Chapter 14
Biosafety, Bioethics, and IPR Issues in Plant Biotechnology

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Abstract Plant biotechnology holds great promises for feeding the world's growing population and for improving the diets of people the world over. To feed the ever-increasing population, global agricultural production may need to be increased by 60–110 % by 2050. First-generation transgenic plants focused on increased yield and other agronomic properties, which primarily benefited agribusiness companies and farmers, whereas the second generation of genetically modified foods emphasized on consumer health. Although concerns over ecological and human health safety have led to doubt over the application of transgenic technology, many of these fears seem unsubstantiated or are based on misinformation.

To evaluate the applicability of genetically modified food and development of new product for the public benefit, efficient collaboration between the field of plant science and nutrition is required. With plant biotechnology promising to deliver great benefits for both producer and consumers, its application is also associated with the potential fear about the concentration of economic power, infringement of developed technologies, and technological dependence, which could deepen the technological gap between developed and developing countries. Appropriate policies developed and publicized can ensure to accurately check the misuse and avoid unnecessary inconvenience.

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14.1 Introduction

The exponential increase in the world population and decrease in crop productivity had dimmed the achievements of green revolution. With the continual expanding global population, the world economy is facing challenges of malnutrition, hunger, and poverty. To meet the nutritional needs, without bringing new farmland into production, it is estimated that yields of rice, wheat, soybean, and maize all need to be doubled by 2050 (Ray et al. 2013). The decline in the crop productivity was due to the drastic changes in climate across the globe, imbalanced nutrients in the soil, altered soil texture, disturbed soil microflora and fauna, frequent incidence of diseases, insect/pest attacks, and exposure of crops to abiotic stresses during developmental stages (Godfray et al. 2010). At this juncture, when there is large gap between demand and supply of the food, the productivity of these crops should be improved by developing novel crop varieties having traits that help them to efficiently extract and utilize water and nutrients from the soil, tolerate/resist biotic and abiotic stresses, translocate photosynthates efficiently to the economic sink, and have a compact plant type that may ensure higher plant density. This will ensure food security which is endangered in the present scenario.

Plant transgenic technology had enabled plant scientists to develop more useful and productive crop varieties by bringing genes encoding specific characters from a wide range of live sources (Young 2004). Using transgenic technology, depending on variety, place, time, and purpose of the plant grown, desirable gene(s) can be incorporated to express beneficial novel trait(s) in desired crop. Thus, transgenic plants with insect resistance, herbicide tolerance, disease resistance, high nutritional quality and high yield potential, delayed fruit ripening, and enhanced ornamental value are now developed and grown globally. Genetically modified (GM) plants are also used as bioreactors for the production of biopolymers, nutraceuticals, antigens, vaccines, and monoclonal antibody.

Upsurge in biotechnological products and services has attracted big players worldwide. With strong scientific and technical pool of human resources, rich biodiversity, and a large agricultural base, India has been recognized as a producer of low-cost, high-quality bulk drugs and formulations and other biotech products and services. As the Indian market harbors some of the top biotech firms and companies functioning in India, it becomes imperative to make effective protection regime for the prevention of any kind of misuse and abuse in this sector.

Agri-Biotech as a subsector is among the fastest-growing biotech sectors in India. It has witnessed the emergence of a single large dominant enterprise, namely, Monsanto that has been alleged by competitors and consumers alike of abusing its dominant position and engaging in behaviors and activities that are prima facie anticompetitive and against the interests of consumers. In India as well as global context, this assumes critical importance with the growing concerns relating to food security.

This chapter identifies valid concerns and risks, recounts regulatory and adoption practices developing transgenic crop and effective protection regime for generated IPR, and provides useful information to lessen the unsubstantiated fears based on misinformation.

14.2 Status of Transgenic Crops

With the discovery of technologies for gene transfer from one organism to another, incorporation of beneficial traits into plants became possible. The transgenic plants were developed and applied successfully first under contained conditions for experiments (Cramer 1996) followed by infield and open-environment condition for commercial applications.

The adoption rate of transgenic crops, however, shows great disparities between different agricultural producing regions worldwide. Farmers especially in developing countries are greatly benefited by increased yields of transgenic crops. The adoption of transgenic crops can further reduce the production costs by reducing pesticide and labor use. A recent meta-analysis concluded that transgenic technology has drastically reduced the use of pesticide by 37 %, increased crop yields by 22 %, and increased farmer profits by 68 % (Klümper and Qaim 2014).

The news of genetically modified FLAVR SAVR tomato with delayed premature fruit softening was received with dramatic responses. The hype against adoption of GM crop technologies was fueled by public misperceptions and prejudice about eating "mutant vegetables." After extensive safety research, Calgene's tomato was found to be safe. In 1994, FDA finally approved the commercial release of FLAVR SAVR tomato. After this there was a rapid increase in GM crop cultivation. Insect-resistant Bt maize as well as Bt cotton and transgenic herbicide-tolerant soybeans as well as oilseed rape were planted on rapidly increasing areas. In 2014, genetically modified (GM) crops were grown by 18 million farmers in 28 countries on a total area of 181.5 million hectares, which correspond to already 13 % of the world's arable land. This rapid increase makes biotech crops the fastest adopted crop technology of the last decade (Clive 2014; Lucht 2015) (Table 14.1).

The annual global hectarage of biotech crops was 179.7 million hectares in 2015 as compared to 181.5 million in 2014. This change is equivalent to a net marginal-to-year change of minus 1 % between 2014 and 2015. Increase and decrease in annual hectarage of biotech crop are influenced by factors such as decreased overall crop plantings (for cotton it was minus 5 % and maize minus 4 %), low procurement prices, and farmers switching from cotton, maize, and canola to a more easily managed crop such as transgenic soybean. However, there is an overall decrease in biotech crop hectarage which was driven by low prices of plant produce in 2015 (Clive 2015).

