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RESULTS & DISCUSSION
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RECOMMENDATIONS/SUGGESTIONS
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PROSPECTS OF GENETICALLY MODIFIED CROPS IN INDIA: CHALLENGES AND ISSUES

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ABSTRACT

Genetically Modified Organisms, are the ones in which the genetic material (DNA) has been altered in such a way as to get the required quality. This technology is often called 'gene technology', or 'recombinant DNA technology' or 'genetic engineering' and the resulting organism is said to be 'genetically modified', 'genetically engineered' or 'transgenic'. GM (Genetically Modified) products (current or those in development) include medicines and vaccines, foods and food ingredients, feeds and fibre. Genetically-Modified Foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy and food labeling. Many people feel that genetic engineering is the inevitable wave of the future and that we cannot afford to ignore a technology that has such enormous potential benefits. However, we must proceed with caution to avoid causing unintended harm to human health and the environment as a result of our enthusiasm for this powerful technology. In this context, the present paper overviews the problematique dimensions of GM Crops and its legal ramifications in relation to social, environmental and intellectual perspective.

KEYWORDS
biodiversity, biotechnology, environmental sustainability, food security, genetically modified crops, intellectual property rights.

1. GENETICALLY MODIFIED CROPS: CONCEPT NATURE AND OVERVIEW

1.1 BIOTECHNOLOGY IN GENERAL

Biotechnology is not a new science. It is based on very old traditions used since the beginning of the civilized world to improve products of the land such as agricultural products and animal farming. The origin of biotechnology can be traced back to prehistoric times, when microorganisms were already used for processes like fermentation. Beer brewing, cheese making and production of sour milk are some of the common examples which are often included in describing what is called biotechnology.[1]

The term 'biotechnology' generally refers to the use of biological processes, as through the exploitation and manipulation of living organisms or biological systems, in the development or manufacture of a product or in the technological solution to a problem. As such, biotechnology is a general category that has applications in pharmacology, medicine, agriculture, and many other fields. In relation to genetic engineering, the techniques have been used to manipulate the deoxyribonucleic acid (DNA) of bacteria and other organisms to manufacture biological products such as drugs. Plants and foods with desired qualities such as prolonged shelf life or increased resistance to diseases and pests have been created through genetic engineering; that is, by inserting DNA from other organisms

1.2 PLANT BIOTECHNOLOGY

In the context of the modern biotechnological revolution, plant genetic resources have become a significant source for plant breeding, crop development and enhancement. Undoubtedly, like most technology, biotechnology can be used for good or ill, but in the field of agriculture, it has the prospect of giving enormous benefits in the quality and yield of foods and the range over which they can be grown. The advent of genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include: pest control traits such as insect and virus resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage prone fruits; male and/or seed sterility for hybrid systems; and output traits such as plant colour and vitamin enrichment.[2]

Despite the fact that some people have been opposing and viewing biotechnology with caution, the remaining section of the public is attracted to the benefits of biotechnology for food, for example as evidenced by the demand for Falvr-savr tomatoes, that is a new variety of tomatoes which remain ripe far longer than normal tomatoes before they rot after their introduction in the United States.

Biotechnology has taken the development of new plants and seeds into the fast lane. The world is experiencing a 'breakthrough in agricultural technology that may soon enable us to harvest crops from deserts, farm tomatoes in seawater, grow super potatoes in many new localities, and enjoy entirely new crops such as tomato. We can now isolate and manipulate the genes that constitute the hereditary materials of each species' genetic makeup.' These recent developments in biotechnology have increased the need to protect inventions and regulate commercial exploitation.[3]

2. INTELLECTUAL PROPERTY (IP) PROTECTION TO GENETICALLY MODIFIED (GM) CROPS AND FOODS

The most important mechanisms for legally protecting agricultural biotechnological inventions are patents and plant variety rights. It has been a subject of debate and a matter of dispute whether plants and agricultural biotechnological inventions can be the subject of patent protection, in addition to or as an alternative to the protection afforded by plant variety rights. Biotechnological patents have been criticized for granting an excessive scope of protection to proprietors, whereas plant variety rights have been slighted for not providing enough protection. This issue is one of many questions in patent law to which no single global answer could be given, owing to the differences of law from one country to another.[4]

The possibility of patent protection for plants and animals was first mooted at about the beginning of the 20th century. However it was a long time before this view was accepted by legislatures, courts and Patent Offices. This is due to the belief that living organisms and cells were non-patentable products of nature. Hence, under the rationale that naturally occurring organism were not new, the assumption was that patents could not be granted. In such a case, it was perceived that the grant of a patent would remove from the public domain something 'which nature has produced and which nature has intended to be equally for the use of all men'.

