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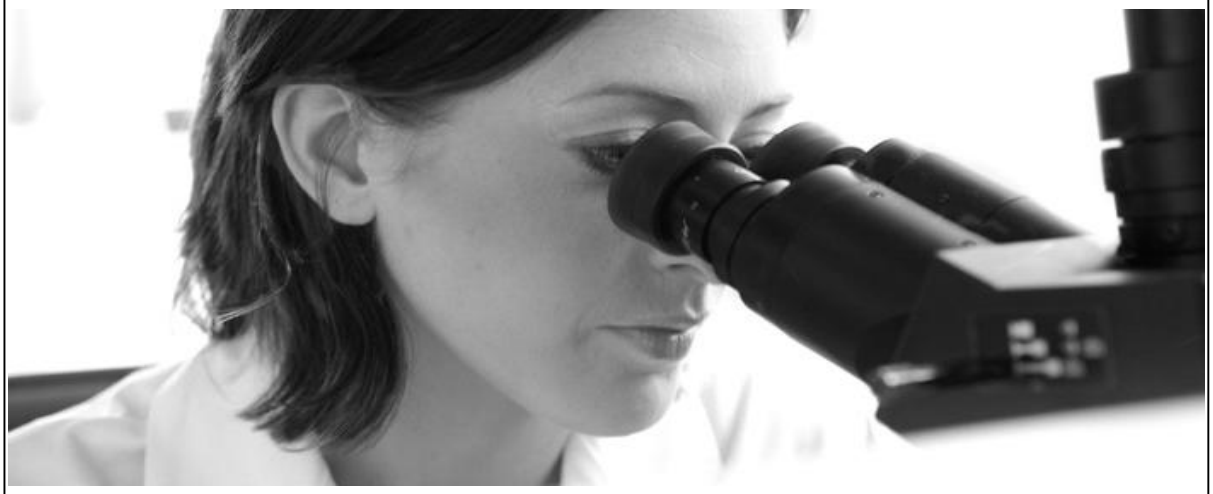
BIOSAFETY ISSUES



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RESEARCH ARTICLE

BIOSAFETY ISSUES

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INTRODUCTION

Biosafety is used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. It has similarly been defined as **"**the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms**".**

Conventional breeding involves crossing related species to develop plants with desired characteristics which are selected among the progeny for reproduction and the selection is repeated over many generations. Genetic engineering transfers gene horizontally from one individual to another as opposed to vertical gene transfer from parent to offspring. It makes use of infectious agents as vectors or carriers of genes so that genes can be transferred between distant species that would never interbreed in nature. Due to horizontal gene transfer in the development of GMOs there have been conflicting reports on the benefits of GMOs, risks, apprehensions, environmental concerns, and social concerns for the release of GMOs. Research is being conducted on field tests of transgenic plants and data is generated and the potential risks from the use of GMOs and products thereof have been described. Formal risk assessment usually considers:

1. what can go wrong?
2. how likely is it to happen? and
3. what are the consequences if it does not happen?

Broadly these risks have been categorized under risks to human health, environmental concerns and social and ethical grounds.

Risk to Human Health

Risk of toxicity: 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. In some cases organism may contain inactive pathways, with the addition of new genetic material which could reactivate these inactive pathways or otherwise increase the level of toxic substances within the plants. Further, the modified metabolism due to introduction of tolerance to chemical substances such as herbicides may also lead to appearance of novel metabolites in the cell.

For example, herbicide resistant varieties have been released to permit the use of glyphosate and bromoxynil herbicides for weed control. It has been reported that bromoxynil causes birth defects in animals and is also toxic to fish. Glyphosate is also reported to be toxic to soil organisms and to fish.

Risk of allergies: Production of GMOs sometimes includes the introduction of newer proteins from the organisms which have not been consumed as foods and may cause allergy. For example, when a methionine-rich 2S storage albumin protein producing gene from the Brazil nut was incorporated into soyabean to enhance its sulphur containing amino acids in the seed storage protein it was confirmed that that consumption of transgenic soyabean could trigger an allergic response in those sensitive subjects who were allergic to Brazil nut.

Antibiotic resistance: Production of GMOs generally involve the use of genes for antibiotic resistance as selectable marker and their use has raised the concern that eating food carrying antibiotic resistance marker would reduce the effectiveness of antibiotic to fight disease when these antibiotics are taken with meals. The antibiotic resistance gene produce enzyme that can degrade antibiotics.

For example, in case of approval process of Calgene's Flavr Savr tomato and Ciba-Giegy's Bt corn 176 this issue was raised, however, it was further confirmed that the enzyme is produced at such low levels that it was absolutely ineffective on the antibiotic.