GM technologies resulting in commercially produced varieties in countries such as the USA, Canada, and European Union have centered on conferring resistance against bacteria, viruses, or insect pests and producing specific herbicide-tolerant plants. The first transgenic plant accepted and approved for use in 1998 in the EU was Corn MON 810, a variety developed by the Monsanto Company, USA. It contained cry gene (commonly called Bt gene) from *Bacillus thuringiensis*

Table 14.1 Global area of biotech crops in 2015, by country (million hectares)[a]

Rank	Country	Area (million hectares)	Biotech crops
1	USA[b]	70.9	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash
2	Brazil[b]	44.2	Soybean, maize, cotton
3	Argentina[b]	24.5	Soybean, maize, cotton
4	India[b]	11.0	Cotton
5	Canada[b]	11.6	Canola, maize, soybean, sugar beet
6	China[b]	3.7	Cotton, papaya, poplar
7	Paraguay[b]	3.6	Soybean, maize, cotton
8	Pakistan[b]	2.9	Cotton
9	South Africa [b]	2.3	Maize, soybean, cotton
10	Uruguay[b]	1.4	Soybean, maize
11	Bolivia[b]	1.1	Soybean
12	Philippines[b]	0.7	Maize
13	Australia[b]	0.7	Cotton, canola
14	Burkina Faso[b]	0.4	Cotton
15	Myanmar[b]	0.3	Cotton
16	Mexico[b]	0.2	Cotton, soybean
17	Spain[b]	0.1	Maize
18	Colombia[b]	0.1	Cotton, maize
19	Sudan[b]	0.1	Cotton
20	Honduras	<0.1	Maize
21	Chile	<0.1	Maize, soybean, canola
22	Portugal	<0.1	Maize
23	Cuba	<0.1	Maize
24	Czech Republic	<0.1	Maize
25	Slovakia	<0.1	Maize
26	Costa Rica	<0.1	Cotton, soybean
27	Bangladesh	<0.1	Brinjal/eggplant
28	Romania	<0.1	Maize
	Total	179.7	

Source: Clive James (2015)

[a]Rounded off to the nearest hundred thousand

[b]19 biotech mega-countries growing 50,000 ha, or more, of biotech crops

that produces proteinaceous toxin inside the bacterial cells. It kills the insect pests specifically coleopterans, lepidopteran, and dipteran. Bt transgenic crops (rice, eggplant, brinjal, cabbage, cauliflower, canola, cotton, corn, maize, tobacco, potato, tomato, soybean, etc.) have been developed and grown in the USA, Brazil, India, China, Argentina, South Africa, etc. Amflora potato became the second GM transgenic plant to be accepted by the European Commission for production in EU

in 2010 (Devos et al., 2006) after long registration period (12 years). The BASF (Ludwigshafen, Germany) succeeded in developing EH92-527-1 (common name Amflora) variety by suppressing the genes for the production of amylase. This variety produces over 98 % of amylopectin (Clive 2010) and has advantage in industry over the normal potato variety as the two starch types don't need to be separated. Another important trait incorporated in plants is herbicide tolerance. Herbicide-tolerant (Ht) crops are genetically modified to survive particular herbicide applications used to check the weed growth. The "Roundup Ready" crop, which is genetically modified by Monsanto to tolerate applications of the company's glyphosate-based herbicide, "Roundup," is the most common Ht crops today.

Four GM crops (corn, soy, cotton, and canola) account for 99 % of acreage under GM cultivation around the globe. GM corn, soy, and canola (and cottonseed oil) proliferate in our food system as ingredients in processed food and in animal feed. GM soybean is cultivated in nearly half of the total GM hectares in the world followed by GM corn (30 %), GM cotton (14 %), and GM canola (5 %). The technology is still to realize its potential in GM crops (fruits and vegetables or GM grains) that are consumed as whole foods. GM squash varieties (USA), GM papaya (USA and China), GM eggplant (Bangladesh), GM sugar beet (Canada and the USA), and GM alfalfa (USA) collectively account for only 1 % of the global GM crop hectares. In 2014, GM herbicide tolerance comprised of 57 % of the world's transgenic crops, 15 % were GM plants toxic to pests, and 28 % were GM plants for insect resistance and herbicide tolerance. Further, GM crops for drought tolerance and virus resistance together account for less than 1 % of global transgenic hectares. The five fast developing countries in transgenic crop production and commercialization are China and India in Asia, Argentina and Brazil in Latin America, and South Africa (Clive 2014). All these collectively grew 71.4 million hectares of the GM crops (44 % of global acreages).

In 2014, 29 countries (among which 79 % were developing countries) approved commercial cultivation of transgenic crops, 31 countries (among which 70 % were developing countries) for food, and 19 countries (among which 80 % developing countries) for feed. The highest number of country approvals of GM crops for feed was in 2011, whereas highest number of country approvals of GM crops for food was in 2014. The data suggest the increasing acceptance of the technology for human use. Highest approved GM crops were for herbicide tolerance followed by insect tolerance. Maize had the highest number of events approved (single as well as stacked traits). Stacking of traits in GM crops is gradually increasing and constitutes approximately 30 % of the total trait approvals. These results indicate growing understanding and acceptance by various countries to be able to effectively exploit commercialization of GM crop (Aldemita et al. 2015).

Around 50 different kinds of genetically engineered plants, each developed from a unique event, have been approved for commercial cultivation in the USA. Table 14.2 enlists some of the commercial traits modified in different crops.

Table 14.2 Crops with various commercial traits

Crops	Modified trait
Soybean, maize, sugarcane	Abiotic stress tolerance
Soybean, maize	Altered growth/yield
Corn, soybean, cotton, canola, sugar beet, rice, flax	Herbicide tolerance
Papaya, squash, potato	Virus resistance
Canola, soybean	Altered oil composition
Tomato	Delayed fruit ripening
Chicory, corn	Male sterility and restorer system (used to facilitate plant breeding)
Corn, cotton, potato, tomato	Insect resistance

14.3 Transgenic Plant in India

The green revolution ushered in the late 1960s has led to a dramatic increase in crop productivity due to introduction of high-yielding seed varieties and the use of fertilizer and irrigation. With farm holdings shrinking in many parts of India due to urbanization, agricultural sector in India is under stress of feeding 1.5 billion mouths more than China by 2030; the challenge is now to replicate this success again. Another such revolution is required in edible oil and vegetable production demand for which is increasing day by day. Edible oil has become the third-biggest imported item by India, after crude oil and gold. India spends $10 billion annually to import edible oil which make for the 60 % of required edible oil.

Bt cotton is resistant to *lepidopteran* insect pests, which incur huge economic losses due to crop failure ranging between 80 % and 100 %, especially in Indian subcontinent. Bt cotton was the first GM crop to be introduced in India in 2002. Even after 12 years of the first GM crop (Bt cotton, a nonfood crop) planted in India, the country is yet to approve the commercial cultivation of GM crops for animal and human consumption. In fact, India is still pondering to allowing field experiments for GM food crops and very recently lifted a year-long embargo on scientific field trials. Bt cotton covers around 95 % of the total cotton growing area. In a short span of 12 years, around 7.7 million farmers have adopted Bt cotton in India (Clive 2015). Further 1128 varieties of Bt cotton transgenic plants have been allowed to be commercially cultivated in various zones of India, by GEAC from 2002 to 2012. The cultivation of Bt cotton has remarkably reduced insecticide used against these pests by 95 %. Further, India's total contribution in world cotton market has risen from 14 % (2002–2003) to 25 % (2014).

