GENETICALLY MODIFIED (GM) CROPS AND BIOSAFETY**

Prof S.Kannaiyan*

Introduction:

Biotechnology is emerging as one of the most innovative achievements in the life sciences and influencing almost every aspect of human life. The achievements of modern biotechnology are the result of scientific discoveries made during recent years where advances in genetics, biochemistry, molecular biology and cell biology have allowed the development of genetic engineering. Progress in Agricultural Biotechnology has occurred at a very rapid pace in the last 25 years. Not only the ability to genetically transform a wide variety of crop species has been enhanced but also the capacity to generate variability for a range of economically important traits in crop plants through biotechnology has been established.

Biotic stress resistance:

Biotic stresses take a heavy toll of crop productivity in agricultural ecosystems. It has been reported that in India biotic stresses caused by insect pest(s), nematodes, fungal, bacterial and viral pathogens and weeds collectively result on an average of 45% yield losses. Management of the important biotic stresses such as insect pests and fungal pathogens has been done mainly through deployment of resistant varieties bred by conventional means and by chemical pesticides. Besides, usage of chemical pesticides

* Chairman, National Biodiversity Authority, Neelankarai, Channai – 600 041, TN

** Inaugural address delivered in the Biosafety Regulatory Framework: Assessment, Decision, Implication and Public and Private Interface held at Madurai Kamaraj University, Madurai, Tamil Nadu during 26 – 27th September, 2007.

often indiscriminately led to the adverse effects on environment and human health. Genes imparting resistance to a variety of insect pests and diseases are either not available in the germplasm or are extremely difficult to transfer through sexual hybridization. The advent of molecular biology and genetic engineering has facilitated rapid development of genotypes that can tolerate biotic stresses in a more effective manner.

Genetically Modified (GM) Crops in India:

Transgenic crops development at global level has attracted much attention and number of transgenic crops have been reported in the western world. The emergence of genetically modified crops revolutionized agricultural productivity and nutritional status of several important crops. The genetically engineered traits include insect pests resistance, herbicide tolerance and virus resistance.

The first and as yet the only GM crop approved for cultivation in India is the “Bt-cotton” which confer resistance to boll worm which is a menace in cotton crop. The transgenic crop acerage in India is currently around 1.2 million hectares. The acreage is likely to increase sharply in forthcoming years because of its high yielding nature with boll worm resistance. The transgenic cotton crop is gaining momentum in India. The other transgenic crops such as Pigeon pea, Brinjal, Potato, Tomato, Bhendi, Mustard, Cabbage, Rice are under experimental and evaluation stage. The major environmental concerns arising from the possible release of transgenics should be evaluated on a case by case basis depending upon the gene, the crop, the trait and the target geographical locations. The priorities

and parameters of environmental impact assessment of the transgenics should be identified. Biosafety issues need to be looked at critically before the release of GM crops.

Modern molecular biology tools are increasingly being used to produce GMOs with novel traits using genetic engineering, genetic modification or recombinant DNA technology. These involve isolation of nucleic acid molecules from one organism and their introduction into another organism altering the genetic make up of the receipient permanently and allowing them to be inherited by offspring.

GMOs have been developed and applied successfully since early 1970s under contained conditions and since mid 1980s for commercial applications in the field and open environment. Various applications of GMOs have been growing at a rapid rate. However, it is widely recognized that use of GMOs should be subject to adequate safety measures because of apprehensions about their potential risk to human health and environment. Such measures should collectively ensure biosafety. Consultations on safety in use of GMOs have resulted in a number of National and International recommendations, guidelines and legislation.

Regulatory Mechanism:

India has a well-defined regulatory mechanism for development and evaluation of GMOs and the products thereof. The Department of Biotechnology (DBT) and the Ministry of Environment & Forests (MoEF) are the two apex regulatory bodies. Rules have been notified by MoEF in 1989 under Environmental Protection Act, 1986 (EPA), as the production

and preservation of the environment is vested upon the government. These rules cover procedures for the manufacture, import, use, research and release of GMOs as well as products made by the use of such organisms. The objective of the rule is to ensure that the use of such products or life forms is safe to the environment and beneficial to the human beings. The competent authorities and their composition for dealing with all aspects of GMOs and products thereof has also been defined.

Guidelines for safety have been issued by the Department of Biotechnology (DBT) in 1990 covering research in biotechnology, field trials and commercial applications. DBT had also brought out separate guidelines for research in transgenic plants in 1998 and for clinical products in 1999. Activities involving GMOs are also covered under other policies such as the Drugs and Cosmetics Act (8^{th} Amendment), 1988, the Drug Policy, 2002, and the National Seed Policy, 2002.