The issue of the patenting of life-forms was finally given a judicial answer in the landmark decision of the United States Supreme Court in 1980 in *Diamond* v. *Chakrabarty*. It was held that a bacterial strain into which a plasmid from another strain had been inserted constituted patentable subject-matter. The Court distinguished the products of nature from man-made inventions and held that statutory subject-matter included 'anything under the sun made by man' and that genetically engineered micro-organisms were not precluded from constituting patentable subject-matter merely because they were living cells. Although this clearly spelled out liberal approach, not many countries have followed up by clear permissive legislation. In fact, there are only a few specific exclusions in those jurisdictions, hence vagueness reins.[5]

Undeniably, Intellectual Property Rights (IPRs) offer a temporary monopoly for the commercial exploitation of an invention and innovation, thus creating an incentive for further research and development. As patents primarily serve an economic function, the basic belief governing the system is the conviction that the protection provides an incentive for people to innovate and invest. Hence the possibility of recouping the high investment in genetic engineering and plant development industry can effectively be guaranteed through adequate legal protection. This justification, though controversial, is equally legitimate from a public policy perspective. Nevertheless, the economic justification for patent is not always uncontroversial, as many IPRs, which include patent laws, have been asserted of going too far in protecting those who produce innovations at the expense of those who use them. Historically, and even today, the way patents have been justified in different countries has depended on the level of industrial development. The use of IPRs in plant breeding especially in developing and least developed countries have raised issues on food security, smallholders' access to technology and the possible monopolization of genetic resources.

Another related concern in developed countries is pertaining to the changes in the structure and composition of the plant breeding and seed industry, in particular the increasing involvement of large companies. The increasing role of the private sector in fundamental research has triggered the issue of the appropriate scope and system of protection for results of such research. For example, Monsanto's decision to co-operate with plant breeders in the development of new plant varieties through the combination of traditional plant-breeding methods with its genetic resources aroused the question of the extent to which IPRs should be used to protect the results of genetic research.[6]

2.1 GLOBAL IPR REGIME AND ECONOMIC CONCERNS

As far as the global intellectual property regime is concerned, the most significant IPR treaties in the context of plants and biotechnological inventions are the Agreement on Trade-Related Aspects of Intellectual Property Rights (henceforward the TRIPS Agreement or TRIPS), and the Convention of the International Union for the Protection of New Varieties of Plants (The UPOV Convention). The former, which is administered by the Geneva-based World Trade Organization (WTO), is so important because it is the first and the only international treaty which seeks to establish enforceable universal minimum standards of protection for all the major intellectual property rights. The latter, which is administered by another intergovernmental organization, the International Union for the Protection of New Varieties of Plants (UPOV), is significant because it deals specifically with plant varieties.[7]

Bringing a GM food to market is a lengthy and costly process, and of course agri-biotech companies wish to ensure a profitable return on their investment. Many new plant genetic engineering technologies and GM plants have been patented, and patent infringement is a big concern of agribusiness. Yet consumer advocates are worried that patenting these new plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds for GM crops, thus widening the gap between the wealthy and the poor. It is hoped that in a humanitarian gesture, more companies and non-profits will follow the lead of the Rockefeller Foundation and offer their products at reduced cost to impoverished nations.[8]

Patent enforcement may also be difficult, as the contention of the farmers that they involuntarily grew Monsanto-engineered strains when their crops were cross-pollinated shows. One way to combat possible patent infringement is to introduce a "suicide gene" into GM plants. These plants would be viable for only one growing season and would produce sterile seeds that do not germinate. Farmers would need to buy a fresh supply of seeds each year. However, this would be financially disastrous for farmers in third world countries who cannot afford to buy seed each year and traditionally set aside a portion of their harvest to plant in the next growing season. In an open letter to the public, Monsanto has pledged to abandon all research using this suicide gene technology.

2.2 PATENTING OF GM CROPS AND FOODS

A relatively new concern raised in the debate on GM is that of IPRs. The issue caught attention of many after the Monsanto-Schmeiser case. The fact that the court dissociated biosafety concerns of the fanners from IPRs of the company showed that there is a loophole within the biosafety regime, which addresses the IPR issue that is so intrinsically linked with biosafety. As mentioned earlier, GMOs introduced into the environment can find their way beyond field in which they had been introduced, to the lands of farmers who neither grow them nor are willing to use GMs. But they end up infringing the patent rights of some company.