Similar to Bt cotton, the release of Bt brinjal was proposed by GEAC; however, its release was stalled in 2010 due to opposition. Bangladesh, in 2013, joined the list of Bt brinjal cultivation and is currently grown in about 50,000 ha. China is the sixth-largest adopter of GM crops worldwide after the USA, Brazil, Argentina, India, and Canada. It grows GM crops (papaya, cotton, poplar, sweet pepper, and tomato)

on over 4 mha. Among other Asian countries, the Philippines grows GM maize covering 62 % of the total area under maize cultivation (Clive 2014).

In India, approximately 18 major crops at present are at various stages of development and/or field trials in India. These include cabbage, brinjal, castor, chickpea, cauliflower, corn, groundnut, cotton, mustard, papaya, okra, potato, rubber, rice, tomato, watermelon, sugarcane, and sorghum. These crops have been targeted for resistance to viral and fungal diseases, insect pests, tolerance to pesticides, male sterility, nutritional enhancement, and tolerance to salinity and drought. There are around 12 government universities and institutes, and not less than 16 private sector organizations, contributing to this research, in India.

14.4 Public Fears

From the beginning of transgenic crop introduction, GM foods benefited the agricultural production, ecosystem, and human health. Industries, governments, and many academic scientists advocated the benefits of GM foods during the 1990s, by actively performing experiments and publishing research on plant transformation and biosafety. This resulted in adoption of GM varieties by farmers at record speed. This pace, however, was nudged by a research finding in 1998 showing GM potatoes expressing a gene for snowdrop sugar-binding protein showed stunted growth in rats and compromised their immune systems (Ewen and Putztai et al. 1999; Enserink 1999). This focused media attention on GM crops and fueled a rumpus in Europe against GM crops and food. With pollen from BT corn found to be toxic to the monarch butterfly, public concern aggravated (Losey et al., 1999). The monarch butterfly study showed that the danger to nontarget insects had not been thoroughly taken into account prior to commercial release. Subsequently, in various public forums, consumers, religious organizations, environmental activists, and some scientists warn of unforeseen human and animal health, environment, and socioeconomic consequences. All this had led to mistrust in the transgenic technology GM foods that gave rise to the concerns about the following issues.

14.4.1 Damage to Mankind

14.4.1.1 Allergenicity

The transgenic technology made possible the biofortification of food with vitamins and essential metals to enhance their nutritional value. At the same time however, the development of transgenic plants (especially staple food crops) with improved nutritional values has also come under the clouds of apprehension that they may introduce allergens into the food supply. So far there is no concrete evidence that gene products that are not allergenic normally will become allergenic when

expressed in a transgenic plant. As no reports on allergies to plant ferritin existed, it was, therefore, concluded that transgenic rice with the entire coding sequence of the soybean ferritin gene poses no allergenicity risk (Goto et al. 1999). The nature of genes that are selected for introduction into engineered host plant, however may some time induce allergic reactions. The reports of allergenic reaction to transgenic soybean in 1996, however, created a fear about GM food among the common people. Brazil nut albumin was expressed in soybean to improve the nutritional quality. The transgenic soybean expressed high levels of methionine which otherwise is low in the plant. The serum from Brazil nut allergic subjects, which were nonallergic to native soybean, were found to react with the transgenic soybean (Nordlee et al. 1996). It was hence concluded that the gene chosen to improve nutritional quality of soybean was one of the genes that trigger allergic reactions. Consequently, this line of soybean was not commercialized as a safety precaution.

Allergenicity assessment is complicated, when the allergenicity of a transgenic protein is not known. Over 200 food allergens have been identified and sequenced; however, no common motif or consensus sequence has been discovered (Gendel 1998). Physicochemical properties of target protein should be examined for potential allergenicity (Mendieta et al. 1997). Stability of a protein during the digestive process is another way to identify potential allergens, as most of the known food allergens are resistant to digestive acids and enzymes (Astwood et al. 1996). If a protein is degraded in the stomach and small intestine, then it is unlikely to reach immune cells and elicit a response. Further, the DNA sequence and structural similarity of the transgenic protein to known allergens should also be examined. Novel proteins that are stable inside the body can further be tested for reactivity with serum from subjects allergic to the homologous allergen (Ladics and Selgrade, 2009). Allergens are common in regular food, but over 90 % of the people having food allergies are allergic to one or more of the following foods: wheat, legumes, nuts, seafoods, eggs, or cow's milk. Thus, even in the absence of exhaustive methods for identifying potential allergenicity, the vast majority of transgenic proteins is suggested to be safe for consumption (Lehrer et al. 1996).

14.4.1.2 Antibiotic Resistance

For determination of the successful genetically modified plant, antibiotic resistance markers are being used. These markers have been selected by scientists after performing extensive safety studies and confer resistance to a narrow range of specific antibiotics with limited application in veterinary and human medicines. The rampant development of the resistance to existing antibiotics, however, has given rise to considerable public concern for the use of antibiotic resistance markers in transgenic crops. As DNA does not always fully defragment in the digestive system, human gut microflora and pathogens can take up modified genetic materials including gene for antibiotic resistance. This horizontal transfer may lead to reduction of effectiveness of antimicrobial therapy (Chen et al. 2010). This fear is termed as unwarranted by scientists with reasons as follows: (1) the antibiotic genes occur

frequently and naturally in soil and gut microbes without any human intervention, and (2) the transfer of genes from a plant to a bacterium is extremely unlikely. Thus, the proponents of commercial production of GM foods believe that these foods are safe as no evidence so far suggested the transfer of transgene from the GM food to gut bacteria.

The most widely used antibiotic resistance marker for the selection of transformed plant cells is the nptII gene, which confers resistance to the antibiotics neomycin and kanamycin. Kanamycin- and neomycin-resistant bacteria are ubiquitous in nature. On an average, 20–40 % of the bacteria that occur naturally in animal or human digestive tracts are already resistant to kanamycin. Moreover, these antibiotics have very limited application in humans and veterinary medicines. This gene is, therefore, most widely used as selection marker to develop GM crops with delayed fruit ripening and herbicide tolerance.