Presently, there are six competent authorities for implementation of regulations and guidelines in the country:

i. Recombinant DNA Advisory Committee (RDAC)
ii. Review Committee of Genetic Manipulation (RCGM)
iii. Genetic Engineering Approval Committee (GEAC), (apex bodies)
iv. Institutional Biosafety Committees (IBSC) attached to every organization engaged in rDNA research
v. State Biosafety Coordination Committees (SBCC) and
vi. District Level Committees (DLC)

Of the above committees, the IBSC is constituted by organizations involved in research with GMOs with the approval of DBT. The IBSC is

the nodal point for interaction within the institution for implementation of the guidelines. Every research project using GMOs has to have an identified investigator who is required to get the research project approved from safety angle and inform the IBSC about the status and results of the experiments being conducted. The functions of IBSC include to:

1 Reviewing and giving clearance to project proposals falling under restricted category as per DBT guidelines.
2 Recommending Category III risk or above experiments to RCGM for approval
3 Tailoring biosafety programme to the level or risk assessment.
4 Training of personnel on biosafety
5 Adopting emergency plans

The role of IBSCs assumes major importance since it is the only Statutory Committee, which operates from the premises of institution and hence is in a position to conduct onsite evaluation, assessment and monitoring of adherence to the biosafety guidelines. The decisions taken by the next higher committee i.e.Review Committee on Genetic Manipulation (RCGM), which operates from DBT are based on the applications submitted by the investigators with the approval of IBSC on the status of the project and its conformity with the regulatory guidelines.

Recombinant DNA technology can be used for insertion of genes in plants not only from related plant species but also from unrelated species such as microorganisms. The process of creation of transgenic plants is for more precise and selective than traditional breeding. Application of recombinant Technology is primarily for the production of transgenic plants

with higher yield and nutritional content, increased resistance to stress and pests. Several commercially important transgenic crops such as maize, soyabean, tomato, cotton, potato, mustard, rice etc. have been genetically modified and reported.

Insect resistance:

Biotechnology has opened up new avenues for natural protection for plants by providing new biopesticides, such as microorganisms, that are toxic to targeted crop pests but do not harm humans, animals, fish, birds or beneficial insects.

Disease resistance:

Plants are susceptible to viral, bacterial and fungal diseases. Much progress has been made in evolving transgenic plants resistant to viruses. For example, expression of a gene that encodes the coat protein of tobacco mosaic virus (TMV) in transgenic tobacco plants has been shown to cause the plants to resist TMV infection. A number of other viral resistant plants species have been developed including squash and potatoes.

Produce quality improvement:

One of the most successful research efforts to change the characteristics of a plant produce was carried out with tomatoes. Tomatoes need to be picked while still green so that they are firm enough to withstand mechanical handling and transport. Unfortunately, they do not develop the same flavor and texture of vine- ripened tomatoes.

Risk to Human Health:

Risks of GMOs to human health are related mainly to toxicity, allergenicity and antibiotic resistance of the new organisms/products. The risk of toxicity may be directly related to the nature of the product whose synthesis is controlled by the transgene or the changes in the metabolism and the composition of the organisms resulting from gene transfer. Every GMO needs to be carefully evaluated for toxicity to human and animals. Most of such toxicity risks can be assessed using scientific methods both qualitively and quantitatively.

Influence of GMOs on Environments:

The gene transferred into an organism or the resultant products can actually remain in environmental leading to environmental problems. The intentional release of GMOs into the environment has led to an increased interest in possible interactions that may occur between other organisms in the environment. Unintended genomic changes can occur as a secondary consequence of genetic modification. Such changes can lead to production of new proteins that may be toxic or allergenic or may disrupt or alter metabolic pathways that play a role in making the GMO successful.

Gene flow:

Accidental cross breeding between GMO plants and traditional varieties through pollen transfer can contaminate the traditional local varieties with GMO genes resulting in the loss of traditional varieties of the farmers.

Resistance / tolerance of target organisms:

The potential benefits of planting insect-resistant transgenic crops include decreased insecticide use and reduced crop damage. However, the innate ability of insect populations to rapidly adapt to environmental pressures poses a serious threat to the long-term efficacy of insect-resistance. Adaptation by insects and other pests to pest protection mechanisms can have environmental and health impacts.

Increased weediness:

Weediness means the tendency of the plant to spread beyond the field where it was first planted. There are apprehensions about GM crops becoming weeds. For example, a salt tolerant GM crop if escapes into marine areas could become a potent weed there.

There is also fear about the development of superweeds i.e. a weed that has acquired the herbicide tolerant gene due to genetic contamination with a herbicide tolerance GMO through in field cross breeding to related species or through horizontal gene transfer.

Loss of Biodiversity/reduction of cultivars:

There have been concerns about reduction in the genetic diversity in cropping systems by the development and global spread of improved crop varieties to the green revolution. This genetic erosion has occurred as the farmers have replaced the use of traditional varieties with monocultures. This is expected to further intensify as more and more transgenic crops are introduced which bring in considerable economic benefits to the farmers. The relative rate of susceptibility to any unforeseen infections or destructive situations increases when single varieties are used in cropping system in

place of multiple varieties.