The process of growing a genetically modified crop to selling it in the market is a lengthy and costly and many GM processes are protected under strict IPR regime. This entails paying of licence fees and bearing increased costs of the genetically modified seeds by the traditional farmers who so far had relied on traditional development and storage of seeds.[9]

Some critics also feel that small number of companies that are involved in the development and application of GM technology are likely to monopolize markets. GM technology has many opportunities and solutions to problems that have plagued humankind since a long time. It can help in enhancing the production and quality of crops with desired area-specific qualities and empowering the species with better pesticide and herbicide resistance, better tolerance of adverse natural conditions like salinity and drought with low toxicity levels, and higher nutritional values. However, playing with nature has its own inherent risks in the form of insecticide resistance, cross-contamination, environmental hazards, and ethical concerns, which may not be acceptable to a particular community or region, thus offsetting the advantages of GM technology. Moreover, GM is a knowledge-based activity and it opens a whole new window of concerns *vis-a-vis* IPR and legal framework along with affordability and danger of monopolization by the developer.[10]

Consequently, there is no doubt that GM technology has many positive aspects but the concerns related to it should be addressed genuinely by conducting better research and long-term studies in community before introducing it in general. Also every effort should be made to develop a legal framework to manage the various aspects of GM technology at both development and user levels with strict regulation but providing enough flexibility so that it is available for people who need it without putting their interest at stake.

2.3 IP PROTECTION TO GM CROPS AND FOODS IN INDIA

Technological advances are always a consequence of human intellectual effort and legal protection of such effort is often sought by the technology developers to protect it from unwarranted copying. Legal instruments exist in many countries recognizing the importance of Intellectual Property protection in various sectors of the economy. However, the extension of Intellectual Property protection to products of genetic engineering particularly genetically modified crop seeds has thrown the system into fresh controversy especially in developing countries. Patents, which are the mechanism of Intellectual Property protection of such crop seeds, not only discourage reuse of patented seed from one growing season to the next but also growing of such seeds without the consent of the patent holder. The implication is that farmers have to buy fresh seed every season, an expensive and largely unaffordable undertaking to a majority of smallholder farmers who are normally resource-constrained. More importantly, the phenomenon threatens to push to extinction an age-old practice of seed saving and free access through sharing among smallholder farmers in developing countries that has formed the basis of food security in these regions. As such food security in these countries is under threat and calls for exclusion of Intellectual Property Rights (IPRs) and the subsequent patenting from crop varieties derive their justification from the foreseen threat.[11]

The dangers linked with genetically modified products especially plants and crops are many. Fears are raised of contamination of the local landraces by the foreign genes in genetically modified relatives. Safety of genetically modified foods for human consumption remains contentious with views largely polarized. As such movement of GM foods across sovereign borders has become a subject calling for strict scrutiny. Genetically Modified (GM) food aid from developed countries, which are also leaders in genetic engineering, to starving nations in the developing world has equally become controversial.

The development of genetic engineering of plants in the 1980s was accompanied by a sequence of increasingly specific confirmations of the patentability of various types of life forms, provided that they met the standard patent criteria of novelty, utility, and non obviousness. The 1980 Supreme Court decision in *Diamond* v. *Chakrabarty* held that regular utility patents could be granted for inventions involving living organisms. This decision specifically addressed the patentability of a newly created microorganism that could break down crude in a manner that might be useful to control oil spills. Subsequent U.S. Patent and Trademark Office and Supreme Court decisions confirmed that plants and animals, including those created by conventional breeding, and particular sequences of genetic material or DNA such as genes, markers, and promoters (which control the expression of genes in cells), could be protected by utility patents.[12]

India is a member of the World Trade Organization (WTO) and a signatory to the WTO Agreement, which spells out the code of conduct of a country's trade with other WTO members. The WTO Agreement has a component on trade-related aspects of Intellectual Property Rights (TRIPS) to which India is committed to enact minimum standards of Intellectual Property Protection. Domestic statutes protecting intellectual property in India include the Acts on Copyrights, Trademarks, Registered Designs and Patents. Article 27.3 (b) of this agreement requires the member countries to provide for protection of plant varieties either by a patent or by an effective *sui generis* system or by any combination thereof. Intellectual Property protection of genetic engineering products particularly GM crop varieties should have been covered under the Patent Act but the Act falls short of excluding biotechnology and products thereof from patentability.[13] The *sui generis* system for protection of plant varieties was developed integrating the rights of breeders, farmers and village communities, and taking care of the concerns for equitable sharing of benefits. It offers flexibility with regard to protected genera/species, level and period of protection, when compared to other similar legislations existing or being formulated in different countries. The Act covers all categories of plants, except microorganisms. The genera and species of the varieties for protection shall be notified through a gazette, after the appropriate rules and by-laws are framed for the enforcement of the Act.[14]

The year 2001 and India gets a plant varieties protection legislation (*The Protection of Plant Varieties and Farmers' Rights Act*, 2001, Act 53 of 2001) heralding agriculture of the 21st century: A `brand' new age, where `new' plant varieties can be labelled and sold; the `creator' breeding seeds for commercial purposes is granted protection by law through Plant Breeder Rights (PBR). Such ensuing rights give exclusive commercial control to the breeder over the propagating material of the `protected' variety. Agriculture, reincarnating as agribusiness in today's global trade system, dares to commodify all plants, seeds, and knowledge related to any of these.

