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CHAPTER

2

Specific Issues Confronting Development, Biosecurity Regulation and Deployment of Genetically Engineered Crops

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ABSTRACT

In 18 years, Genetically Engineered (GE) crops and products have gained farmer and consumer acceptance globally. The area under GE crops has increased from 1.7 million hectares in 1996 to 175 million hectares in 2013. Currently 27 countries, including 19 developing countries, cultivate them and an equal number of countries import them for use as food and/or feed. The bio-security regulatory regimes that assure efficacy and safety of GE crops are scientifically sound, robust and stringent, and are validated by about 30 years of research and 18 years of cultivation experience. They are more or less the same in all the countries that adopted GE crops. In India, the hectarage under Bt cotton has grown from 0.5 million hectares in 2002 to 11.0 million hectares (95 per cent of cotton area) in 2013, made the country a cotton exporting country, now occupying the 4th global position in hectarage under GE crops. Vehement and persistent anti-GE crop activism, supported by international funding, has severely curtailed wide adoption of GE crops globally. The scientists, industry and governments in most countries have not taken seriously the important activity of public education and this resulted in the activists hijacking the agenda, more particularly in some countries in the European Union and Africa, and in India and Philippines. Activism has thrown to the fore a number of issues, which have seriously affected the development and deployment of GE crops. Some of these issues are related to a) the need for and efficacy of the products of GE crop technology, b) the scientific relevance and validity of the regulatory regimes in establishing bio-safety and environmental safety of the GE crops, c) the benefits they offer to the farmers and consumers, d) management issues projected as technology deficiencies, and d) the socio-economic benefits that emanate from the adoption of the GE crops. This chapter is a review of, a) the scientific/professional position on these issues, b) the benefits of GE crops vis-a-vis the alternatives often suggested, c) remedial measures to enhance public confidence to promote wide acceptance of GE crops, and d) the role of GE crops in enhancing food production contributing to food security.

***Key words*:** Genetic engineering, Genetic modification, Transgenics, Next generation genetic technologies, Organic farming, Agriculture, Food production, Food security, Biosecurity, Biosafety, Environmental safety, Biodiversity, Anti-tech activism, *Bt* cotton, Golden rice, Regulation of GE crops.

1. INTRODUCTION

'Biotechnology', the short form of Biological technology, means in simpler terms 'the industry-scale use of organisms and/or their products', and includes both the goods and services that emerge from it. The term biotechnology also covers the scientific, technological and commercial aspects, which touch almost every area of human welfare from agricultural production to pharmaceuticals to pollution control. The ancient fermented food processes, such as making bread, wine, cheese, curds, cereal based snacks, some of which are over 6,000 year old, and the pharmaceutical and industrial products developed for over a century, can also be included under classical biotechnology. Conventional agriculture is a well-developed industry in its own right, but in practice, this is not included in biotechnology. Modern biotechnology differs from the classical in that it comprises sophisticated and elegant methods that produce precisely designed products in agriculture, medicine and industry. Modern biotechnology, often equated with 'genetic engineering' (GE), is predominated by the 'recombinant DNA' (rDNA) protocols, used to insert genes from any organism into the genomes of any other organism irrespective of the degree of genetic relationship, resulting in 'transgenic organisms', which was impossible earlier. Nevertheless, GE may also mean addition or removal of genes, enhancement or suppression of gene expression, or somatic hybridization. Several other new GE techniques that are in the early phases of development are discussed in this chapter.

The bio-security of the currently commercialized GE crops has been established by a mandatory bio-security regulatory regime in every country that developed them. Over 30 years of research on GE crops and 18 years of their commercialization have demonstrated their safety and benefits. Nevertheless, from the very early stages of development of GE crops, there has also been a vehement opposition for political and other reasons. This anti-tech activism, which excludes medical and industrial biotechnology, has severely affected the progress of agricultural biotechnology, more particularly in Europe and in some developing countries including India, Philippines, Bangladesh and Thailand.

Biotechnology is a complex science that encompasses different areas of biology, biochemistry and others. The depth, spread and rigidity of the biosecurity regulatory regime, which is an equally complex science, has been incrementally escalated under the pressure of activism and politics. Regulatory evaluation often costs more in terms of time and money, than product development itself. Today there is a large number of issues of technology, regulation, politics and management, which seriously impinge on the development and deployment of GE crops, more particularly in the developing countries. There are huge gaps in the understanding of the soundness of the current regulatory evaluation process, resulting in controversies on what kinds and numbers of regulatory tests are needed to ensure safety of GE products.

The objective of this chapter is a) to review the scientific position on various issues, b) to indicate the benefits and safety of the GE crops now in cultivation, c) to highlight the activist generated controversies *vis a vis* scientific realities, and d) to suggest policy modifications, to promote GE crops for the benefits they offer. While the issues are discussed in a global perspective, the focus is more on India which suffered most damage from activism and politics, and as the issues are common to the majority of countries.

2. BIOSECURITY EVALUATION

The concept of 'Biosecurity' includes 'Biosafety', the safety of GE products to humans and animals as food, feed and medicine, and 'Environmental safety', the safety of non-target organisms (biodiversity), soil and water. Biosecurity means different things to different scientific groups. Food and Agriculture Organization (FAO) and World Health Organization (WHO) do not have identical definitions of biosecurity and biosafety, and the two terms cannot be satisfactorily translated into other languages.

Genetic stability and efficacy of the GE crops and products is ensured during contained green house and open field trials. Ensuring biosafety and environmental safety also involves similar trials. Though conducted concurrently, the whole of this process would take 10 to 15 years.

