modified gene outcrossing. This can be carried out by assessing the selective advantage of modified organisms.

In assessing whether or not a trait is likely or unlikely to result in a significant, lasting effect on population levels in the environment, it is useful to consider issues in the context of existing situation like practice in agriculture.

Issues in the Risk Management Strategies

In cases where the risk assessments indicate that there is significant risk management strategies need to be developed.

Appropriate risk management measures for releases will vary considerably from case to case. In addition to general precautions to control releases, risk management measures often focus on the control of the dissemination of the released organisms and control of the gene flow from the released organisms.

The type of risk management measures to be employed should be commensurate with the risks identified. Therefore, there might be cases where very few, if any, risk management measures will be necessary. Consequently, not all of the examples given below are likely to be relevant for any given controlled release.

Examples of risk-management measures for controlled releases include (UNEP, 1998):

General precautions

- Appropriate information and training is provided for those involved in handling the organisms;
- Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;
- The dissemination of the released organisms and/or gene flow from the released organisms are controlled;
- Controlling access to the release site.

For plants

- Applying reproductive isolation, by:

    - spatial separation;
    - temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
    - biological prevention of flowering (e.g. by omitting verbalization);
    - removal of the male or female reproductive structures;
    - bagging of flowers;
    - making use of sterility.

Controlling the persistence or dispersal of reproductive structures such as propagules or seeds.

- Destroying volunteer plants after harvest; control of volunteers may be necessary during longer periods, depending on the species.

For animals

- Confining by appropriate means such as fences, filters, islands, ponds;
- Applying reproductive isolation by using sterile animals;
- Isolation from feral animals of the same species.
- Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.

For micro-organisms

- Using organisms with impaired ability to grow or persist in the environment;
- **Minimizing gene transfer by:**
  using organisms that do not contain known self-transmissible mobilizable or transposable genetic elements;
  ensuring that introduced traits are stably located on the chromosome.

These measures will often not be applicable once an organism with novel traits, such as a modified crop plant, is at the stage of being marketed as a product if, as a result of testing during research and development, it has been shown that the risks are acceptably low.

Decision Making

After risk assessment has been carried out and management plans drawn up the next step is to make a decision on the basis of results and other inputs received.

The decision making process is not only based on information but also on the regulatory framework available within the country. The decision on a request can be to allow, with or without conditions, or to deny permit or approval for the requested activity. Decision making can also be based on the kind of activity (eg; Philippines regulations).

To make decision the minimum required information include:

- A summary of the request or application
- A description of procedures followed, including the solicitation of advice and comments, and the reaction of the competent authority to the input received
- A summary of risk assessment carried out, based on the approach described earlier
- A summary of risk management plan, if needed.

Depending on individual country's decision the decision making process can be transparent and objective with active participation of diverse stakeholders. However, it is important to maintain some confidentiality to parts of information provided by the applicants so that necessary protection is provided for the intellectual property contained in the application.

Areas of Advice, Support; Policy Options and Regional Collaboration

Considering the limited capacities of countries in Asia to implement provisions of risk assessment and management it is important to understand that it will be difficult for all countries to have all capacities within a short period of time. After a careful consideration of policy, scientific, legal and participatory options countries need to identify ways of collaborating with each other either at sub-regional or inter-regional levels. The option for such cooperation not only provides opportunities for better services but also provides countries an opportunity to embark on testing and using the modified organisms.

INDICATIVE LIST OF AREAS OF ADVICE AND SUPPORT FOR IMPLEMENTATION OF THE CARTEGENA PROTOCOL

RISK ASSESSMENT	RISK MANAGEMENT
General risk assessment capacities a) Ability to coordinate multi disciplinary analyses b) Enhancement of technological and institutional capacities for risk assessment c) Capacity to identify and access appropriate outside expertise d) Understanding of relevant bio technology processes and applications **Science and socio-economic capacities** a) Analyse risks to conservation and sustainable use of biodiversity b) Undertake life-cycle analysis c) Analyse risks to human health of effects on biodiversity d) Analyse ecosystem effects of living modified organism introduction e) Assess food security issues arising from risks to biodiversity f) Value and roles of biodiversity to local and indigenous communities g) Other socio-economic considerations related to biodiversity h) Enhancement of related scientific, technical capacities Note: Specific types of scientific expertise required will vary from case to case, but broadly involve two areas: - Evaluation of genetic modifications - Evaluation of interactions with the receiving environment	**General risk management capacities** Understanding application of risk management tools to different biotechnology sectors **Decision-making capacities** a) Identification and quantification of risks, including through sound application of the precautionary approach b) Capacity to assess relative effectiveness of management options for import, handling and use, where appropriate c) Capacity to assess relative trade impacts of management options, where appropriate d) Impartial review of proposed management regime prior to decision-making **Implementation of decisions** a) Identification and handling of living modified organisms at point of import and export b) Monitoring of environmental impacts c) Capacity to monitor, enforce and report on compliance *Source: UNEP/CBD/ICCP/2/15*

