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Available online at www.marumegh.com

 ISSN: 2456-2904

BIO-SAFETY AND PUBLIC ACCEPTANCE OF TRANSGENIC PRODUCTS

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Introduction

Biotechnology is emerging as one of the most innovative achievements in the life sciences and influencing almost every aspect of human life. 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. Rapidly growing population, decline in agricultural yield increase, malnutrition, over consumption of certain nutrients in developing countries and declining natural resources such as arable land and water are the problems and challenges to tackle in 21st century. Transgenic can add value to global agriculture. Soybean, cotton, maize and canola are principal GM crops globally (James, 2013).

Transgenic: An organism in which a foreign gene is incorporated into its genome
Globally approved transgenic plants:

Product	Genetically Altered Traits
Tomato	Delayed ripening: Antisense technology
Cotton	Bt gene incorporated plants (bollworm & budworm resistant)
Soybean	Resistant to glyphosate for control of weeds
Potato	*Bt* gene incorporated (Colorado potato beetle resistant) *Cry III* gene from *Bacillus thuringiensis*
Maize/Corn	*Bt* gene incorporated (resistant to borer) *Cry II* gene from *B. kurstaki*
Rapeseed / Canola	Altered oil composition (high lauric acid content), Resistant to glufosinate

Genetically Modified (GM) Crops in India

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 acreage 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.

Biosafety; The avoidance of risk to human health and safety to conservation of environment, as a result of use for research and commerce of infectious or genetically Modified Organism-

-comes under bio-safety.

Risk to Human Health

Risks of GMOs to human health are related mainly to toxicity, allergenicity (Guimaraes *et al.*, 2010) 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.

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 (Saxena *et al.*, 2002).

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 there 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 (8th 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

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). The Protocol was adopted on 29th January 2000 and entered into force from September 11, 2003. 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.

Conclusion

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.

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.

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