2.1. Biosafety of Conventional Food and Medicinal Products

All through human history, the safety of foods and medicine has been a matter of great concern throughout the world. The development and use of drugs has come under stricter mandatory regulations during the past 50 years, while the development of new crops did not attract any regulatory protocols even when they were developed using such methods as induced mutations and 'wide crosses' in which genetic material from weedy or poisonous plants was altered and/or transferred across natural barriers. During these efforts, trait selection often involved examining over 50,000 individual plants and there were instances of examining over a million individual specimens (Federoff and Brown, 2004). While there were no specific mandatory procedures to determine safety of the new varieties to the consumer and the environment, the long history of plant breeding and consumption of improved varieties have not thrown any instances of food toxicity or environmental harm from varieties of crops produced through induced mutations or 'wide crosses'.

All plant species, including most of food plants, contain a large number of toxicants and anti-nutrient chemical substances (Cheeke, 1989; Harborne and Baxter, 1996). There were not any set norms for determining food safety, but through trial and error, and a laborious and time taking process of selection, first the breeder-farmers and then agricultural scientists and nutritionists, have reduced toxicants and anti-nutrient factors, simultaneously enhancing the nutritional quality of foods, building up a long *'history of safe use'* for the foods we now consume. The indigenous systems of medicine in different countries, including the Indian systems, have used animal experimentation and occasionally human volunteers, to determine the efficacy and safety of medicines. The advent of synthetic pharmaceuticals has brought in new procedures of establishing efficacy and safety of the new medicines. Though not imposed by official/legal regulatory regimes, the pharmaceutical industry has developed norms for drug testing, opening an entirely different discipline, the chemical toxicology. For the most part of time, drug evaluation was neither universal nor as rigorous as it should be. The Thalidomide tragedy has changed the whole scenario of drug testing bringing in several strict and mandatory procedures. The new system led to a policy of product patents, a more sensible approach than the earlier process patents, but did not completely eliminate drug induced hazards as still once approved drugs are often recalled on finding new side effects. There are also hundreds of drugs that never come under the purview of the Drug Control Authorities, but are freely available in almost every country.

The emergence of GE crops and foods has brought in new concerns about their safety to the consumers and the environment. Persistent and vehement activism against GE crops brought them under strict biosecurity protocols. Today, parallels are drawn between food and drug safety and many safety protocols such as those used in chemical toxicology, are being imposed upon GE crops without much justification. Often there is excessive and unnecessary regulation of GE crops entailing enormous time and financial costs and hindering a smooth regulatory processing of the new crops. This is a matter of great concern and it is necessary to develop a global system of rational evaluation of GE crops and foods derived from them.

2.2. Genesis of Biosecurity Regulatory Evaluation of Products of Modern Biotechnology

In 1973 Herbert Boyer and Stanley Cohen achieved a major breakthrough in genetic engineering by perfecting the recombinant DNA (rDNA) techniques, incorporating chosen genes from the African clawed toad into the DNA of *E. coli,* and the expression of the transferred genes (transgenes) in the new environment. The rDNA technology opened up immense possibilities for developing an entirely new range of novel products in medicine, environment and agriculture. Soon, the first rDNA human insulin (approved in 1983), first transgenic plant (1986), and the first GE potato (1995) were marketed, soon followed by several others.

The first transgenic crop was not commercialized till 1996. Long before the products of modern agricultural biotechnology were developed, the scientists themselves (not the activists) were conscious of the possibility of risks to the consumers and the environment from rDNA products involving microorganisms. In 1974, the Asilomar Conference of scientists expressed confidence in the modern technology, but put into place a voluntary ban on rDNA research until risks could be better appreciated. In 1976 a 'Recombinant DNA Advisory Committee' was established by the US National Institutes of Health (NIH) (Fukuyama, 2002). In course of time, the NIH (1976), the WHO (1982), the Organization for Economic Cooperation and Development (OECD, 1986) and the US National Academy of Sciences (NAS, 1987) published critical studies of modern biotechnology and set guidelines to establish their safety. The following are the conclusions from these studies, as summarized by Cantley and Kershen (2013):

(a) Modern biotechnology is an extension and refinement of prior genetic engineering in plant breeding. Genetic engineering is not new. Indeed, all but a very small number of food crops are the product of genetic selection and breeding due to human intervention.

(b) Modern biotechnology allows for more precise, better understood, more predictable, and more limited genetic modifications than traditional breeding techniques that also introduce genes from distant (beyond species) relatives.

(c) The scientific basis for regulation focuses on risks, not speculative hazards, and balances the benefits of the new microorganism, crop or animal, with identifiable risks known from comparable organisms. Science urges that regulators think carefully about the benefits and risks. Science does not support a regulatory structure that insists upon no risks.

(d) The scientific basis for regulation focuses on the product (the crop or food) and not the process by which the product is produced. A regulatory structure rooted in science would be a product-based, not process-based, regulatory structure.

Soon as the guidelines of NIH, WHO, OECD and NAS were released, the major US developers of GE crops approached the United States Department of Agriculture (USDA) to issue guidelines for the evaluation of biosafety and environmental safety. To the USDA guidelines were added the recommendations of the *Codex Alimentarius* Commission (CAC), the international food standards institution established by the FAO and the WHO. However, with the rise of biotechnology, the work of CAC has become considerably more politicized (Fukuyama, 2002), affecting GE food products more than the others.