POLICY STANCES FOR GENETICALLY MODIFIED CROPS – THE CHOICES FOR DEVELOPING COUNTRIES				
Policy area	**Promotional**	**Permissive**	**Precautionary**	**Preventive**
Biosafety	No careful screening, only token screening or approval based on approvals in other countries	Case-by-case screening primarily for demonstrated risk, depending on the product's intended use	Case-by-case screening for scientific uncertainties owing to novelty of development process	No careful case-by-case screening; risk assumed because of development process
Food safety and consumer choice	No regulatory distinction made between modified and unmodified foods when testing or labelling for food safety	Distinction made on some food labels but not so as to require segregation of market channels	Comprehensive labelling of all modified foods required and enforced with segregated market channels	Sales of genetically modified food banned, or warning labels required that stigmatize modified foods as unsafe
Investment in public research	Treasury resources spent on development and local adaptation of modified crop technology	Treasury resources spent on local adaptation of modified crop technology but not on development of new transgenes	No significant treasury resources spent on modified crop research or adaptation; donors allowed to finance local adaptation of modified crops	Neither treasury nor donor funds spent on adapting or developing modified crop technology
Trade	Genetically modified crops promoted to lower commodity production costs and boost exports; no restriction on imports of modified seeds or plant materials	Imports of modified commodities limited in the same way as unmodified commodities in accordance with World Trade Organization standards	Imports of modified seeds and materials screened or restrained separately and more tightly than unmodified ones; labelling required for imports of modified foods and commodities	Imports of genetically modified seeds and plants blocked; unmodified status maintained in hopes of capturing export market premiums. *(Source: UNDP-HDR, 2001)*

Even though regional cooperation is talked about, we fail to address the critical questions of how, when, who and where questions. It is essential that countries sit together and discuss these issues in greater details at the earliest possibility.

HARMONIZE STANDARDS THROUGH REGIONAL COLLABORATION

One of the first steps in promoting trust in technology is to develop health and environmental standards and harmonize those being developed independently in different countries. Divergence in safety norms between environmental and trade rules threatens to create conflict in addressing the safety of foods derived from biotechnology. Differences in planting and regulating genetically modified crops are already causing trade frictions. Consistent approaches, where they are possible, would reduce such conflicts, and harmonization could make more information available to the public and so promote accountability,

Regional cooperation in sharing knowledge, best practices, research findings, biosafety expertise and regulatory approvals across similar environments and ecosystems could achieve major efficiencies –laying the information base for regionally harmonized risk assessment and management. The Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) has begun to do just this, enabling regional expertise to be pooled and member countries with less regulatory capacity to benefit from the more advanced scientific capabilities in the region. Given the informal movement of plant material across national borders within the region, such coordinated research and regulation will be critical to ensuring the safe use of

Conclusions

From 1986-1997, approximately 25,000 transgenic crop field trials were conducted by 45 countries on more that 60 corps and ten traits. Transgenic soybean and maize accounted for 52% and 30% of global transgenic are respcectively. The International Seed Trade Federation predicts the world market for genetically modified seeds raises from $2billion in 2000 to $ 20billion in 2010 (James 1998; Bernard Le Buanec 1998).

Given this scenario it looks obvious that increased interest in genetic modification is come here to stay. Consumer choices however, are going to decide on how the technology will be used and where they will be commercialised. Policy and global trade issues are bound to eclipse the choices of consumers be it developed or developing countries. Private sector investment into biotechnology is bound to raise where public sector investment, even in market driven economy, might be stable. One of the main options available for both practitioners and opponents of biotechnology is that of assessing the safety of modified organisms/products with best possible scientific rigor, transparency and precautionary approach. Complexity should not be an excuse for inaction.