The Indian law, which has been hailed as progressive, pro/developing country legislation, has some notable features. Apart from a well-defined Breeder's Right, it has strong and proactive Farmers Rights. In fact the Indian legislation succeeds in balancing the rights of Breeders and Farmers and exploits the flexibility granted in TRIPS, in an intelligent manner. There are clauses to protect the rights of Researchers and provisions to protect the public interest.[15]

The Indian legislation is the first in the world to grant formal rights to farmers in a way that their self-reliance is not jeopardized. What is very significant and positive about this legislation is that it charts its own course, deviating from the norms set by UPOV. The Union for the Protection of New Plant Varieties (UPOV) is at present the only platform for regulating Plant Breeders Rights. It is a developed country platform, which is modulated to protect the interests of agriculture in industrial countries. It does not even have the notion of Farmers Rights. The innovative Indian legislation has opened up interesting possibilities for developing a developing country platform for regulating Breeders and Farmers Rights so that both, not just one, are acknowledged and protected.[16]The objectives of the Act are as follows:

(i) To provide for the establishment of an effective system for protection of plant varieties.
(ii) To provide for the rights of farmers and plant breeders.
(iii) To stimulate investment for research and development and to facilitate growth of the seed industry.
(iv) To ensure availability of high quality seeds and planting materials of improved varieties to farmers.

3. IMPACT OF GM CROPS ON BIODIVERSITY AND THE ENVIRONMENT

The beneficial role of biotechnology in improving crop yields is well established. However, several recent studies have also revealed that there are significant risks associated with genetically modified crops-risks that may adversely affect our health and environment. Long-term studies are urgently needed to produce results which may be able to resolve these questions, yet such data have not been forthcoming. If this book raises too many questions, it is because they are timely. Biotechnology is at a critical juncture where several developing countries are poised to make large investments in GM crop research and expand their cultivation nationwide. The need for risk evaluation has never been greater than it is today. Underneath this critical approach is the basic optimism that biotechnology will be able to provide the means to feed the world's hungry, provided that the potential risks are first evaluated and dealt with. It would be unwise to proceed with the planting of GM crops on a large scale until the risks to health and environment are fully evaluated.[17]

3.1 BIOTECHNOLOGY AND BIODIVERSITY

Since the exciting and hopeful prospect of abundance that was initially expected of biotechnology, we have come a long way. Biotechnology has indeed produced many benefits. Food production has increased manifold, although population growth has outstripped achievements in agriculture. It has become clear during the last several years that the "green revolution", pioneered by Prof. M.S. Swaminathan that was so successful in carrying India forward during the last 30 or 40 years is no longer adequate. This is due to several complex factors which have been discussed by others. What is needed is an "evergreen revolution", or perhaps several such revolutions, occurring periodically to meet the demands of an ever-growing population. The area of agricultural land is shrinking rapidly, due to the explosive growth of human and animal populations followed by habitat destruction.[18]

3.2 CAUSES FOR DECLINING AGRO-BIODIVERSITY

The principal underlying causes for declining agro-biodiversity include the rapid expansion of industrial and Green Revolution agriculture, intensive livestock production, and industrial fisheries and aquaculture (some production systems using GM varieties and breeds) that cultivate relatively few crop varieties in monocultures, rear a limited number of domestic animal breeds, or fish for or cultivate few aquatic species. Variety replacement is the main cause of losses. The replacement of local varieties or landraces by "improved" and/or exotic varieties and species is reported to be the major cause of genetic erosion around the world.

Globalization of the food system and marketing, as well as the extension of industrial patenting and other intellectual property systems to living organisms, has led to the widespread cultivation and rearing of fewer varieties and breeds for a more uniform and less diverse, but more competitive, global market. The consequences are marginalization of small-scale, diverse food production systems that conserve farmers' varieties of crops and breeds of domestic animals, which form the genetic pool for food and agriculture in the future; reduced integration of livestock in arable production, which reduces the diversity of uses for which livestock are needed; and reduced use of "nurture" fisheries techniques, which conserve and develop aquatic biodiversity.[19]

Genetic erosion refers to the loss of genetic diversity, including the loss of individual genes and gene complexes (particular combinations of genes), such as those manifested in locally adapted landraces. The main cause of genetic erosion in crops, as reported by almost all countries, is the replacement of local varieties by "improved" or exotic varieties and species. As old varieties in farmers' fields are replaced by newer ones, genetic erosion frequently occurs because the genes and gene complexes found in the diverse farmers' varieties are not containedin the modern varieties. In addition, the sheer number of varieties is often reduced when commercial varieties are introduced into traditional farming systems. There have been few systematic studies of the genetic erosion of crop genetic diversity that have provided quantifiable estimates of the actual rate of genotypic or allelic losses.