Today, there are no serious differences between the regulatory regimes of different countries. Nevertheless, the provisions of the Cartagena Protocol (CP) have to be adopted in case of trans-boundary movement of GE crop products, to the satisfaction of the importing country.

2.3. Time and Financial Costs of GE Crop Technology

The time and financial costs of GE crop development are currently very high, the burden falling on the farmers and consumers. The cost of discovery, development and authorization of a single trait 'Event' in a crop introduced between 2008 and 2012 was US$136 million and the time taken was about 13 years (McDougall, 2011). Some other estimates indicate that the development of a GE crop from idea to commercialization takes 12 to 15 years, costing between US$ 120 to 150 million. Registration and regulatory processing affairs took the longest time and often costing more than the other phases. There is a pressing need to reduce both time and financial costs for the benefit of farmers and consumers.

Royalties have to be paid to patent holders of essential technological protocols, even when most of them come from the public sector research institutions. For example, the development of the first version of Golden Rice involved 70 patented processes owned by about 10 Patenting Institutions/Universities. Irrespective of the developer being from the public or private sector, high technology costs could not be avoided. In the case of the public sector, the costs of development and deployment may seem lower, since a part of the cost burden is borne by the Central or State exchequer as salaries of personnel and infrastructure, which often are not taken into consideration for cost accounting.

No time consuming and expensive technology can come free of cost burden, without governmental support. In the absence of a policy of governmental control of seed costs, marketers attach higher prices. Farmers even in developing countries have long realized that seed of hybrids has to be purchased every planting season to maintain quality of the crop and see the high seed costs as an investment against higher returns. The cost of the seed of Bollgard I *Bt* cotton hybrids released in India in 2002 was three times higher than that of non-*Bt* cotton. The product developers did not heed to the advice to lower the seed costs. The activists seized the opportunity, branded the technology as exorbitant and pressurized the government of Andhra Pradesh to intervene, which resulted in reducing the cost of *Bt* cotton seed considerably. Now governments in each State determine the costs of *Bt* cotton seed.

In the case of *Bt* brinjal, the varieties (not hybrids) come free of technology costs through international agreements, as also the seed of Golden Rice. In both the cases the cost of GE crop seed would be on par with the non-GE variety of the crop on the market. The Central or State Governments should negotiate international agreements that reduce technology cost burden on the farmers and consumers, and when this is not possible ensure that reasonable seed costs are fixed and subsidize them if necessary, to protect the farmers from exploitation and to avoid undue controversies.

3. BIOSAFETY EVALUATION OF GE CROPS

The biosafety assessment of GE foods involves, a) direct health effects caused by the food (toxicity), b) tendencies to cause cancer (carcinogenicity), c) tendencies to provoke allergic reactions (allergenicity), d) nutritional effects associated with genetic modification, and e) any unintended effects which could result from the gene insertion.

The plant foods we are consuming today have undergone extensive genetic modification through natural mutation or hybridization or through the efforts of plant breeders. They have a long '*history of safe use*' (HOSU) for millennia, which is regarded as an adequate evidence of their safety and this should guide us on what biosafety tests are actually needed (Sesikeran, 2010). Hammond *et al.* (2013) reviewed the status of toxicological evaluation of introduced proteins in food crops and concluded that, a) experience in case of proteins with HOSU shows that it is highly unlikely that modification of amino acid sequences can make a non-toxic protein toxic, b) in general, food products from crops such as rice, wheat, maize, potato, soy, tomato and canola undergo a variety of processing conditions, which along with mechanical shearing, modification of pH conditions and cooking denature proteins resulting in a loss of potential for adverse health effects, and c) safety testing of an introduced protein could be indicated only when its biological function was not adequately characterized and/or it was shown to be structurally/functionally related to proteins that are known to be toxic to mammals.

Neither during the toxicity tests conducted for over 30 years nor in 18 years of consumption as food and feed, GE crop products have caused any adverse health effects. Over 350 million people in North America and elsewhere have been consuming GE crops containing diverse transgenic products for 18 years. Millions of meat cattle have been fed on GE maize and soybean, and their meat consumed by people in different parts of the world for over one and half decades. None of this resulted in any proven adverse effects either in humans or in cattle. This actually constitutes the largest long term transgenic food safety evaluation, with normal daily quantities of consumption in normal combinations with other foods. This does not suffer the disadvantage of overdose caused by exclusive forced feeding of pure constituents of the transgenic crops during laboratory tests. Nevertheless, the activists repeatedly raise issues of biosafety of GE crops and want more and more biosafety tests.

3.1. Toxicity of GE Crops and Foods

'Acute toxicity' is the adverse effects of a single exposure or multiple exposures in a short time (less than 24 hr) to a substance, occurring within 14 days of exposure. 'Chronic toxicity' is adverse effects of a substance on a continuous or repeated exposure to it. There may be prolonged internal exposure when the substance remains in the body for a long time. As it is widely considered unethical to use humans as test subjects for acute or chronic toxicity research with food or drugs, animal models are used.

Currently feeding studies for 90 days are the global norm as recommended by the *Codex Alimentarius* Commission, the WHO and the FAO, which are followed in the majority of countries including USA, Canada, Australia, Argentina, Brazil, and India. The 90-day period in the life of a laboratory mouse is a phase of maximum growth and is equivalent to testing for 24.5 years in human life and beyond 90 days of feeding studies no new data would emerge (Sesikeran, 2010). The activists question the adequacy of 90-day studies and demand for long term inter-generational safety tests. Snell *et al.* (2012) reviewed the literature on the health impact of GE plant diets in long-term and multigenerational animal feeding trials and found nothing of concern showing that such studies are not a scientific need.