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ANNEX 1

Checklists of Risk Assessment (OECD, 1995)

1. OVERVIEW OF REGULATORY OVERSIGHT SYSTEMS

General Approach	**Remarks**	**Action**
1. General Regulatory Oversight System		
2. National Expert Committee		
3. Co-ordination of Agricultural Biotechnology Activities		
Environmental Biosafety		
4. Regulatory Oversight for Research and Development		
5. Regulatory Oversight for Scale-up		
6. Regulatory Oversight for Commercialisation		
7. Simplified Procedures for Oversight of Field Testing		
8. Benefits Analysis		
Food Safety		
9. Regulatory Oversight for Food		
10. Regulatory Oversight for Feed		
11. Regulation of Composition and Nutritional Value of Conventional Products		
12. Use of "Subtantial Equivalence"		
13. Use of Benefits Analysis		

Varietal Registration and Seed Certification		
14. Varietal Registration		
15. Requirement that Varieties Be Sold as Certified Seed		
16. Use of OECD Seed Certification Schemes		
17. Use of National Seed Certification Schemes		
18. Signatory to UPOV		

Characteristics of Donor Organisms

Taxonomy, identification, source, culture		
Names and designations		
Degree of relatedness between the donor organism and recipient plant, and evidence indicating exchange of genetic material by natural means		
Charateristics of the organism which permit identification and the methods used to identify the organisms		
Techniques employed in the laboratory and/or environment for detecting the presence of, and for monitoring, numbers of the organism		
Sources of the organisms		
Other:		
Trait intended for transmittance		
Genetic characteristics of donor organisms		
History of prior genetic manipulation		
Characterisation of the donor genomes		
Pathogenic and physiological traits of donor organisms		

Nature of pathogenicity and virulence, infectivity or toxigenicity		
Host range		
Other potentially significant physiological traits		
Stability of these traits		

Characteristics of Recipient Plants

Taxonomy, identification, source, culture		
Names and designations		
Degree of relatedness between the donor organism and recipient plant, and evidence indicating exchange of genetic material by natural means		
Characteristics of the plant which permit identification and the methods used to identify the plant		
Techniques employed in the laboratory and/or environment for detecting the presence of, and for monitoring, numbers of the plant		
Sources of the plants		
Information on the recipient plant's reproductive cycle (sexual/asexual)		
Factors which might limit the reproduction, growth and survival of the recipient plant		
Other:		
Whether recipient plant is exotic and its distribution		
History of cultivation and safe use		
Genetic characteristics of recipients plants		
History of prior genetic manipulation		
Characterisation of the recipient		
Stability of recipient plant in terms of relevant genetic traits		

Other:		
Pathogenic and physiological traits of recipient plants		
Nature of pathogenicity and virulence, infectivity or toxigenicity		
Host range		
Other potentially significant physiological traits		
Stability of these traits		
Other:		
Relatedness of recipient to plants known to be weeds		
Potential for cross-pollination with wild relatives		

4. Character of the Modified Plant

Description of the modification		
Description of the nature, function and source of the inserted donor nucleic acid, including regulatory or other elements affecting the function of the DNA and of the vector		
Description of the method(s) by which the vector with insert(s) has been constructed		
Description of methods for introducing the vector – insert into the recipient plant and the procedure for selection of the modified plant		
Description of the structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified plant		
Characterisation of the site of modification of the recipient genome. Stability of the inserted DNA		
Frequency of mobilisation of inserted sequence and/or genetic transfer capability		

Rate and level of expression of the introduced genetic material. Method and sensitivity or measurement		
Influence of the recipient plant on the activity of the foreign protein		
Degree of similarity between type of genetic modification and those achieved using plant breeding or other conventional methods of genetic modification		
Other:		
Makers that will enable the modified plant to be identified		
Genetic features that limit the modified plant's ability to reproduce or transfer it.		
Phenotype of the modified plant compared to the unmodified one		

5. Human Health Considerations

Characteristics of the Modified Plant		
Comparison of the modified plant to the recipient plant regarding pathogenicity		
Capacity for colonisation		
Other:		
Comparison of modified plant to recipient regarding toxicity		
Naturally occurring toxicants and anti-nutrients		
Health Considerations Generally Associated with the Presence of Non-viable Plants or with the Products of RDNA processes		

Toxic or allergenic effects of non-viable plants and/or their metabolic products		
Product hazards		
Other:		
Secondary effects		
Management of Personnel Exposure		
Biological measures		
Availability of appropriate prophylaxis and therapies		
Availability of medical surveillance		
Physical and organisation measures		
Other:		
Proper management, training		
Exposure to allergens, toxins		
Availability of appropriate protective clothing		