Eating foreign DNA: There have been apprehensions about danger from eating the foreign DNA in GM foods i.e. the

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pieces of DNA that did not originally occur in that food plant. DNA being present in all living things such as plants, animals, microorganisms and is eaten by human beings with every meal. Most of it is broken down into more basic molecules during the digestion process whereas a small amount that is not broken down is either absorbed into the blood stream or excreted.

For example, the use of promoters of virus origin e.g. 35S promoter of cauliflower mosaic virus (CaMV) which causes cauliflower mosaic disease in several vegetables, such as cauliflower, broccoli, cabbage and canola was suspected to be harmful if it invades human cells and turns on certain genes. However, a multistep chain of events would have to occur for the CaMV promoter to escape the normal digestive breakdown process, penetrate a cell of the body and insert itself into a human chromosome. Such a probability is extremely low (virtually impossible), as the normal body defense eliminate any stray fragments of foreign DNA that enter into the bloodstream from the digestive tract.

Changes in nutritional level: Concerns about the accidental changes in the nutritional components of transgenic crops while incorporating other traits have been raised.

For example, isoflavone levels in Roundup-Ready herbicide resistant transgenic soyabean showed minor difference in comparison to conventional varieties.

Risk to Environment

Gene Flow or dispersal from transgenics: Accidental cross breeding between GMO plants and traditional varieties through pollen transfer can contaminate the traditional local varieties with GMO genes resuting in the loss of traditional varieties for the farmers. The wind, rain and insect pollinators can contribute in these aspects.

For example, Corn originates from Mexico which holds the greatest biodiversity of corn species in the world of both wild and cultivated species but now it has been reported that wild corn variety located in some areas of Mexico have been contaminated by some GMO genes.

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 the development of strains which are resistant to these genes is a serious threat to the long-term efficacy of insect resistant transgenics.

For example, adaptation by insect populations to an environmentally benign pest control technique could result in the use of chemical pesticides with higher toxicity.

Generation of new live viruses/super viruses: The existence of virus resistant plants could encourage viruses to grow stronger or give rise to new or stronger variants that can infect plants through recombination and transcapsidation. Recombination can occur between GMO produced viral genes and closely related gene of any incoming virus infecting that GMO and it may produce viruses that can infect a wider range of hosts or that may be more virulent than the parent viruses. Transcapsidation in a GMO, involves the encapsulation of the genetic material of infecting virus by the GMO produced viral proteins. Such hybrid virus could transfer viral genetic material to a new host plant that it could not otherwise infect.

Ecological Concerns

Increased weediness: Weediness or invasiveness means the tendency of the plant to spread beyond the field where it was first planted, causing undesirable ecological changes.

For example, "kudzu" was introduced into the Southern United State to control soil erosion, but now it has became a major invasive weed in the region. 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.

Creation of super weeds: Transgenes can spread to wild relatives by cross – pollination, thus creating superweeds. This has occurred in oilseed, rape and sugarbeet, creating potential superweeds. A large proportion of transgenic varieties under commercial cultivation have herbicide resistance. There is a fear about the development of super-weeds i.e. a weed that acquires the herbicide tolerant gene due to genetic contamination or through horizontal gene transfer.

Loss of biodiversity/reduction of cultivars: There have been concerns about reduction in the genetic diversity in cropping systems (i.e. *in situ*) 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.

Persistence of the transgene or transgene product: The gene transferred into an organism or the resultant product can actually remain in environment leading to environmental problems.

For example, in case of Bt crops it was suspected that insecticidal proteins can persist in the environment but experiments have proved that these are degraded in the soil. GM herbicide resistant oil seed rape, maize, sugarbeet and GM potato expressing either Bt toxin or pea lectin also did not survive well outside the agricultural field and did not take a weedy character in UK where field trials were conducted over a 10 year period. There are also concerns in case of microorganisms about their capacity to adapt to new environment conditions and persist in the environment as spores.

GM crops affect the purity of other crops: Conventional non-GM crops will inevitably receive transgenes from GM crops, resulting in situations that are either undersired or unlawful. This has already happened in the case of GM Starlink maize containing the cry9C gene which was found in non-GM maize

grains in the US. The organic farming industry is also particularly concerned about genetic mixing through pollen dispersal and mixing of seed. Liability may become a major issue.