Although the risks from antibiotic resistance genes in transgenic plants appear to be low, still precautions can be taken to make it even more unlikely and resolve the public issues. Scientists can avoid using gene and protein sequences with homology to known bacterial genomes and proteomes, for the development of transgenic crops. Antibiotics that are not commonly used for the treatment of human diseases can be used to avoid acquired resistance to the antibiotics in case of any horizontal gene transfer to microorganisms in the body. Marker genes can be bred out leading to removal of the antibiotic resistance genes before the plants are released for commercial use, so that these genes can only be used during development and finally eliminated from the end product (Dale and Ow, 1991; Zuo et al. 2001; Rukavtsova et al. 2013; Ebinuma et al. 2001). Other non-antibiotic markers like mannose, GFP, or GUS can be used (Joersbo et al. 1998).

14.4.1.3 Eating Foreign DNA

Another public fear against GM food is that normal food could become metabolically dangerous or even toxic because of the presence of DNA fragment that is not naturally present in that plant. Very often these pieces of DNA come from either related (trans) plants or entirely different species (cis) such as viruses and bacteria. The properties of transgenes may change in a new chemical environment. Even if transgene itself is not dangerous or toxic, the presence could upset complex metabolic networks leading to production of new compounds or change the concentration of unseen and unwanted compound (Bawa and Anilakumar 2013).

We take in DNA unintentionally in abundance, in the form of food products, bacteria, and viruses found clinging to the meats, cereals, and vegetables. But there have not been any conclusive reports that DNA from transgenic crops is more hazardous to us than DNA from the conventional crops, animals, and microorganisms infesting them which we have been eating all through our lives. Schubbert et al. (1997) detected about 5 % of the DNA, consisting of short pieces (100 base pairs to 1700 base pairs long) in the small intestine, large intestine, and feces of mice fed with harmless detectable DNA sequence, up to 8 hours after a meal. A very small

amount of DNA (about 0.05 %) was found in the blood stream up to 8 hours after feeding. A study tracking the survival of the transgene *epsps* from GM soybean, in the small intestine of human ileostomists, showed low-frequency gene transfer from GM soybean to the microflora of the small intestine (Netherwood et al. 2004). The low level of *epsps* in the intestinal microflora even after consumption of the GM soybean meal showed that gene transfer did not occur during the feeding experiment. Thus, the possibility of transgene transfer from GM plants to intestinal enterocytes and microflora is unlikely (Netherwood et al. 2004).

14.4.1.4 Vector and Vector Elements

To make a GM crop, the gene of interest is mobilized and integrated into the target crop's genome using a DNA delivery vector. This vector might contain important elements, including viral promoters, marker genes, antibiotic resistance, and transcription terminators. The transgenes incorporated may reside anywhere in the genome, causing mutation in the host genome, and move or rearrange after its insertion in the same or next generations. It might break up and cause recombination (reintegrate into the genome) leading to chromosomal rearrangement in successive generations. This recombination could potentially change the GM plant such that it might produce protein(s) that causes specific allergy or related health problems (Goto et al. 1999; Hammond 1996).

Keeping the safety of animals and humans in mind, after extensive safety studies, scientists have proposed some promoters which are safe to use. Constitutive 35S promoter of cauliflower mosaic virus (CaMV) is the most widely used promoter in transgenic technology. CaMV causes cauliflower mosaic disease in broccoli, cauliflower, canola, and cabbage. Although other promoters have been used in developing transgenic crops, however, the CaMV promoter remains the first choice in laboratory as it drives large amount of protein production in a wide variety of situations. The opponents of the technology fear that the fragments of DNA may integrate into the host genome and cause ill effects. However, till now there is no evidence of invasion of CaMV promoter in human genome and function as a promoter regulating the unwanted nonfunctioning gene(s). Human chromosomes do contain the bits and pieces of DNA sequences from many different origins; however, these sequences have become nonfunctional due to multiple internals that have occurred during the course of evolution, over thousands of years.

14.4.1.5 Changed Nutrient Levels

Constant concern of the public against the use of transgenic technology is about the nutritional equivalence of genetically modified foods to their naturally occurring counterparts. Reduced levels of isoflavones (genistin and daidzin) were found in Roundup Ready® soybeans and thus having positive effect on human health

(Lappé et al. 1999). These two compounds have potential to prevent heart disease, breast cancer, and osteoporosis. Study performed by Monsanto suggested that Roundup Ready soybeans and unmodified soybean contain nearly the same amounts of isoflavones (Padgette et al. 1996; Clark and Ipharraguerre 2001). A conclusive study has not been performed; however, a comparison of available results reveals only small differences. Further, variability in isoflavone content is common in soybeans due to individual varietal influences and environmental factors such as weather, soil nutrient, etc. Also, samples of both Roundup Ready soybeans and the conventional counterparts produced similar growth and feed efficiencies for chickens, quail, rats, and catfish (Hammond et al. 1996; Clark and Ipharraguerre 2001).

14.4.2 Damage to the Natural Environment

The opponents of the technology have expressed great concerns about GM plants with regard to their adverse effect on the wildlife populations, environment, biodiversity, and wild relatives. The escape of transgenes and potential integration and establishment into the natural or agricultural ecosystems is threat to developing GM crops.

14.4.2.1 Impact on Nontarget Organisms

The impact on the nontarget organisms is a significant concern expressed by the opponents of GM foods. Pest-resistant crops may produce toxin which may have detrimental effect on other organisms including animals, plants, and microorganisms and is an important public concern regarding transgenic crops. Saxena and Stotzky (2001) showed that Bt toxin released from biomass of Bt corn and root exudates has no obvious effect on soil protozoa, bacteria, fungi, nematodes, and earthworms. The studies, however, showed that insect-resistant transgenic crops may negatively affect the beneficial insect predators such as ladybird beetles (Birch et al. 1997) and lacewings (Hilbeck et al. 1998).

With decrease in monarch butterfly population, in and around the fields of GM corn containing Cry1 toxins, public concern grew very strong. Studies showed that the butterfly population was reduced by destruction of their habitat (milkweed) by killer herbicides as well as by the ingestion of deposited pollens of Bt corn on milkweed leaves by butterfly. High mortality was observed in monarch butterfly larvae feeding on milkweed leaves dusted with Bt corn pollen, whereas no mortality in larvae feeding on leaves dusted with pollen from non-transgenic corn (Losey et al. 1999). Another study, however, showed negligible impact of pollens from Bt corn on monarch butterfly (Sears et al. 2001; Wraight et al. 2000). All the studies were based on laboratory experiments; therefore, the exact threat to monarch butterfly population in field conditions is difficult to assess.