6. Environmental and Agronomic Considerations

Ecological Traits Relating to the Donor and Recipient		
Natural habitat and geographic distribution; climatic characteristics of original habitats		
Significant involvement in environmental process		
Pathogenicity –host range, inefectivity , toxigenicity, virulence, vectors		
Interactions with and effects on other organisms in the environment		
Ability to form survival structure (e.g. seeds,		

spores, sclerotia)		
Frequency of genotypic and phenotypic change		
Role of genetic material to be donated on the ecology of the donor organism		
Predicted effects of the donated genetic material on the recipient plant		
Application of the Modified Plant in the Environment		
Geographical location site, physical and biological to man and/or any other significant biota		
Containment and decontamination		
Introduction protocols including quantity and frequency of application		
Methods of site disturbance or cultivation		
Methods for monitoring applications		
Contingency plans		
Treatment procedure of site at the completion of application		
Other:		
Transport arrangements		
Post-release monitoring of the site		
Impact of plant		

6. Environmental and Agronomic Considerations

Survival, Multiplication and Dissemination of the Modified Plant in the Environment		
Detection, Identification and monitoring techniques		
Description of detection, identification and monitoring techniques		
Specificity, sensitivity and reliability of detection techniques		
Techniques for detecting transfer of the donated DNA to other organisms		
Characteristics affecting survival, multiplication and dissemination		
Biological features which effect survival, multiplication or dissemination		
Behaviour in simulated natural environments such as microcosms, growth rooms, greenhouses etc.		
Known and predicted environmental conditions which may effect survival, multiplication and dissemination		
Other:		
Possible competitive advantage of the modified plant		
Methods to minimise dissemination of the modified plant or trait		
Interactions of Modified Plant(s) with Biological Systems		
Target and non-target populations		
Known and predicted habitats of the modified plant		

Description of the target ecosystems and of ecosystems to which the plant could be disseminated		
Identification and description of target organisms		
Anticipated mechanism and result of interaction between the modified plant and the target organism(s)		
Identification and description of non-target organism(s) which might be exposed		
Stability		
Stability of the plant in terms of genetic traits		
Genetic transfer capability		
Likelihood of post-release selection leading to the expression of unexpected and undesirable traits by the modified plant		
Measures employed to ensure genetic stability, if any		
Description of genetic traits that prevent/minimise dispersal of genetic material		
Routes of dissemination		
Routes of dissemination, physical or biological		
Known or potential modes of interaction, including inhalation, ingestion, surface contact, burrowing and injection		

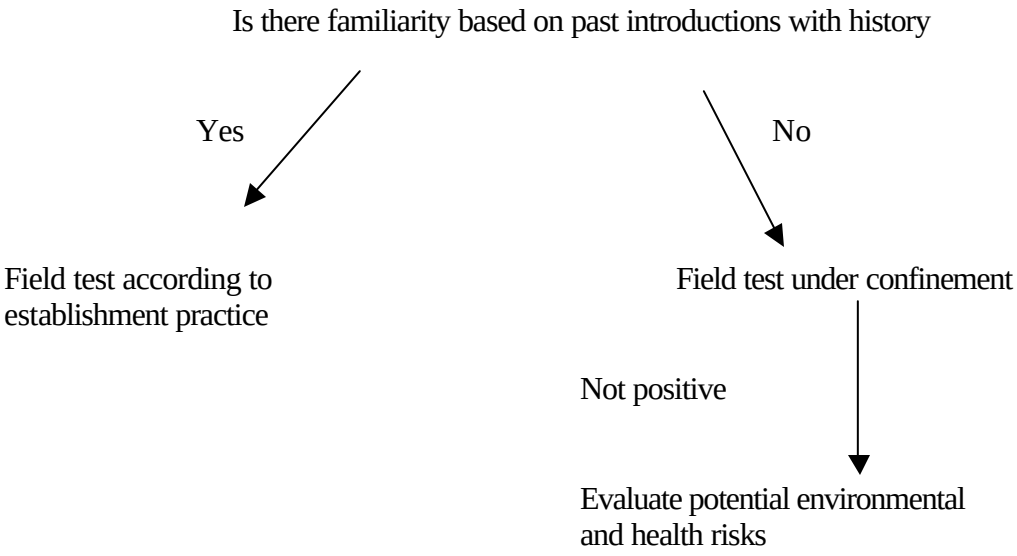
7. Potential Environmental Impacts

Pathogenicity, infectivity, toxigenicity, virulence, vector of pathogen, allergenicity, colonisation		
Known or predicted effects on other organisms in the environment		
Likelihood of post-release shifts in biological interactions or in host range		
Other:		
Effects on other species and possibility of transfer of introduced trait to other species		
Effect on plant's competitive advantages		
Effect on plant's biodegradability		
Any other possible ecological effects		
Ecosystems effects		
Known or predicted involvement in biogeochemical processes		
Potential for excessive population increase		