3.3 BENEFITS OF AGRICULTURAL BIODIVERSITY

Prime Minister Manmohan Singh of India pointed out that in the past, the community food tradition assured that a wide range of food crops rich in protein, iron, micronutrients, and vitamins was available to the people; however, commercial agriculture has narrowed the range of food crops available.

Agricultural biodiversity can help in developing decentralized community food security systems that benefit local communities. They are also beneficial for long-term security through the establishment of gene banks, seed banks, and grain banks, which can be managed by local people. The diversity of crops could also reduce pesticide use. Furthermore, tropical fruits, sweet potato (with beta-carotene), and other vegetable crops can fight vitamin A deficiency in children.

Agricultural biodiversity provides the important raw material for improving the quality of crops, livestock, and fish. It can also create opportunities for entrepreneurship by generating employment and additional income from a whole range of value-added foods, medicines, nutraceuticals, biofuel and other sources. On a global scale, nearly 2.5 billion people depend directly on wild and traditionally cultivated plant species to meet their daily needs.[20]

3.4 TOXIC EFFECTS

Unfortunately, there are other consequences of biotechnology that are clearly undesirable. The picture that has emerged from recent studies is unfavorable, even alarming, if the results are confirmed in long-term studies. While we are even more convinced today that biotechnology will continue to be needed for feeding the world's billions in the future, there is evidence which indicates that a cautious approach is very much warranted. The method of achieving greater food production by utilizing GM crops, as we have done so far, appears to have some significant associated risks to our health and environment.[21] A few examples will suffice.

An analysis of results obtained when rats were fed GM corn (MON 523 produced by Monsanto Corp.) was published by Prof. Gilles-Eric Seralini, 2007 from the University of Caen, France. The study, completed at CRIIGEN (Caen, France), examined the raw data on MON 863 feeding experiments on rats, initially suppressed by Monsanto but later obtained by others in 2005 after a court action in Germany. Using more sophisticated analytical methods than those employed by Monsanto, the new study uncovered an increase of up to 40% in blood triglycerides in female rats, and a more-than-30% decrease in urine phosphorus and sodium in male rats, specifically linked to the GM diet. The reasons for these changes are unclear, but they may provide clues to the deaths of many animals which consumed Bacillus thuringiensis (Bt) feed in other animal experiments. However, these data should be confirmed further using large numbers of experimental animals. Similar observations were reported by the Russian scientist Irena Ermakova, who fed GM soy to female rats. Other studies have shown the deleterious effects of GM pollen on Monarch butterflies and caterpillars as well as other insects.

The scientists conducted laboratory tests to establish the relative toxicity of Bt toxins and pollen from Bt corn in monarch larvae. They found that first instars are sensitive to Cry1Ab and Cry1Ac proteins, and that pollen contaminants can dramatically influence larval survival and weight gain and produce spurious results. The biologist examined the ecological consequences of transgenic Bt in a meta-analysis of 42 field experiments. They indicated that non-target invertebrates are generally more abundant in Bt cotton and Bt maize fields than in non-transgenic fields managed with insecticides; however, in comparison with insecticide-free control fields, certain non-target taxa are less abundant in Bt fields. The central goal of this study was to quantitatively investigate whether changes in invertebrate abundance were statistically significant. The failure to find significant differences in previous studies was generally viewed as a signal of environmental safety, but they were often based on small samples. Whether statistically significant differences in abundance truly indicate ecologically significant changes is not clear. The study revealed, however, that Bt crop acreage has less insect biodiversity than untreated fields. It is unclear whether the reduced abundance of various groups (coleopterans, hemipterans, and hymenopterans) is due to direct toxicity or is a response to reduced availability of prey in Bt crops.[22]

4. IMPACT ON ENVIRONMENTAL SUSTAINABILITY IN INDIA

Environmental activists, religious organizations, public interest groups, professional associations and other scientists and government officials have all raised concerns about GM foods, and criticized agri-business for pursuing profit without concern for potential hazards, and the government for failing to exercise adequate regulatory oversight. It seems that everyone has a strong opinion about GM foods. Most concerns about GM foods fall into three categories: environmental hazards, human health risks, and economic concerns.[23]