14.4.2.2 Super Plants

The suspicion among critics of the technology aroused because of the fact that interbreeding between cultivated plants and their wild relatives is a natural and constant phenomenon and the transgenic plants are no exception (Snow 2002). Cross-pollination of crops with nearby related weeds may enable weeds to acquire newer traits and pose real threat to environment by giving rise to super plants. Many cultivated crops are sexually compatible with their wild relatives. They could, therefore, hybridize with them under favorable circumstances. In case of GM crop hybridizing with its wild relatives, the wild plant might take up transgenes. This introgression may change their behavior in a way that they could be a serious threat as competitors or weeds in natural environment. However, the likelihood that transgenes spread in particular part of the world can be different for each crop. For example, cross-pollination of transgenic corn is less likely to occur in Europe or the USA in the absence of wild relatives of corn. Further, with wheat and soybean being self-pollinating crops, the risk of transgene, moving to nearby weeds, is minimal. However, some risk is there for GM wheat in the USA as they do have wild relatives of wheat.

14.4.2.3 Contamination of Environment with GM Proteins

Many plants leak chemical compounds into the immediate environment through their root and pollen or from field leftover of plant material after the harvest. This unintentional release of the active proteins into the surrounding is a potential environmental problem with GM crops. It is important to be able to monitor the extent of these losses, because the proteins are found to be toxic to conventional crop-associated microorganisms. Further, through nematodes they could find their way into streams and rivers and may threaten other organisms.

Bt corn roots seep out Bt toxin into the soil. This toxin when bound to soil components is protected from degradation, persists in soil for long time (200 days), and has the ability to kill insect larvae present in soil (Saxena and Stotzky 2001). This seepage of the toxin is only of advantages if soil-living insects are the target. The samples of Quebec's Saint Lawrence River sediments near a field of Bt corn were shown to contain five times more toxin than samples taken from water drainage and sediments around the field indicating the building up of toxin over a period of time on the riverbed. However, conclusive research is necessary to support the results of such results. Also it is not clear how the leakage of toxin in the soil from roots of GM crops might affect nontarget insects and microorganisms inhabiting the soil. The fact is that GMOs have the potential to provide numerous advantages, yet they are still being shown in negative lights by anti-GMO activists who are using arguments without any scientific background.

14.4.2.4 Reductions in Pesticide Spraying

The selling point of the GM crops by the proponents was that the new crop varieties would reduce the use of pesticides as the plant itself produces a toxin that kills major insect pests (Federoff et al. 2010; Carpenter 2001). Thus, if the field is sprayed with the herbicide (Roundup Ready) that kills every other plant in the field except crop transgenic for Roundup Ready, then only small quantity of this herbicide would be needed to keep crop free from weeds. However, opponents of life-saving transgenic technology acknowledge the reduction in pesticide consumption to the following reasons: first, the variation in the population of other insect pests influences the amount of spraying; second, the introduction of new more potent insecticidal active ingredients that are effective at progressively lower rates of application and the use of older insecticides decline; and third, with the development of insect resistance to a chemical, farmer may switch to newer chemicals as they are made available. Thus, because of several factors affecting the amount of pesticide that is sprayed, it is difficult to say that the introduction of Bt corn varieties is solely responsible for the change in pesticide use pattern.

14.5 Biosafety

Cultivation of GM crops is changing the farming practices, chemical application, and land usage. Despite the potential benefits of transgenic crops, public have negative apprehension about the possible impact on environment, agronomy, economy, and ethics. Further, evaluating the short- and long-term impact of these GM crops on the environment is an important hurdle for safe release in areas with rich genetic biodiversity. Biosafety protocols ensure adequate level of protection to minimize the perceived risks to environment and human health in managing live modified organisms developed through modern biotechnology. In the developing years of transgenic technology, a major role was played by molecular biologist. With increase in number of field releases of transgenic plants, biosafety implications attracted global attention, and ecologists and environmentalists too joined to address the perceived ecological risks.

Soon it became very imperative to have expert bodies to be responsible for formulation and implementation of regulatory rules on genetic modification applications for approval of new planting material and genetically engineered foods, nationally and internationally. With growing commitment of people for sustainable agricultural development, the Convention on Biological Diversity (CBD) was established. Biodiversity safety with respect to its sustainable use and conservation is the key elements in the Convention on Biological Diversity (CBD) treaty. CBD attends to the issues of theoretical as well as probable potential exploitation of modern biotechnology, while simultaneously safeguarding against potential risks from its usage. The Cartagena Protocol on Biosafety adopted in 2000 is an international

treaty under the Convention on Biological Diversity, describing the movements of living modified organisms (LMOs) across borders of different countries. Under this treaty, the exporting countries have an obligation to display all the relevant information about the materials or products that are genetically modified, so that the importing countries make appropriate and informed proclamation. Endorsed and signed by 130 countries, the treaty sets out effective methods for risk assessment and management. The Advance Informed Agreement (AIA) procedures look into the methods adopted to keep an account of the intentionally introduced transgenic plants into the environment which may threaten biodiversity, capacity building, and technology transfer. It is imperative for the participating countries to take necessary and appropriate administrative actions and implement defined obligations to eliminate the negative consequences which may cause risks to animal and human health. These countries are also involved in developing common National Biosafety Frameworks (NBFs) for the development and utilization of GM products. NBF is a combination of administrative, technical, and legal policies that are developed to ensure an adequate protection in case of transfer, handling, and use of LMOs which may have adverse effect on the sustainable use and conservation of biodiversity. The Global Environment Facility of the United Nations Environment Programme (UNEP-GEF) has supported these participating nations since 2001 to develop their own NBF. It formulates biosafety guidelines to conduct research on biotechnology and genetic engineering and also take care of the transboundary movement of genetically modified (GM) crops and their products. Synchronization of each and every regulation at the regional, national, as well as international level to building capacities is critical for the coordinated implementation and generation of the benefits of biotechnology to farmers, researchers, and consumers (Singh et al. 2014). Various institutions over the world are actively supporting this cause. IFPRI (International Food Policy Research Institute) compiles the research implications of genetic engineering technologies and policy to alleviate poverty problems in countries under development. The Centre for the Application of Molecular Biology to International Agriculture (CAMBIA) has been commissioned by most of the developing nations to develop a database aiming at the technology ownership. The technology ownership determines the extent of freedom enjoyed by the scientists for manipulation of particular germplasm and crops. An information initiative of United Nations International Development Organization (UNIDO) named as BINAS (Biotechnology Information Network and Advisory Service) serves as a center for disseminating information of biotechnology laws and regulations.