Annex II

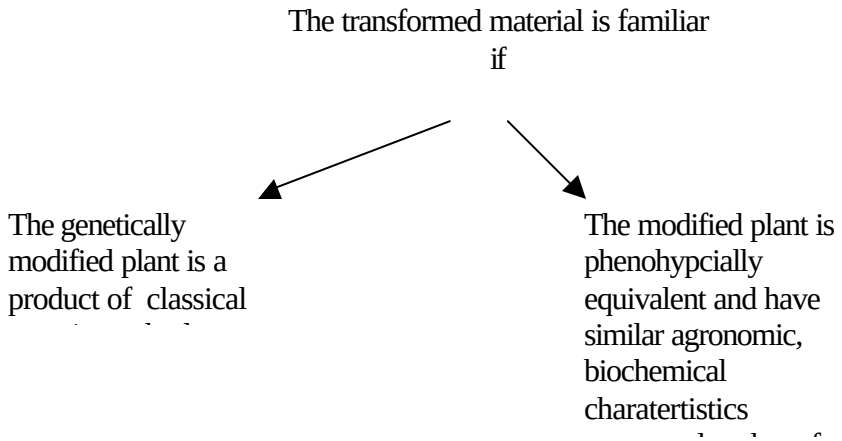
Framework for Risk Assessment

1. Framework to assess field testing of genetically modified organism



(modified after Persley et.al. 1992)

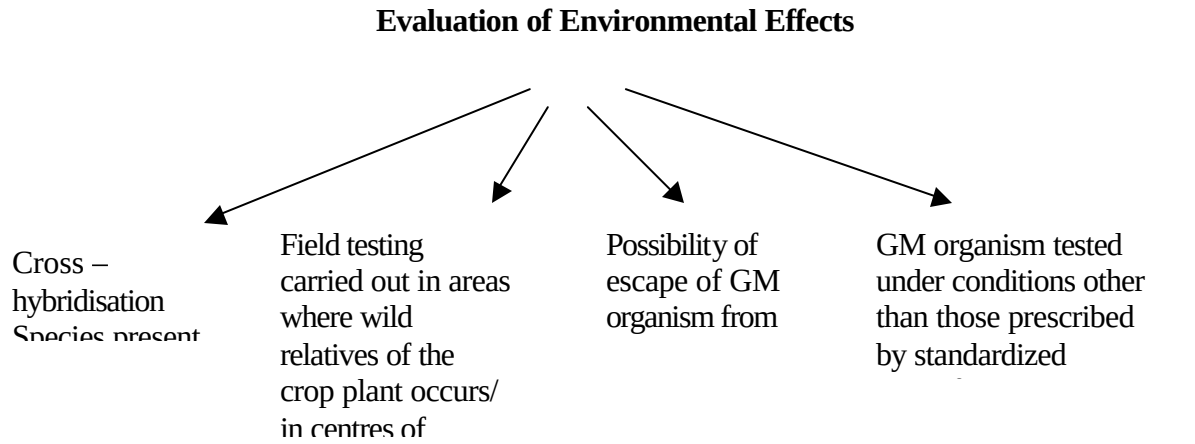
2. Where Risk Assessment can be optional



If the modification is effected by addition or adjustment of human genes/markers that have no adverse environmental effects.