The number of tests demanded by the activists has escalated in time to 39. It was also suggested that chemical toxicology tests such as 'Ames test', used to determine the potential to cause cancer and the 'micronucleus test' used to determine the extent of genetic damage, should be done without concern for their relevance and science based need to establish biosafety and environmental safety. The tests should be based on the 'need to know' rather than 'nice to know' basis. All tests need not be done in all cases. Under the practice of Event-based approvals, in the case of transgenics with the same gene as was approved for cultivation, such as Bt cotton with Cry 1Ac gene, the number of tests and period of field trials could be reduced, when new varieties of the same Event are approved for commercial release.

3.2. Carcinogenicity of GE Crops and Foods

Activists presumed that GE crops and products are carcinogenic but none of the claims was ever scientifically confirmed. In a major effort to project Monsanto's herbicide tolerant (HT) maize NK603 as highly carcinogenic, Seralini *et al.* (2012) claimed that NK603 caused extensive tumors in laboratory rats. Rattled by the poor scientific methodology and unwarranted claims, Regulatory Authorities, Scientific bodies, Animal Rights Organizations, Journal editors, English and French Media, individual Scientists, and others addressed the Editor of the journal protesting against the publication which was finally retracted by the journal (Elsevier, 2013). This issue was reviewed by Kameswara Rao (2013c). As of now, there is no credible evidence to show that GE crops and foods are carcinogenic.

3.3. Allergenicity of GE Crops and Foods

Activists endlessly repeat that GE crops and products are allergenic and project GE soybean containing genes for methionine from Brazil nuts and the *Bt* corn containing Cry 9c gene, as evidence for allergenicity of all GE crops. Both these claims were clinically demonstrated to be baseless (Kameswara Rao, 2009b). Even so, the two crops were withdrawn, which serves as an example of self-regulation by the industry.

Kameswara Rao (2009b) has discussed in detail clinical allergy, allergenic foods and highlighting that GE crops and products are not potentially more allergenic than their counter parts. As there are no suitable animal models to test for allergenicity, the basis is comparison of sequences of amino acids known to be allergenic. It is time consuming, expensive and almost always wasteful to test for allergenicity, yet it is now routinely done. If the isogenic were not allergenic, there is no need to test the transgenic for allergenicity, as the products of the transgenes in the currently commercialized crops have not been clinically proven to be allergenic in 18 years of consumption.

Groundnuts (peanuts), fish, eggs, and several others including mother's milk, may cause allergy in some individuals. Somehow the activists forget about 120 conventional foods, which were clinically proven to be allergenic, often with serious consequences to consumers (Kameswara Rao, 2009b).

4. ENVIRONMENTAL SAFETY OF GE CROPS

4.1. Impact of GE Crops on Non-target Organisms

The products of genes introduced into GE crops are aimed to control targeted pests (cotton bollworm, stem and fruit borers of brinjal, the egg plant), pathogens (ring spot virus of papaya) or weeds, should be safe for all other organisms. The primary use of crops is as food and feed and their safety to humans and animals is ensured through biosafety studies. What became contentious is if GE crops and products are safe to a wide range of non-target organisms such as a) the insects other than the targeted pest that live on the plants, b) the predatory insects that feed on the pests and other insects, c) the bees and butterflies that may pollinate, d) the birds that feed on all these insects, and e) the sheep and cattle that may feed on the GE crop produce or crop stubble. All the evidence from decades of research and cultivation experience shows that GE crops and products are safe to the non-target organisms as they are to the consumers.

Bt is one of the few pesticides recommended for widespread application in North America. *Bt* suspensions were air sprayed to control various crop, forest and urban pests in the US, Canada and New Zealand, without any adverse effects on the human and animal health (Glare and O'Callaghan, 2000). Transgenic *Bt* cotton pollen was shown to be safe to monarch butterfly larvae, bumble bees and to parasitoids that control pest populations in many crops (see Kameswara Rao, 2009d).

The official investigations into the reported death of birds, sheep and cattle did not prove the claims of the activists that these deaths were due to eating *Bt* cotton seeds or stubble (see Kameswara Rao, 2007a, b). It is interesting to note that these reports originated only from the Warangal, Khammam, and Adilabad Districts of Telangana, a well known centre for anti-GE crop activism and not from any of the other eight States cultivating *Bt* cotton in India (Kameswara Rao, 2007a).

4.2. Impact on Biodiversity and Environment

The impact of transgenic crops on the environment and biodiversity depends on gene flow (Kameswara Rao, 2010a). There is no evidence of free gene flow among the conventional varieties of any of the crops that are being used to develop transgenics. There are over 1,00,000 varieties of rice, 75,000 varieties of potato, 70,000 varieties of beans, and thousands of varieties in every food crop. This would not be possible if there were free gene flow among the varieties of a crop. GE technology does not change reproductive behavior to enhance gene flow. The much touted case of gene flow from transgenic maize into native varieties of maize in Mexico was disproved (Ortiz-Garcia *et al.,* 2005).

The enrichment of biodiversity in GE crop fields is discussed in 8.7, on 'Organic farming *vs* GE crops' in this chapter.