14.5.1 Levels of Biosafety

The goal of biosafety is to prevent dissemination of the modified species (transgenic plants) outside its growing area. Biosafety levels are defined in terms of using specific laboratory practices and techniques, safety equipments, and laboratory

facilities required for different categories of plants and plant-derived products based on their nature to cause damage to environment and living beings. The NIH Guidelines specifically address the effective containment of recombinant DNA. These recommendations, however, are equally relevant to nonrecombinant research. Biosafety level (BSL)1-plants (P), BSL2-P, BSL3-P, and BSL4-P are recommended for research involving transgenic plants in Appendix P of NIH Guidelines.

BSL1-P is the moderate level of containment for biological experiments. It is designed to contain the possible survival, transfer, or dissemination of recombinant DNA into the environment. This containment level is also extrapolated to all such experiments where there is no recognizable and predictable risk to the human health and environment in case of accidental release. It supports the accepted scientific practices for conducting research in an ordinary greenhouse or growth chamber facilities and integrates accepted procedures for effective pest control and cultural practices. BSL1-P facilities and procedures also provide a protected environment, modified for the propagation of plant-associated microorganisms, and at the same time also adequately curtail the potential for release of live plants, plant parts, and microorganisms associated with them.

BSL2-P is designed to ensure a higher level of containment for experiments related to plants and certain associated organisms in which there is an evident possibility of survival, transmission, or dissemination of genetically modified organism containing recombinant DNA. The consequence of such an inadvertent release, however, has a predictably minimal biological impact. BSL2-P depends upon accepted practices for conducting scientific research in greenhouses with organisms infesting or infecting plants. This facility minimizes or prevents unintentional release of plants within or surrounding the greenhouse.

BSL3-P and BSL4- P describe higher containment conditions for research with plants and plant pathogens and other organisms that require special containment because of their known potential for significant damaging effect on managed or natural ecosystems. As BSL2-P, BSL3-P also relies upon accepted scientific practices for conducting research in greenhouses with organisms infesting or infecting plants in a manner that minimizes or prevents unintentional release of plants within or surrounding the greenhouse. BSL4-P describes facilities and practices to provide containment of certain exotic pathogens of plant.

14.5.1.1 Biological Containment Practices (Plants)

Containment is crucial in transgenic plant research in the labs, greenhouses, and growth chambers. The containment principles, practices, and facilities aim to minimize the possibility of an unforeseen injurious effect on organisms and ecosystems outside of the experimental facility. The inadvertent spreads of a hazardous pathogen from a greenhouse facility to nearby agricultural crop and the inadvertent introduction and establishment of an organism in a new ecosystem are serious threat. The effective containment facility ensures prevention of transgenic interbreeding

with native species, decontamination or inactivation of transgenic plant waste prior to disposal, containment of species that could have detrimental impact on local and agriculturally important species, and control of insect vectors and seeds and pollen of transgenic crops from dispersal and pollination of other transgenic crops. All researchers working with transgenic plants must be register with the IBC, determine the appropriate biosafety level for the work to be performed by them, and have standard operating procedures in place for storage, transport, and handling of GM seeds and plant materials with proper labeling and segregation of transgenic and non-transgenic plant materials and curtailing the dissemination of genetic material in the environment.

The level of containment is determined using the knowledge of the organisms and judgment based on accepted scientific practices. Any genetic modification that has the objective of increasing pathogenicity or converting a nonpathogenic organism into a pathogen should be done in high level of containment, depending on the organism, its mode of dissemination, and its target organisms. According to NIH Guidelines, the experiments falling under Section III-E require Institutional Biosafety Committee notice simultaneously with the start of the experiment. Experiment falling under Section III-D requires Institutional Biosafety Committee approval before its initiation. BSL1-P is recommended for all experiments with recombinant DNA-containing plants and plant-associated microorganisms (excluding those covered under Section III-D). For example, plant transformation experiments using recombinant *Agrobacterium* as the genetic modification are not expected to increase undesirable characteristics therefore, BSL1-P can be used.

Experiments requiring BSL2-P or a higher level of containment involve plants that are harmful weeds or that can interbreed with harmful weeds in the immediate geographic area or have recognized potential for rapid and widespread dissemination or for severe harmful impact on managed or natural ecosystems.BSL2-P or BSL1-P+ biological containment is recommended for:

1. Plants modified by recombinant DNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area [Section III-E-2-b-(1)].
2. Plants in which the introduced DNA represents the complete genome of a nonexotic infectious agent [Section III-E-2-b-(2)].
3. Plants associated with recombinant DNA-modified nonexotic microorganisms that have a recognized potential for severe harmful effect on managed or natural ecosystems [Section III-E-2-b-(3)].
4. Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious harmful effect on managed or natural ecosystems [Section III-E-2-b-(4)].
5. Experiments with recombinant DNA-modified arthropods or small animals associated with the plants. These also include recombinant DNA-modified microorganisms associated with arthropods or small animals, and the recombinant DNA-modified organisms have no recognized potential for harmful effect on managed or natural ecosystems [Section III-E-2-b-(5)].

BSL3-P or BSL2-P+biological containments are recommended for:

1. Experiments involving most exotic infectious agents with recognized potential for serious harmful effect on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants [Section III-D-5-a]
2. Experiments involving plants containing cloned genomes of readily contagious exotic infectious agents with recognized potential for serious harmful effect on managed or natural ecosystems in which a possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in plants exists [Section III-D-5-b]
3. Experiments with microbial pathogens of insects or small animals associated with plants, if the recombinant/synthetic nucleic acid molecule-modified organism has a recognized potential for serious harmful effect on managed or natural ecosystems [Section III-D-5-e]

BSL3-P is recommended for experiments relating to potent vertebrate toxins encoding sequences to be established into plants or plant-associated organisms [Section III-D-5-d].

14.5.1.2 Biological Containment in the Greenhouse

Greenhouses are the containment structures created by using transparent or translucent covering and provide a controlled environment for growing plants or plant-associated organisms. The plant-associated organisms include fungi, viruses, bacteria, protozoa, nematodes, insects, mites, and others. The physical and biological containment conditions and practices in greenhouse are carried out as specified in Appendix P of the NIH Guidelines. Appendix P applies when the research plant number, size, or growth requirements prevent the use of laboratory containment conditions (in growth chambers, tissue culture rooms, or open benches) as described in Appendix G, Physical Containment. It enlists the physical and biological containment procedures and management protocols applicable to each of four biosafety levels, designated as BSL1-P, the lowest level of containment through BSL4-P, the highest level.

14.5.1.3 Biological Containment of Plants

Growing plants need to be contained to prevent the effective spreading of genetic material. This can be achieved by covering or removing the reproductive structures to prevent pollen dissemination at flowering and seed dispersal at maturity, harvesting plant material prior to sexual maturity, and removing reproductive structures by using male sterile strains. Further it should be ensured that the cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant or induce flowering in experimental plants at a time of year when no flowering occurs in cross-fertile plants, within the normal pollen dispersal range.