Changes in the soil ecology:

Many plants leak chemical compounds into the soil through their roots. There are concerns that transgenic plants may leak different compounds than conventional plants, as and unintended sequence of their changed DNA. Speculations are that this may change the ecology of the soil in terms of functional composition and biodiversity. The interaction between plants and solid microorganisms is very complex, with the microorganisms living around plant roots also secreting chemical compounds into the soil.

Bio-safety and Cartagena Protocol:

The Cartagena Protocol on Bio-safety is the first international regulatory framework for bio-safety, negotiated under the aegis of the Convention on Biological Diversity (CBD). Named after the Columbian city where the final round of talks were launched, the Cartagena Protocol on Bio-safety sets out a comprehensive regulatory system for ensuring the safe transfer, handling and use of Living Modified Organisms (LMOs) with a focus on transboundary movement. The Protocol deals primarily with LMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans addressed by other international agreements and organizations or products derived from LMOs, such as cooking oil from genetically modified corn.

The Protocol was adopted on 29th January 2000 and entered into force

from September 11, 2003. As on date, 135 countries have ratified the Protocol. The governing body of the Protocol is the Conference of Parties to the Convention serving as the meeting of the Parties to the Protocol i.e. COP/MOP. The main function of this body is to review the implementation of the Protocol and make decisions necessary to promote its effective operation.

India ratified the Protocol on January 23, 2003 and the Ministry of Environment & Forests (MoEF) is the nodal ministry for implementation of Cartagena Protocol. MoEF has taken several initiatives to meet its obligations to the Protocol including capacity building of various stake holders for its effective implementation in the country. MoEF is implementing a GEF- World Bank funded Capacity Building Project on Bio-safety with an objective to strengthen of regulatory framework, particularly on transboundary movement of living modified organisms (LMOs)/ genetically modified organisms (GMOs), risk assessment and management, training and human resource development and information sharing.

Major elements of the protocol:

The various elements of the protocol are:

1 Advance informed Agreement procedure
2 Simplified system for agricultural commodities
3 Risk assessments
4 Risk management and emergency procedures
5 Export documentation
6 Bio-safety clearing House
7 Capacity-building and finance
8 Public awareness and participation

9 Issue of non-parties.

Risk Assessment and Management:

Risk is defined as the probability of harm. Risk analysis consists of three steps:-

1 Risk assessment
2 Risk management
3 Risk communication

Risk assessment evaluates and compares the scientific evidence regarding the risks associated with alternative activities. Risk management develops strategies to prevent and control risks within acceptable limits and relies on risk assessment. In addition to the scientific assessment, it also takes into consideration various factors such as social values and economics. Risk communication involves an ongoing dialogue between regulators and the public about risk and options to manage risk so that appropriate decision can be made. Risk assessment should be carried out on case by case basis.

It has been generally accepted that details of risk assessment procedures may vary from case to case but there are few logical steps that need to be followed:

1 Identification of potential adverse effects on human health or environment
2 An estimation of likelihood of these adverse effects
3 An evaluation of identified risks
4 Considerations of appropriate risk management strategies
5 Assessment of overall potential environmental impact and consequences
6 A recommendation as to whether or not the risks are acceptable or manageable.

Conclusion:

The Convention on Biological Diversity (CBD) Article 19(3) deals with the safe transfer, handling and use of any genetically modified organism resulting from Biotechnology. Bio-safely is a critical element in the CBD which addresses the Conservation and sustainable use of Biodiversity in all its aspects i.e., Biological Diversity including the genetic resources associated with it. Bio-safety is a critical component of both public and the International acceptability of the products arising out of transgenic manipulation through biotechnology. It is expected that there will be a large scale exchange of biotechnology products at global level may occur in future. But apprehensions are there in the mind of public as to whether these are safe or not. The regulating agencies should strongly address the bio-safety mechanism in case by case and they need to assure the public at large that these new GM products are absolutely safe. This issue has to be done in an open and transparent manner using the best possible scientific expertise and knowledge. At the same time the public perception and cultural practices should be taken into account in risk assessment.

It should be borne in mind that no generalized prescription is possible about the behaviour of a transgenic crop in the open environment and therefore it is important to assess the impact on the environment on a case by case basis. The major concerns raised by the public relates to the impact of the GM crops on the near relative wild plants or other elements of biodiversity in the environment in which they are introduced causing genetic contamination and potential loss of genetic diversity, development of pest(s) and disease(s) and herbicide resistance which may likely to affect the human health through the food chain. In the context of Bio-safety the social

scientists and biotechnologists should work-together in terms of risk assessments and bio-safety of the GM crops/GM products on case by case basis and clear the apprehensions of the public to achieve the progress and economic development of our Nation by utilizing the modern biotechnology tools for the human welfare.