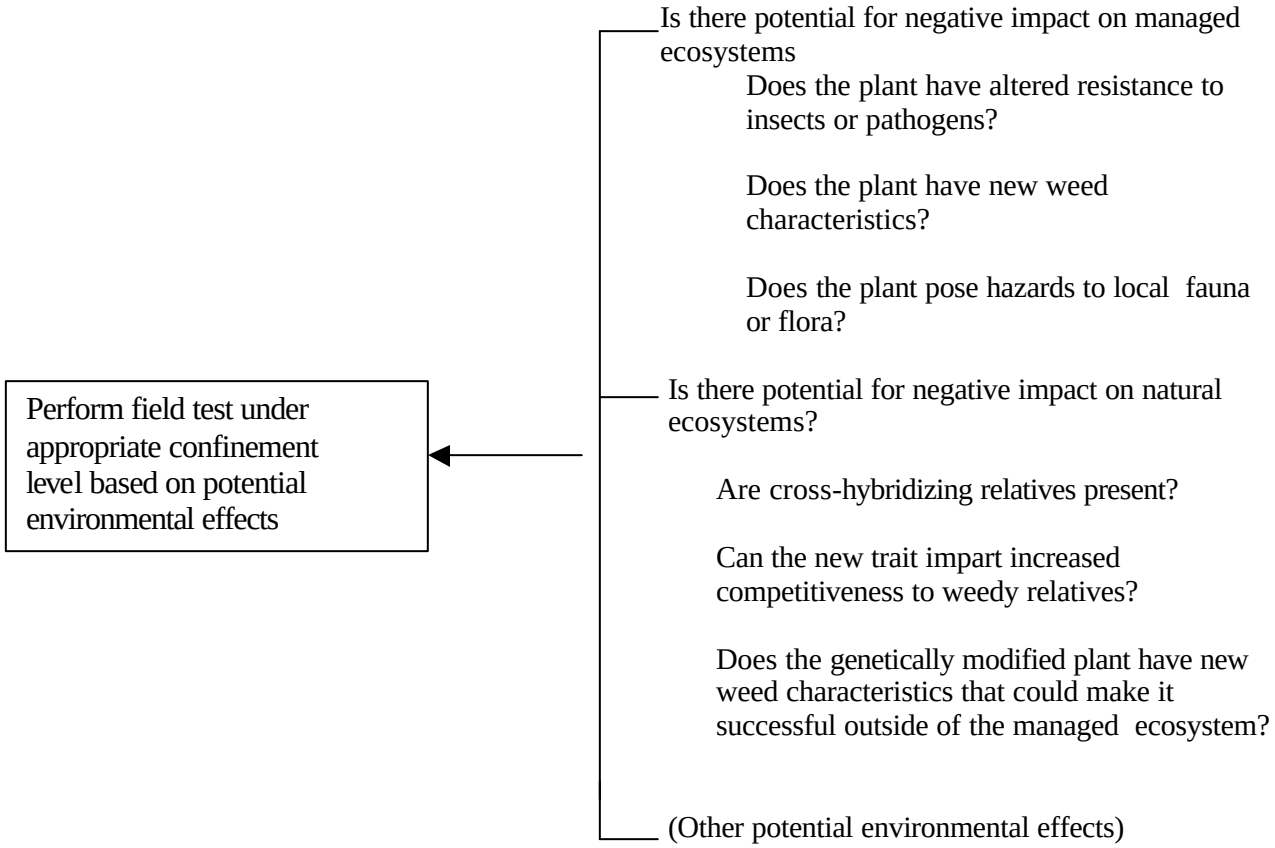
(*modified after Persley et.al. 1992)*

3. Risk Assessment Mandatory



(*modified after Persley et.al. 1992)*

4. Environment effects and its assessment



(Source : Persley et.al. 1992)

Additional Sources of Information

1. UNEP Technical Guidelines for Safety in Biotechnology
2. (http://www/unep.org/unep/program/natures/biodiv/irb/unepgds.htm)

3. CBD Biosafety Protocol
(http:// www. biodiv.org/biosafe/Protocol.asp)

4. EC Directive 2001/18/EC for release of GMOs into the environment
(http://europa.eu.int/eur-lex/en/oj/2001/1_10620010417 en. html)

5. APHIS Regulations – USA
(http:// www.aphis.usda.gov/biotech/7 efr340.html)

6. Country Regulations
(http://rbp-iucn.lk/biosafety./Mainpage.htm)

7. Guidance notes on documents, applications
(http://www. environment.detr.gov.uk/acre/indes.htm)

8. Public Information about requests and permits
(www.defra.gov.uk/environment/acre/exper.htm)

9. Checklists for Information needs
(www.inspection.gc.ca/english/ppc/biotech/enviro/evale.shtml)

10. Risk assessment – ICGEB database
(www.icgeb.trieste.it/~bsafervsrv/rasm.html)

11. OECD database on field trials
(EN/home/O,,EN-home-528-nodirectorate-no-no-no-27.FF.html)

11. Biology of Crop Species
(http://www/aphis.usda.gov/biotech)
(http://www.oecd.org/ehs/service.htm)

12. General Information on Biosafety – Biosafety Resource Kit
(http://www.rbp-iucn.lk/biosafety/Mainpage.htm)

Transgenic plants expressing insecticidal proteins derived from the soil bacterium, Bacillus thruingiensis (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 rare 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 Govt. of India for commercial cultivation.