Various commercial containment facilities are available, or inexpensive systems can be constructed with easily available disposable plastic sheeting. These systems contain seeds, soil, and plant parts resulting in less housekeeping, less contamination between shelves, and better humidity control resulting in less watering of plants.

14.5.1.4 Biological Containment of Microorganisms Associated with Plants

Prevention of dissemination of plant-associated microorganisms beyond the confines of the greenhouse is very important. This can be achieved by confining all operations, from manipulation of genetic material to injection thereof in microorganisms that limit replication or reproduction of viruses and microorganisms, and confine these injections to internal plant parts or adherent plant surfaces. Further ensuring the nonexistence of the organisms that can serve as hosts or help in the transmission of the virus or microorganism within the longest distance that the airborne virus or microorganism may be expected to cover to be effectively disseminated by these hosts or vectors may curtail the contamination. Containment can naturally be achieved if experiments are conducted at a time of year, when plants that can serve as hosts to plant-associated microorganisms are either not growing or are not susceptible to active infection. The use of microorganisms that are genetically modified to minimize their survival outside of the research facility and whose natural mode of transmission requires damage of the target organism, or assures that unintentional release is unlikely to initiate productive dissemination of organisms outside of the experimental facility, is also effective containing methodology for plant-associated microorganisms.

14.5.1.5 Biological Containment of Macroorganisms

The spreading of arthropods and other related small animals can be prevented by using flight-impaired, nonflying, or sterile arthropods and/or by using sterile or nonmotile strains of small animals. Dissemination can be prevented by conducting experiments at a time of year that are hostile for escaping organisms, by using animals that have an obligate involvement with a plant that is absent from the dispersion range of the organism, or by preventing the escape of organisms present by chemical treatment in runoff water or evaporation of runoff water.

14.5.2 Biosafety Boards Operating in India

The Indian biosafety regulatory system has evolved in response to scientific advances and the growing concerns of public, scientists, and government organizations about the biotechnology products. The Indian regulatory system ensures that

GM crops pose no major risk to food quality and safety, environmental safety, and agricultural production with no adverse economic impacts on farmers. The GMOs and products thereof are regulated articles in India in view of potential risks to human health and environment. The first set of rules is formulated under the Environment Protection Act (EPA), 1986, by the Ministry of Environment and Forests (MoEF) to stop the indiscriminate use of GMOs and referred to as Rules 1989. It provides "Rules for manufacture, use, import, export and storage of Hazardous microorganisms/Genetically engineered organisms or cell." The act ensures protection and improvement of "environment," which includes "water, air and land and the inter-relationship, which exists among and between water, air and land, and human beings, other living creatures, plants, microorganism and property." The Rules 1989 cover (1) manufacturing, import, and storage of microorganisms and gene technological products; (2) genetically engineered organisms/microorganisms and cells and correspondingly to any substance, products, food material, etc., of which such cells, organisms, or tissues form part; and (3) newer transgenic technologies along with hybridization of cell and genetic engineering.

The Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT) are the two apex bodies of the Government of India responsible for regulation of rDNA products and implementation of the rules regarding GMOs. MoEF has developed guidelines for the manufacture, import, use, research, and release of GMOs as well as products produced from GMOs to ensure the safety of human beings and the environment. Safety guidelines were developed by DBT in 1990 for carrying out research in the field of biotechnology, field trials, and commercial applications. Separate guidelines are developed by DBT for research involving transgenic plants in 1998 and for clinical products thereof 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. India has ratified the international regulatory framework Cartagena Protocol which is a sequel to the convention on biodiversity enacted in 1992 at the Rio Summit, in 2003.

The Rules 1989 also define the competent authorities and the composition of such authorities for managing various aspects of the rules. There are six competent statutory bodies under the DBT and state government for the implementation of regulations and guidelines across the country as listed below:

1. Institutional Biosafety Committee (IBSC): It is established under the institution engaged in GMO research to oversee such research and to streamline them with the RCGM for the regulation.
2. District Level Committee (DLC): These committees have a major role in monitoring the safety regulations in installations engaged in the use of GMOs/dangerous microorganisms and their applications in the environment.
3. State Biotechnology Coordination Committee (SBCC): These committees have a major role in monitoring. SBCC also has powers to inspect, investigate, and take penalizing action in case or violations of statutory provisions.

4. Genetic Engineering Approval Committee (GEAC): It was established under MoEF and is the apex body. GEAC was structured under Rules 1989 for approval of activities involving large-scale use of unsafe microorganisms and recombinant organisms in research and commercial production with respect to environmental safety. Any release of GMO and its products thereof into the environment which include the experimental field trials (Biosafety Research Level trial-I and II, known as BRL-I and BRL-II) should have approval by GEAC.
5. Review Committee on Genetic Manipulation (RCGM): The RCGM is established under the Department of Biotechnology (DBT), Ministry of Science and Technology, to monitor the safety-related aspects in ongoing scientific research activities and projects (including small-scale experimental field trials) and specify the protocols to be followed to implement regulatory procedures with respect to activities involving GMO research, usage, and applications in research and industry, to ensure environmental safety bring out manuals and guidelines.
6. The Recombinant DNA Advisory Committee (RDAC): RDAC acts as an advisory body which reviews the biotechnology development at international as well as national levels. The recommendation on suitable and appropriate safety regulations in recombinant DNA research, usage, and applications, from time to time, is used to frame Indian policies for environmental safety.

Thus various agencies are involved in approval of new transgenic crops. RCGM monitors ongoing research activities in GMOs and small-scale field trials at national level. GEAC authorizes large-scale field trials and environmental release of GMOs. The Recombinant DNA Advisory Committee (RDAC) monitors the developments in biotechnology at international as well as national levels and proposes appropriate recommendations. The State Biotechnology Coordination Committees (SBCCs) coordinate the research activities involving GMOs in the state with the central ministry. SBCC inspects, investigates, and takes punitive action if violations occur. Similarly, District Level Committees (DLCs) monitor the safety regulations in installations engaged in the use of GMOs in research and application, at district level.

14.6 IPR in Plant Biotechnology

Intellectual property rights (IPR) are about protection of rights of person creating a new and original concept in the global context. These exclusive rights are awarded by the government and define the possession in similar ways as for all tangible things such as house, land, vehicle, and so on. This restrains others from using the property without consent or permission of the creator. Further these rights are awarded under certain laws and valid over a fixed time period. After the end of validity period of this protection, others are free to use the intellectual property (IP).