4.1 ENVIRONMENTAL HAZARDS

(i) **Unintended Harm to Other Organisms: A** laboratory study was published in Nature showing that pollen from B.t. corn caused high mortality rates in monarch butterfly caterpillars. Monarch caterpillars consume milkweed plants, not corn, but the fear is that if pollen from B.t. corn is blown by the wind onto milkweed plants in neighboring fields, the caterpillars could eat the pollen and perish. Although the Nature study was not conducted under natural field conditions, the results seemed to support this viewpoint. Unfortunately, B.t. toxins kill many species of insect larvae indiscriminately; it is not possible to design a B.t. toxin that would only kill crop-damaging pests and remain harmless to all other insects. This study is being reexamined by the USDA, the U.S. Environmental Protection Agency (EPA) and other non-government research groups, and preliminary data from new studies suggests that the original study may have been flawed[22]This topic is the subject of acrimonious debate, and both sides of the argument are defending their data vigorously. Currently, there is no agreement about the results of these studies, and the potential risk of harm to non-target organisms will need to be evaluated further.

(ii) **Reduced Effectiveness of Pesticides**: Just as some populations of mosquitoes developed resistance to the now-banned pesticide DDT, many people are concerned that insects will become resistant to B.t. or other crops that have been genetically-modified to produce their own pesticides.

(iii) **Gene Transfer to Non-Target Species**: Another concern is that crop plants engineered for herbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicide resistance genes from the crops into the weeds. These "super weeds" would then be herbicide tolerant as well. Other introduced genes may cross over into non-modified crops planted next to GM crops. The possibility of interbreeding is shown by the defense of farmers against lawsuits filed by Monsanto. The company has filed patent infringement lawsuits against farmers who may have harvested GM crops. Monsanto claims that the farmers obtained Monsanto-licensed GM seeds from an unknown source and did not pay royalties to Monsanto. The farmers claim that their unmodified crops were cross-pollinated from someone else's GM crops planted a field or two away. More investigation is needed to resolve this issue.[24]

There are several possible solutions to the three problems mentioned above. Genes are exchanged between plants via pollen. Two ways to ensure that non-target species will not receive introduced genes from GM plants are to create GM plants that are male sterile (do not produce pollen) or to modify the GM plant so that the pollen does not contain the introduced gene. Cross-pollination would not occur, and if harmless insects such as monarch caterpillars were to eat pollen from GM plants, the caterpillars would survive.

Another possible solution is to create buffer zones around fields of GM crops. For example, non-GM corn would be planted to surround a field of B.t. GM corn, and the non-GM corn would not be harvested. Beneficial or harmless insects would have a refuge in the non-GM corn, and insect pests could be allowed to destroy the non-GM corn and would not develop resistance to B.t. pesticides. Gene transfer to weeds and other crops would not occur because the wind-blown pollen would not travel beyond the buffer zone. The estimates of the necessary width of buffer zones range from 6 meters to 30 meters or more. This planting method may not be feasible if too much acreage is required for the buffer zones.

4.2 HUMAN HEALTH RISKS

(i) **Allergencity**: Many children in the US and Europe have developed life-threatening allergies to peanuts and other foods. There is a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions. Extensive testing of GM foods may be required to avoid the possibility of harm to consumers with food allergies. Labeling of GM foods and food products will acquire new importance.[25]

(ii) **Unknown Effects on Human Health**: There is a growing concern that introducing foreign genes into food plants may have an unexpected and negative impact on human health. A recent article published in Lancet examined the effects of GM potatoes on the digestive tract in rats. This study claimed that there were appreciable differences in the intestines of rats fed GM potatoes and rats fed unmodified potatoes. Yet critics say that this paper, like the monarch butterfly data, is flawed and does not hold up to scientific scrutiny. Moreover, the gene introduced into the potatoes was a snowdrop flower lectin, a substance known to be toxic to mammals. The scientists who created this variety of potato chose to use the lectin gene simply to test the methodology, and these potatoes were never intended for human or animal consumption.

On the whole, with the exception of possible allergenicity, scientists believe that GM foods do not present a risk to human health.[26]

5. LEGAL SAFEGUARDS UNDER ENVIRONMENTAL LAW

In India, the Genetically Modified Organisms are regulated under the *Environment Protection Act*, 1986 (EPA).[27] In addition the Indian biosafety regulatory framework comprises 1989 *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Modified Organisms and Cells* (1989 Rules), and Department of Biotechnology guidelines, the 1990 *Recombinant DNA Safety Guideline*" (1990 DBT Guidelines) and 1994 Revised *Guidelines for Safety in Biotechnology* (1994 DBT Guidelines) and 1998 *Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts* (1998 DBT Guidelines).