Increased use of chemicals: Most of the transgenic varieties released for cultivation are against a particular herbicide and the farmers have to use a particular herbicide e.g. Roundup (Trade name of Monsanto herbicide) for a transgenic variety Roundup Ready Soyabean. It is reported that farmers growing such varieties used a specific Roundup herbicide 2-5 times more in per unit area of land as compared to other weed management programmes. This increased use of herbicides is due to the fact that there is increased tolerance to Roundup of key weed species.

Effect of rhizosphere and microflora: Transgenic plants can influence the composition of microflora in their root zones or rhizosphere. There was no difference in the bacterial cell consortia extracted from rhizosphere of non-trangenic and transgenic expressing cry1A maize plants. Significant differences were observed in the composition of bacterial communities associated with the rhizosphere of non-transgenic and transgenic plants of tobacco and eucalyptus.

Unpredictable gene expression or transgene instability: There is considerable evidence that transgenes show instability because they become deleted or modified following their integration in to the plant genome. The level of transgene expression may also decline with the passage of generations as gene silencing may occur. Unintended genomic changes can also 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 pathway that plays a role in making the GMO successful.

Non-target effects: Non-target or unintended effects is another perceived risk as transgenics growing in a particular ecosystem can cause direct or non-target effects on certain microbes or insects growing in a particular ecosystem. GM crops containing insect-resistant Bt (*Bacillus thuringiensis*) toxin have been comprehensively studied. Possible environmental effects include direct effect on non-target insects due to exposure to GM plant material and also indirect effect on non-target insects via so called multi-trophic food chains.

For example when Bt cotton was released for commercial cultivation, extensive analysis was carried out on the effect of Bt crystal proteins on various non-target insect populations, mammals, birds and other organisms within the environment. Bt gene product (Cry proteins) is rapidly degraded by the stomach juices of vertebrates, but they could have harmful effects on non-target insect species. Any non-target insects that are vulnerable to Bt toxin will be affected if they eat any part of the GM crop.

Potential Economic Concerns

Increasing dependence on industrialized nations by developing countries: The IPR system intrinsic to the WTO is heavily biased against developing countries. Not only does it provide MNCs the right to seize and patent genetic resources without any/adequate compensation, but it also prevents farmers from saving and reusing the modified seeds. Therefore, being forced to come back to seed giants year after year, for seed purchases would be financially unviable for them, leading to increased vulnerability. Since 1990, Monsanto has sued 145 farmers for "patent infringement". Monsanto claims that farmers are using their GMO plants without paying for them.

Biopiracy or foreign exploitation of natural resources: Plant breeding relies on genetically diverse germplasm for progress to be made and maintained, which in traditional agriculture is regarded as a common resource of great value and is freely available. It is unethical to treat such traditional forms of agriculture as markets to be conquered by private interests.

Poor farmers might become dependent on international corporations for seed: Some transgenic crops are designed with terminator technology that produces infertile seeds. This ensures a steady stream of income to the company that designed and sells the seeds. Because farmers they become dependent on buying seed every year rather than saving seed from one year's crop to plant the following year.

Only large scale farmers are benefitted: GM seeds enable farmers to practise precision agriculture and narrow row farming, for small farmers, having fragmented land holdings with few technological inputs it is very difficult to achieve. Only the rich farmers would be able to afford these more expensive seeds. Moreover, these crops have led to increased flexibility in agricultural practices, such as simplified weed control, conservation tillage, broad spectrum control etc., all of which have led to reduced labour requirements. Thereby, having adverse economic impact on labour intensive developing country (India agricultural sector employs 64% of workforce).

Commingling of PMP crops and food or feed crops: Commingling of PMP crops and food or feed crops may occur. This could happen through improper labelling, mixing of seed in planting, harvesting, transportation, or processing. In a 2001 case, ProdiGene failed to eliminate volunteer bio-pharm corn plants from a soybean crop planted later in the same field as the PMP corn. The company was fined $250,000 by USDA and was required to reimburse the government $3 million for expenses related to destruction of 500,000 bushels of potentially contaminated soybeans.

Social And Ethical Considerations

1. Violation of natural organisms' intrinsic values.
2. Tampering with nature by mixing genes among species.
3. Strict vegetarians might object to gene sequences from animals being introduced into plants.
4. Use of animals in biotech research cause greater suffering to the animals.
5. It is felt that by using animal for production of pharmaceutical proteins we reduce them to mere factories.
6. Some people feel that animals should be regarded as equal to human in order they have the same basic right as humans.

7. Introduction of human genes into animals or vice-versa may be seen which is interfering the definition of humanness.
8. There are different social and ethical issues confined with the involvement of sacred and religious trees and animals in transgenic research.

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