Intellectual property is thus described as the property which originates through the creative effort of the inventor, produced or originated by human skill, intelligence, labor, and efforts, and gives the owner a right to such property.

IP rights is a body of law that is developed to give creative people, who have disclosed their work for the benefit of mankind, an ownership right over their creation. These rights protect the work of innovators from being copied or imitated without their consent. Intellectual property plays an important role in growth of economic interests of a country. The technology developed, research made, or invention done in a country is protected which in turn strengthens the economy of that country.

Except geographical indications and trademark, IPR are for the fixed time period. Geographical indications and trademark have indefinite life even after the stipulated time by paying official fees. IPR have to be renewed after the expiry period to keep them enforced except in case of copyright and trade secrets. Except copyright, IPR are largely territorial rights. Copyright is a global right. IPR can be held only by legal entities, self-governing entities having the right to purchase and sell property. These rights can be used, assigned, sold, licensed, and gifted. IPR can be enjoyed in more than one country, simultaneously.

14.6.1 IPR Categories

Presently the following categories of IPRs are recognized the world over:

(a) Patents
(b) Copyrights
(c) Trademarks
(d) Designs for industrial use
(e) Lay out design of integrated circuits
(f) Geographical indications
(g) Protection of undisclosed informations
(h) Protection of new plant variety and farmers' rights

Significance of IPR

- Launching new products, processes, and services
- Helping to take lead in the market
- Licensing and assignments
- Joint ventures and mergers
- Takeovers
- Enhancing market value
- Raising funds
- Strategic purpose

14.6.2 IPR in Plant Biotechnology

Research and development in the plant biotechnology and agricultural sector is unique among industries, and in relation to other industries, research and innovation in plant biotechnology and agriculture are far more geographically dispersed. Research and development in plant biotechnology is dominated by public research institutions, and nearly two thirds of share in research and development in these areas are contributed by these institutions. Private sector involvement in innovation in these areas is a recent phenomenon. Presently public as well as private sectors are involved in generation of IPRs in these areas.

Grant of intellectual property protection to living organisms and plant varieties is contentious and faces stiff opposition from environmentalist and other groups opposed to genetic modification/engineering ostensibly on account of biosafety and public health issues as well as on the core issue of grant of IP protection on living organisms being unsuitable and against the laws of nature. There is considerable concern that the intellectual rights protection might adversely affect food sovereignty and security as well as result in abuse of competition by creation and perpetuation of a small number of ever-growing very large players controlling technology and production rights over agricultural produce.

Presently developments in agriculture and plant biotechnology are protected by following IPR categories:

14.6.2.1 Patents

Patents are the legal rights that protect processes and product inventions which are made from tangible things. They give exclusive right to owner to decide its usage and discourage others to use invention as claimed in the document, describing the patent. Innovations in agricultural biotechnology such as transformation processes, transformation vehicles and other vectors, and components of vectors (origin of replication, promoters, genes of interest, and markers) are covered under utility patents.

Patentability of plants and plant varieties varies in different countries. Laws in the USA are liberal in this regard. US patent laws allow patentability of transgenic plants and their parts under "plant patent." The US government grants a plant patent to an inventor (or his assigns or heirs) who has invented or discovered and reproduced a distinctly new plant variety asexually, excluding tuber-propagated plant or a plant found in wild state. The grant is for 20 years from the application filing date and protects the right holder to discourage others from using or selling the new plant or asexually reproducing it. As the plant patents are exclusive patent in agriculture, they must also satisfy the general patentability requirements. Thus a plant invented or discovered by applicant and has been found to be stable after asexual reproduction should be the subject matter of the patent application. Indian and European patent statutes, however, do not allow protection of plants under patents.

14.6.2.2 Plant Breeders' Rights (PBR)

Plant breeders' rights are the protection provided to breeders by member nations of the International Union for the "Protection of New Varieties of Plants" (*Union Internationale pour la Protection des Obtentions Végétales*, UPOV) founded in 1961. After adopting the convention in 1961 in Paris, it was revised in 1972, 1978, and 1991 with an objective of encouraging the new plant variety development programs for the benefit of public in general.

Under the rules established by UPOV, to grant plant breeders' rights, the new variety must be:

(a) Novel, that is, it must not have been previously marketed where the country rights are applied for.
(b) Different from other available varieties.
(c) Exhibiting homogeneity.
(d) Stable with respect to unique traits and the plant remains true even after repeated cycles of propagation.

Any of the methods, conventional breeding techniques or genetic engineering, could be used to develop new plant variety (legally defined) for which protection is filed.

14.6.2.3 Indian Legislation on Protection of Product and Services in Agri-Biotech Sector

The regulatory and policy framework in India with respect to protection of the new plant varieties did not exist in the past because of sole control and dominance of the public sector. The private sector played minimal role. At the advent of green revolution, the need was felt to give farmers more incentives and encouragement, to use seeds of high-yielding crop varieties.

Now there are many legislations and statues which are enacted by the Indian legislature involving Ministry of Agriculture/ICAR and Ministry of Environment and Forests. The **Protection of Plant Variety and Farmers Right Act, 2001** (PPVFR Act), under the Ministry of Agriculture/ICAR, is an act of the Parliament of India formed to provide for the effective system for protection of plant varieties, to protect the rights of farmers and plant breeders, and to encourage investments in development and cultivation of newer plant varieties.

Essential requirements to be eligible for registration for new plant variety under the Protection of Plant Variety and Farmers Right Act, 2001, is that it must conform to the criteria of novelty, distinctiveness, uniformity, and stability (NDUS), as described in Section 15 (1)–(3) of the act.

14.7 Summary and Future Prospects

Extremely strong discussion about the potential benefits and danger associated with GM crops is going on in various parts of the developing world. Despite the current uncertainty over GM crops, this technology, with its great potential to create economically important crop varieties, is drawing good amount of attention. The two broad groups are formed due to this a pro-GM group comprising of agro-biotechnology institutions, many government departments, and seed breeding and marketing industries and an anti-GM group comprising of consumer and environmental organizations. The farmers' associations and the media are split between the two sides. The principal issues of disagreement are the extent of yield enhancement, pesticide and herbicide usage decrease, impact on the ecology and biodiversity, animal and human health, the socioeconomic position and livelihood of small farmers, and finally the ownership and control of genetic resources and trade. Thus, the benefits of advancement in agricultural biotechnology can be effectively harnessed by appropriate knowledge of the areas like biosafety, production patterns, biodiversity, and intellectual property rights.

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