The objective of EPA is protection and improvement of the environment. The Act calls for the regulation of Environment Pollutants, defined as any solid, liquid or gaseous substance, present in such concentration that tend to be injurious to the environment. The 1990 and 1994 DBT guidelines recommend appropriate practices, equipments and facilities necessary for safeguards in handling GMOs in agriculture and pharmaceutical sectors. These guidelines cover the R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research. The 1998 DBT guidelines cover areas of recombinant DNA research on plants including the development transgenic plants and their growth in soil for molecular and field evolution. It also calls for the toxicity and allergenicity data for ruminants such as goats and cows, from consumption of transgenic plants. It also requires the generation of data on comparative economic benefits of a modified plant.[28]

6. REGULATORY MECHANISM IN INDIA

When assessing the Indian legal framework for biotechnology, attention must be paid both to international compromises and internal norms. India is party to several international treaties that directly impact biotechnology regulation and management. These treaties pertain to several public international law regimes, such as international trade law, international environmental law, intellectual property law and international human rights law. On the other hand, the national normative framework is the outcome of a relatively unsystematic evolution which has its origin in the *Environment (Protection) Act*, 1986. The norms of the Environment (Protection) Act provide the legal background to the *Rules for Manufacturing, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells*, which are the other key pieces of legislation.

The majority of the agencies that enact rules and control activities in the biotechnology field pertain to four ministries of the central government. The Ministry of Science and Technology controls the Department of Science and Technology, the Department of Scientific & Industrial Research and the Department of

Biotechnology. The Ministry of Health governs the Indian Council of Medical Research. The Ministry of Agriculture controls Indian Council of Agriculture Research. The Ministry of Human Resource and Development control the University Grants Commission. Finally, the Department of Scientific & Industrial Research funds the Council of Scientific and Industrial Research (both of whom directly fund biotechnology).[29]

A series of committees set up a multi-tiered regulatory framework aimed at ensuring the biosafety of genetically engineered organisms in India. These agencies are the Review Committee on Genetic Manipulation, the Genetic Engineering Approval (Appraisal) Committee, the Recombinant DNA Advisory Committee, the Institutional Biosafety Committee, the State Biotechnology Coordination Committee and the District Level Committees. In the biopharmaceuticals domain, these bodies work together with the Central Drugs Standard Control Organization and the Drugs Controller General of India, which have a broader mandate covering all pharmaceuticals.

The multiplicity of regulatory agencies and the complex approval procedures have been identified as factors that negatively affect the functioning of the Indian biotech sector. In response to sector specific reports time-frames for approval of biotech products have been streamlined, but the implementation of other proposed reforms, such as the establishment of a single-window agency, is still pending. If created, the National Biotechnology Regulatory Authority will regulate the research, manufacture, import and use of genetically engineered organisms and products derived thereof.[30]

7. PROSPECTS OF GM CROPS

Biotechnology was born about three decades back in the laboratory of the industrial west. It holds the promise of bringing prosperity not through machine, but through living organisms. Though this discipline was born in the west, its application will bring maximum benefit to the agrarian east because of its inherent life-based nature. Two decades ago, many agricultural scientists rightfully saw the emerging recombinant DNA technology as a potent tool in enhancing crop productivity and food quality while promoting sustainable agriculture. Much of the early excitement and expectation was met with successive breakthroughs in scientific research on plant gene transfer methods, identification of valuable genes, and the eventual performance of transgenic crops. Plant breeders saw the technology as an additional means of crop improvement that could complement the existing methods. For the first time, plant breeding was subjected to rigorous testing, and a regulatory framework was developed to oversee the commercialization of GM crops on a case-by-case basis.[31]

There has been widespread acceptance and support for biotechnology from the scientific community. The accumulated experience and knowledge of decades of crop improvement, combined with expert judgment, science-based reasoning, and empirical research has led to the scientists' confidence in GM crops. They are of the view that GM crops will pose no new or heightened risks that cannot be identified or mitigated, and that any unforeseen hazard will generally be negligible, effectively manageable, or preventable. Therefore, transgenic crops have been widely accepted by the farmers, and an unprecedented adoption rate of this technology was observed during the last decade. The use of biotechnology for the development of improved plant varieties has been endorsed by dozens of scientific bodies. FAO (Food and Agriculture Organization), WHO (World Health Organization), The American Medical Association, and The French Academies of Medicine and Science, among others, have studied plant genetic engineering techniques and given them a clean bill for human health. In a report published in July 2000, the UK's Royal Society; the National Academies of Science from Brazil, China, India, Mexico and the US; and the Third World Academy of Science encouraged funding for research on genetic engineering, arguing that it can be used to advance food security while promoting sustainable agriculture. 'It is critical', declared the scientists, 'that the potential benefits of GM technology become available to the developing countries'. An FAO report issued in May 2004, argued that 'effective transfer of existing technologies to poor rural communities and the development of new and safe biotechnologies can greatly enhance the prospects for a sustainable improvement of agricultural productivity today and in the future', as well as 'help reduce environmental damage caused by toxic agricultural chemicals'.[32]