Rooted in the presumption of free gene flow among crop varieties is the contention that transgenic crops should not be permitted in the countries that are the Centres of Origin as they would affect the native germplasm. Scientific evidence points to the fact that issues of Centers of Origin and Centers of Diversity and Domestication are inconsequential where there is no pollen mediated gene flow. Thirty years of regulatory research and over 18 years of commercial cultivation of several transgenic crops in the world have not produced even an iota of evidence for free gene flow that would affect the native germplasm of any of the crops or biodiversity. The contention that transgenic crops should not be permitted in the countries that are the Centres of Origin is political and not based on scientific evidence (Kameswara Rao, 2010a). That India is the country of origin of important crops such as brinjal and rice is an emotional argument rooted in outdated publications and is not supported by sound scientific evidence.

The activist terms '*gene contamination'* and/or '*gene pollution'* for gene flow are a scientific travesty, used to agitate the public mind, and to castigate technology and its regulation. The contention that GE crops will '*contaminate*' biodiversity has no scientific basis as GE crop products are consumables and their residues are biodegradable, and are not pollutants in the same sense as the industrial and other pollutants are.

Ammann (2005) reviewed the impact of agricultural biotechnology on biodiversity. Biosafety and environmental safety of transgenic crops have been reviewed in a number of other publications (Ramessar *et al*., 2007; Sanvido *et al.,* 2007; OECD, 2007; Brookes and Barfoot, 2012). Basing on a decade of research on

GE crops, the European Union office has stated that *'The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies* (European Union, 2010).

The following respected scientific organizations that examined the evidence have come to the conclusion that consuming foods containing ingredients derived from GE crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques and support GE crops for developing countries to ensure food security: a) US National Academies of Sciences (1987, 1989), b) Research Directorate of the European Union (81 studies, 2001), c) French Academy of Science and Medicine (2002), d) Royal Society, UK (2003), e) British Medical Association (2004), f) Union of German Academies of Science and Humanities (2004), g) Food and Agricultural Organization (2004), h) Advisory Committee on releases to the environment, UK (2007), i) Pontifical Academy of Sciences (2010), j) European Union (2010), k) Indian Inter-Academy Panel (six Indian Academies of science, agriculture, engineering and medicine, 2010), and l) American Association for Advancement of Science (2012).

4.3. Super Weeds

A serious claim of the activists has been that the GE crops would escape cultivation, not due to pollen based gene flow, but through seed dispersal, become competitive and establish as aggressive 'super weeds' replacing other vegetation. Crawley *et al*. (2001), basing on a 10-year study of pest and herbicide tolerant transgenic crops, demonstrated that the transgenics do not become more competitive to invade the environment as super weeds, and that in fact they perished earlier than their isogenic counterparts. Outside cultivation, crop species do not get the care and inputs they essentially require to flourish.

5. BIOSECURITY REGULATORY REGIME FOR GE CROPS IN INDIA

The Indian biosecurity regulatory regime for GE crops was based on similar regimes of other countries such as the US, Canada, Australia, Argentina and Brazil, and is actually more stringent than that of most other countries. Powered by several Acts of Government, managed by the Department of Biotechnology and the Ministry of Environment and Forests (MoEF), and supported by a large number of public sector research institutions and scientists, the Indian regulatory regime functioned well, though not to the satisfaction of the activists.

5.1. The Legal Structure of the Biosecurity Regulation in India

The Indian regulatory process, based on the Environment Protection Act 1986 (Rules of 1989), should satisfy different provisions in several Acts of the Government of India, such as a) Prevention of Food Adulteration Act 1954, b) Recombinant DNA Guidelines 1990, c) Research in Transgenic Plants Guidelines 1998, d) Protection of Plant Varieties and Farmers' Rights Act, 2001, e) National Seed Policy 2004/05, f) Patent Act Amendment 2005, g) Food Safety and Standards Bill 2005, and h) Labeling Rules (under processing). This process involves the following Central Ministries at one or the other stage: a) Environment and Forests, b) Science and Technology, c) Agriculture, d) Health and Family Welfare, and e) Commerce, takes much more than a decade.

The Indian regulatory framework is conducted by the following competent authorities: a) Recombinant DNA Advisory Committee (RDAC), b) Institutional Biosafety Committees (one for each institution in GE development) (IBSC), c) Review Committee on Genetic Manipulation (RCGM, located in the Department of Biotechnology), d) Genetic Engineering Approval Committee (GEAC, located in the MoEF, is the apex body, that approves large scale field trials and release of GE crops into the environment for commercialization on receiving satisfactory inputs from the Indian Council of Agricultural Research (ICAR) and RCGM), e) State Biosafety Coordination Committees (SBCCs, one for each State that develops or cultivates GE crops), and f) District Level Committees (DLCs, one for each district that develops or cultivates GE crops). The SBCCs and DLCs are monitoring bodies at the State and District level and it is illegal to cultivate GE crops in any State without these committees in place. Nevertheless, only a few States constituted such Committees, in spite of reminders from the Government of India.

The Indian Government has issued the following documents to guide product developers and evaluators through the regulatory oversight: a) Handbook for IBSC Members (2005), b) Regulatory Frame Work for GMOs in India (2007), and c) Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants (2008).

A number of public sector organizations such as the a) the ICAR, b) the Indian Council of Medical Research (ICMR), c) the State Agricultural Universities (SAUs), and d) the Drugs Controller General of India (DCGI) are contextually involved in the biosecurity regime.

Over a dozen private and public sector institutions are involved in biosafety evaluation of GE Crops. The ICAR and its designated institutions evaluate agronomic performance and environmental safety and recommend the crop for commercial release. The SAUs and the State Departments of Agriculture are involved in the pre- and post-release monitoring of the GE crops.