Bt-crops, like any other GMO's have undergone 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 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 conducted 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 environment impact of these crop is negligible. The human and environmental safety of Bt-crops is negligible. It 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 selective advantage in the environment form 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 form roots of Bt-crops or from incorporation of above-ground plant tissues into soil after harvest, or by pollen deposited on the soil. Exposure may occur by breeding on living or dad 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 or cry proteins to non-target organisms like avain, 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. thurigniensis 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, helicoverpa 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.

Selected References (Reviews):

Fred S. Betz, Bruce G. Hammond and Roy L. Fuchs (2000). Safety and Advantages of Bacillus thuringiensis-Protected Plants to Control Insect Pests. Regulatory Toxicology and Pharmacology, 32: 156-173.

Anonymous (2001). Bt Plant-Pesticides Biopesticides Registration Action Document, USDA.

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

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Introduction

Capacity building needs are considered to be the key milestones to be successfully crossed by the developing regions including at least some developing countries in the region to enable the confidence building exercise. In other words there should be societal acceptance of the technologies of living modified organisms (LMOs) and in the context capacity building needs become most relevant aspect in the safe use of LMOs. The capacity building element constituents are elaborated below:

Institution Building

Risk assessment includes capacity to plan, analyze and take decisions on the basis of data generated on LMOs on a case by case basis. Data are to be generated on sound scientific basis. Risks from LMOs include 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 compatibles promoters, the target transgene and the hosts need to be analysed and understood through scientific methods. Core competence include 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 of sophisticated instruments. Besides, 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. Besides, 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, right relationships among the related institutes are also to be developed in order to enable them to broaden their horizon of activities.

The first steps in the capacity building needs of institutes are 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 strategy 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 in the transformed prokaryotic hosts are to be constructed and isolated. In addition, there is a need foe 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 completed to some satisfaction, the right kinds of transformants with better agronomic benefits and traits are to be selected that concomitantly have minimum risks to the environment and to human health.

In order to carry out different experiments in molecular biology efficiently in areas of LMO plants in 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. Inspite 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 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 form 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. Unless, therefore, the critical mass is in place, it would be difficult to make inventions by developing countries on a stand-alone basis. Even it would be difficult to appreciate the complexities of the products and technologies.

There are several companies in the private sector such MAHYCO, Pro-Agro PGS, Syngenfa, Ankur Seeds, SPIC, Rasi seeds, Rallis India, Indo-American Hybrid seeds, Bejo-Sheetal etc. Which 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 Indian environment. This situation will not give India strength in the long run

when one compares 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 form foreign laboratories that have competence in this area. These include training in isolating genes and polynucleotide sequences of interest, regeneration potential of transformed cells/calli and creation of stronger insfrastructure.

There can also be great wisdom in collecting economically valuable Indian germplasms and use 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 of comparison of money spent in India on a bench level researcher 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 against US Dollar 1000-2000 per person per year in average laboratories in the country, 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 environment. The scenario in other developing countries is not much different.

Risk Assessment Capacities

Besides capacity in molecular biology, most developing countries yet do not 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 have been stated as under.

Environmental risk assessment capacities include study of extent of pollen flow, implications of out crossing /cross fertilization, the aggressiveness charateristics of LMOs, susceptibility to diseases and pests, stability of the transgenic genome, germination rates, resistance to abiotic stresses etc. Food safety evaluation includes capabilities of determination of 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 the acceptance of LMOs, the scientific assessment can not be the ultimate basis of decision making, how so ever precise the scientific study may be scientific evaluation can not guarantee cent percent safety, although this statement does not any way belittle the great assurance the scientific experiments provide for. The gray area often constitute a miniscule percentage of suspected risks and the present scientific development does not allow to find precise answers 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 along with 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, the societies would have to decide on accepting or rejecting LMOs. Such decisions would have to be take on the basis of other non-scientific considerations such as cost benefit analysis, 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 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 the 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 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.

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