Developments in the field of biotechnology and molecular biology can help in better understanding complex pathways of plants such as the photosynthetic pathways. It will be possible to increase the efficiency of these pathways to ultimately result in high crop yields. Rapid disease diagnosis with molecular methods will have significant impact on agricultural productivity. Enhancing stress tolerance in crop plants will permit productive farming on currently unproductive lands. The growing season of crops could be increased, and the losses from abiotic factors such as drought, heat, cold, salinity, and acidity could be minimized. The shelf life of fruits and vegetables can be prolonged to reduce losses due to food spoilage, expand the market vista, and improve the food quality. Undesirable traits such as the presence of neurotoxin in kesar dal; cyanide in tapioca; aflatoxins in groundnut and antimetabolites in chickpea, horsegram and sweet potato could be 'silenced'. The quality of food crops could be improved to provide better nutrition to underprivileged and resource-poor consumers. Prolonged 'vase life' of cut-flowers will help broaden the market for horticulturists, while reducing losses and minimizing dependency on expensive cold storage. Human and livestock health can be improved through crops with enhanced nutritional quality such as iron-rich rice (Golden Rice) and vitamin A-rich rapeseed oil (Golden Mustard), and through the production of edible vaccines and other pharmaceutical proteins. Industrially applicable crops such as those producing enzymes, 'designer' starch and oils, biodegradable plastics, and industrial chemicals can also be developed to reinvigorate the Indian economy and create a large number of jobs. Crop plants that can clean up soil, water and air through 'phytoremediation' can be developed and planted in critical areas. Trees that grow faster with fewer diseases and pest problems can be developed for their positive impact on rural economy and the environment. In fact, a revolution is now occurring in the field of gene identification and cloning from every useful biological entity and its subsequent transfer to others. Large-scale genome sequencing has accelerated the identification of diverse genes, and development in the field of functional genomics has helped in assigning a role to those genes. Thousands of novel genes with diverse function are cloned and characterized every day. Therefore, we are passing through an era of gene revolution that can immensely benefit modern agriculture, facilitating a sustainable development that will greatly help the poor, developing, and populous countries. However, we have to prioritize our efforts in addressing most chronic agricultural problems that cannot be mitigated by conventional methods. The strategic integration of biotechnology tools for developing new crop cultivars with better pest resistance, higher yield, better nutritional quality and better factor productivity can revolutionize Indian farming. Compared to 'Green Revolution', the 'Gene Revolution' would be environment-friendly and relatively scale-neutral, benefiting big and small farmers alike. Thus, it can be of great help to small farmers with limited resources, in increasing their farm productivity by making available improved and powerful seeds. It can also reduce their dependence on chemical inputs such as pesticides and fertilizers. India desperately needs such technologies to march into the next century, fulfilling its vision of economic upliftment and prosperity for two-thirds of its population, which is dependent on farming. However, a strong public-private sector is essential to ensure that the poor people benefit from the Gene Revolution.[33]

8. CONCLUSION

India has placed a heavy emphasis on agriculture biotechnology and the government sees this technology as the harbinger of a second Green Revolution, one that will bring about the same jump in food production that the original Green Revolution did. There are many reasons why this is unlikely to happen in the foreseeable future. For one, there seem to be little that Ag-biotech has to offer to bring about significant yield increase. On the other hand, channeled properly and accompanied by stringent bio-safety testing, Ag-biotech has the potential to solve certain specific problems in agriculture. Phenotypic traits that are dependent on single genes have a better chance of success than polygenic traits like drought tolerance. There is more on offer than just transgenic technology in the field of agriculture. The future holds the promise of at least two new technologies that have the potential to make plant breeding more precise and effective as also to bring about an increase in food production. These two technologies are Marker Aided Selection (MAS) leading to Marker Assisted Breeding, the other is Apomixis. Still largely in the experimental stage (apomixis more than MAS), both are promising technologies without the baggage safety concerns.[34]

MAS is a combination of molecular biology and traditional genetics which allows the selection of genes of interest by tracking the marker DNA to which the gene is linked. This makes plant breeding more precise thus saving time and allowing varieties to be developed quickly. Apomixis which is essentially 'freezing' a hybrid biologically so that the advantages of hybrid vigor are perpetuated through the next generations, without segregating the way normal hybrids do. This means, once a hybrid with favorable traits is developed, it can be stabilized and farmers will be able to save seed for the next crop which they cannot do with the usual hybrids without losing the hybrid advantage. Given the high cost and public distrust and rejection associated with Ag-biotechnology as well as the difficulties of establishing biosafety, it would seem to be in India's interest to go slow on this costly and controversial technology and invest heavily in MAS and apomixis to pave the way for a safer and more sustainable basis to food security.

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