Important developments are posted on the website of the GEAC and lists of Events approved for field trials are available at IGMORIS (2014).

5.2. The Biotechnology Regulatory Authority of India

The activists have criticized the present Indian regulatory process and attributed to it several kinds of lapses in the content and management and charged the competent authorities with vested interest, conflict of interest and even corruption. In view of this and in pursuance of the recommendations of different task forces, the Government of India has introduced into the 15thLok Sabha (the lower house) the 'Biotechnology Regulatory Authority of India Bill, 2013' (BRAI), on April 22, 2013. The objective of the BRAI Bill is to '*regulate research, transport, import, manufacture and use of organisms and products of modern biotechnology to promote the safe use of modern biotechnology by enhancing the effectiveness and efficiency of robust regulatory procedures'* (BRAI, 2013). The BRAI Bill was referred to a Parliamentary Standing Committee, to which many changes were suggested by the activists and others. Since the five year term for the 15thLok Sabha has expired, the BRAI Bill of 2013 has now lapsed.

Among the suggested changes to the BRAI Bill, some are significant. Chaudhary *et al.* (2014) examined the regulatory system of GE crops in India and suggested options that are critical for GE crops to take roots.

An issue of greater concern is the demand by the activists, supported by some architects of the BRAI, to adopt the 'Gene Technology Act of Norway on the production and use of GMOs' (The Norwegian Act, 1993) as the 'Way ahead'. The current regulatory regime has been in place for over 15 years and the BRAI Bill was under processing since 2007, yet The Norwegian Act was not in the picture till a couple of years ago. The new found respect for this Act is based in fact that it would make commercialization of any GE crop impossible for the following reasons: a) Norway has a 'No GMO' policy and does not allow even imports of GE crops or products for any purpose, b) Norway has a zero tolerance policy on GEOs and does not permit even unintended mixup of GE component, even though the EU permits up to 0.9 per cent, c) the Norwegian Act which is hardly used in Norway is more rigid than even EU policy, and d) NGOs from the Scandinavian countries, Norway being one of them, support anti-tech activism in India (PM's interview, 2012).

The BRAI Bill may not be in place till mid-2015, as it has to be tabled before the 16thLok Sabha for discussion and approval, which makes it pointless to discuss the current version of the Bill at this stage. The most important concern now is that till the BRAI gets into place, the current regulatory authority should be allowed to function without political and activist influences.

6. EIGHTEEN YEARS OF GE CROP CULTIVATION IN THE WORLD

The latest survey on the global status of GE crops in 2013, issued on February 13, 2014, highlighted the following (see James, 2013, for details):

(a) In 18 years the global hectarage of biotech crops increased from 1.7 million hectares in 1996 to over 175 million hectares in 2013, involving 18 million farmers in about 30 countries in 2013;

(b) Of the 27 countries which planted biotech crops in 2013, 19 were developing and eight were industrial countries;

(c) The collective area under biotech crops in Latin America, Asia and Africa in 2013 was 54 per cent of 175 million hectares, while it was 46 per cent in the industrial countries;

(d) Crops with two or more stacked traits were planted in 13 countries in 2013, of which 10 were developing countries;

(e) EMBRAPA, Brazil's agricultural R&D organization, obtained approval to commercialize its own transgenic golden yellow mosaic virus resistant bean, to be released in 2015;

(f) India cultivated *Bt* cotton on a record 11.0 million hectares (on 95 per cent area under cotton) and replaced Canada at the fourth global position in hectarage under GE crops, with only one GE crop;

(g) China grew 4.2 million hectares of *Bt* cotton (90 per cent of the area under cotton), and a record 148,013 hectares of *Bt* maize;

(h) Biotech crops contributed to food security and climate change by i) increasing crop production valued at US$116.9 billion, ii) providing a better environment, by saving 497 millon kg a.i. of pesticides, iii) reducing CO_2 emissions by 26.7 billion kg in 2012 alone, equivalent to taking 11.8 million cars off the road for one year, iv) conserving biodiversity in the period 1996-2012 by saving 123 million hectares of land, and v) helped alleviate poverty of over 16.5 million small farmers, and their families, totaling more than 65 million people, who are some of the poorest in the world;

(i) Biotech crops promoted sustainability by: i) Contributing to a '*sustainable intensification*' strategy which allows productivity/production to be increased exclusively on the current 1.5 billion hectares of global crop land, thereby saving forests and biodiversity, ii) Contributing to food, feed and fiber security and self sufficiency, including more affordable food, by increasing productivity and economic benefits sustainably at the farmer level, iii) Contributed to land saving and aiding biodiversity conservation, iv) Contributing to the alleviation of poverty and hunger, v) Reducing agriculture's environmental footprint, and vi) Helping mitigate climate change and reducing greenhouse gases;

(j) As of 30 November 2013, a total of 2,833 regulatory approvals involving 27 GE crops and 336 GE Events were issued by competent authorities, of which 1,321 are for food use (direct use or processing), 918 for feed use (direct use or processing) and 599 for environmental release or planting, in 36 countries (35 + EU-27), since 1994;

(k) Japan has the most number of Events approved (198), followed by the U.S.A. (165 not including stacked Events), Canada (146), Mexico (131), South Korea (103), Australia (93), New Zealand (83), European Union (71 including approvals that have expired or under renewal process), Philippines (68), Taiwan (65), Colombia (59), China (55), South Africa (52) and other countries with several approvals;

(l) Maize has the most number of approved Events (130 Events in 27 countries), followed by cotton (49 Events in 22 countries), potato (31 Events in 10 countries), canola (30 Events in 12 countries) and soybean (27 Events in 26 countries);

(m) In 2013, the global value of biotech seed alone was about US$15.6 billion;

(n) Biotech crops are essential but are not a panacea and adherence to good farming practices, such as rotations and resistance management, are mandatory for biotech crops as they are for conventional crops; and

(o) Bangladesh, Panama and Indonesia will plant GE crops in 2014.

7. GLOBAL ACTIVISM AGAINST GE CROPS

The activists do not oppose medical and industrial biotechnologies, but there has been well orchestrated multifaceted and well funded activism against GE crops in all the countries for over two decades. The activists trash the combined global scientific wisdom based on about 30 years of biosecurity regulatory research and 18 years of experience in the cultivation and consumption of GE crops and foods, and demand that they be banned altogether. The activists have been stronger where the governments are weaker, as in such countries as India, Philippines Bangladesh and some African countries, which suffered a serious setback to their plans to develop and deploy GE crops.

7.1. Dimensions of Anti-GE Crop Activism

The activist groups used every trick of the trade, such as pamphlet distribution using impressionable students, newspaper articles, group meetings, protests by hired and tutored demonstrators, radio and TV presentations, videos, lecture tours by professional speakers, international multi-location of release of commissioned anti-GE documents and publications, dedicated websites and daily internet news reports, petitions in courts, and vandalizing laboratories and GE crop trial plots, to mould public opinion against GE technology and to pressurize the Governments to slow down, if not ban the technology altogether.

Activist groups have coined pseudological terms such as a) '*gene contamination*' or '*gene pollution*' (for gene flow from GE crops to other varieties; see section 4.2 in this Chapter), b) '*terminator gene*' (for gene use restriction technology, discussed in 8.4 in this Chapter on Terminator technology), c) '*biopiracy*' (for using native varieties of a country to develop GE crops by companies and scientists of the same country, which is projected as a criminal act (discussed in 7.4d in this Chapter), d) '*fool's gold*' (for Golden Rice) and e) '*ecocide*' (for ecological damage). None of these terms have any status in official or legal documents but agitate the public mind. Unfortunately, unthinking scientists have added to the credibility of these terms by sometimes using them.

Activists do not actually represent the groups they claim to. Their gatherings are a hotchpotch melee. There are thousands of farmer and consumer groups in every country, which are not unified constituencies as they are formed out of political and other compulsions and frequently splinter for the same reasons. In India some farmer groups support GE crops (for example, Bharat Krishak Samaj and Consortium of Indian Farmer Associations) while some others oppose (for example, Bharatiya Krishak Samaj and Centre for Sustainable Agriculture), with political and financial considerations dictating their stand.

The activists have wisely used the media to spread misinformation, disinformation and outright lies. They fed factoids (untruths believed to be truths on constant repetition), and churned the same information again and again (this kind of journalism is called 'churnalism'). The activists enhanced their credibility in the public eye by bringing in some people with degrees and/or faded careers in science. Most of the time either these frustrated 'scientists' are out of tune or even belong to such unrelated fields as 'philosophy of physics' and do not have an adequate background in biotechnology and agriculture.

The issues raised by the activists to project GE crops in bad light are discussed in Sections 3, 4,7, 8, 9 and 10, of this chapter.

7.2. Anti-GE Activism in India

Anti-tech activism which opposes GE crops is the most serious threat to India's future food security. The bureaucracy, scientific community and the product developers are all wary of the aggressive stance of the activists who have no holds barred and nothing to lose.

The Indian activists who failed in stopping *Bt* cotton, but scored impressively in engineering a moratorium on *Bt* brinjal by raising a variety of emotional issues, including that *Bt* brinjal will jeopardize the use of brinjal in the Indian systems of medicine, when brinjal is not used in any system of medicine (Kameswara Rao, 2011). The activists have also succeeded in preventing international collaborative research projects, in creating hurdles in conducting field trials and pressurizing the Biodiversity Authority to legally proceed against GE crop developers in India.

7.3. *Bt* Brinjal Moratorium is a Political Decision

The 19-page *Bt* brinjal moratorium order, the 535 pages of appendices to it and the statements of the Minister of Environment and Forests (MoEF) from the time he became the MoEF till June 2010 were reviewed by Kameswara Rao (2010a), which leave no doubt on the MoEF's opposition to *Bt* brinjal and biotech crops, but the pro-tech groups failed to read between the lines to realize that he has been all along on the side of the activists. That the imposition of moratorium on *Bt* brinjal was in fact a political decision and not a compulsion for any safety or environmental concerns, should be evident from the following statements of the then MoEF:

(a) *'It is for the political system to decide whether to introduce Bt brinjal'* (The Hindu, January 10, 2011;
(b) *'If I said yes to Bt brinjal, the civil society would have jumped on me'* (Malhotra, 2011, June 10, 2011)*;*
(c) *'If 90% of the GM seed is going to be controlled by one company…'* (meaning Monsanto) (Malhotra, 2011, June 10, 2011). Responding to a similar statement by the MoEF, Dr MS Swaminathan said that *'I don't think there is a risk of big business dominating Indian agriculture, at best they can control some areas'* (Forbes India, February 20, 2010);
(d) In the moratorium order the MoEF said earlier *'I have no bias whatsoever'* (*Bt* brinjal moratorium order, p. 11), but later said *'I had a personal bias'* (Malhotra, 2011, June 10, 2011); and
(e) The Deputy Chairman of the Planning Commission was reported to have said that *'the public consultation process on Bt brinjal initiated by Jairam Ramesh is one sided'* (to Dinesh Sharma, India Today, September 3, 2011).

7.4. Activist Influenced Developments

Besides blocking *Bt* brinjal and Golden Rice, the activists have successfully influenced the following developments:

(a) A collaborative research programme between the Indira Gandhi Agricultural University, Raipur, Chattisgarh State and Syngenta International, to explore the University's rice germplasm collections to identify rice varieties and genes to develop new hybrids that meet with specific requirements of the farmers, was initiated in 2002. Threatened by a violent agitation, Syngenta withdrew from the arrangement.
(b) The Indo-US Knowledge Initiative on Agriculture (KIA) was finalized in 2006, by the US President and the Indian Prime Minister. The KIA was aimed to boost agricultural cooperation between India and the US. The activists and the opposition parties have vehemently opposed the deal and the government relegated KIA to low priority and has not been heard of ever since.

(c) On the initiative from the Chief Minister of Bihar, the then MoEF issued a directive that the developers of GE crops should obtain the permission of the State Governments to conduct open field trials of GE crops, even before the GEAC permits these trials. The activists argue that since agriculture is a State subject, a 'No objection certificate' from the State Governments is essential, ignoring the fact that open field trials do not constitute agriculture as the products do not go to the farmers or markets. Only a few States issued permission for open field trials but as most State Governments side with the activists, this entirely political move has now become a serious impediment to the development of GE crops, as the whole process is blocked at the first step itself.

(d) The developers of *Bt* brinjal are charged with biopiracy and violation of the provisions of the National Biodiversity Act (Kameswara Rao, 2013b). The National Biodiversity Authority (NBA) is being pressurized by the activists to prosecute the developers, including the two agricultural Universities, for using native germplasm without prior permission of the NBA. The hybrids and varieties used in *Bt* brinjal development were the proprietary material of the developers, being distributed or marketed for years. Since all germplasm of all crops grown in India can be interpreted as native, the NBA being under the influence of the activists, no product developer is likely to get permission in future to use Indian germplasm for any purpose.

7.5. International Support to Anti-GE Activism

Supporting global antitech activism costs enormous amounts of money. When we consider who is affected by large scale deployment of GE crop technology, the sources of the broad and deeply committed financial or other support for anti-tech activism become clear. In general such sources are, a) the pesticide industry and dealers, b) conventional seed developers, c) organic lobby, d) exporters of organic and other food crops afraid of rejection by importing countries on the assumption that they may have GE component, e) European Union/Commission, f) Ideological differences, g) Political differences, h) anti-American and anti-MNC prejudice, i) internecine rivalries and jalousies among scientists and institutions, j) vote bank politics, k) neophobia and others.

A considerable quantum of financial and logistic support certainly comes from the Indian sources, but it was recognized for long that the whole of global anti-GE crop activism is sustained through direct or indirect liberal international funding, more particularly from the European Union (EU) countries. There is a lot of evidence in the public domain on foreign funding of activism in different countries (Kameswara Rao, 2010a; Reddy, 2013). No organization would get foreign funds, particularly from the EU, if it were to support GE crops and foods anywhere. And so, the anti-tech groups cannot be called independent in the arena of policy. Absolute objectivity does not exist as the survival of the activist groups depends upon how effectively they agitate and coerce governments into adopting the policies of their sponsors.

While a few activist groups may be dedicated to genuine causes, most others have vested interests in ensuring certain outcomes. The future donor grants often depend on sustaining one's influence in the policy space.

The Indian Government had used the 'Foreign Contribution Regulation Act' of 2010 only selectively, but should push for a stricter transparency regime from the NGOs, by bringing all of them under cover of the Right to Information Act, since they enjoy tax benefits in India. It is necessary that both the Indian and overseas players of anti-tech activism in India are made to publicize the details of the sources of their funding and expenditure.

Well funded activism is a source of livelihood and not a calling for most of the activist groups operating in India. Once the funding stops, so would the activism. Unfortunately the public is not aware of the forces behind anti-tech activism and so carried away by the din caused by the activists.

8. MISINTERPRETED PROVISIONS THAT ESCALATED REGULATORY BURDEN

Disregarding scientific concepts, the anti-tech lobbies have distorted and misinterpreted the intent and reach of some of the well meant regulatory protocols, basing on which the political systems were pressurized to escalate regulatory burden to retard approvals for commercialization of GE crops. Emanating from the EU lobbies, spreading to the developing countries, these influences have created serious hurdles in the development and deployment of GE crops, preventing their wider adoption, particularly in Europe and the developing countries. The science behind the provisions, the serious controversies, problems and consequences of activist interpretations, are discussed here.

8.1. Convention on Biological Diversity and Cartagena Protocol

The activists frequently invoke the bogie of contravention of the provisions of the Convention on Biological Diversity (CBD) and the Cartagena Protocol to the CBD (CP), to influence governments and to inflame public opinion, against biotech crops. Member of the CBD do not attract any additional burden to hinder GE technology. Other Member nations of CBD such as the USA, Argentina, Brazil, Canada, and China are leaders in the adoption of GE crop technology. The CBD only commits Member nations to balancing the benefits and risks of utilization of biological resources. The CP is concerned only about transboundary movement of GE crops and products, to ensure that importer's rights to the safety of GE crops and/or products are protected. No provision of either the CBD or the CP is meant to prohibit, or intentionally impede, new agricultural technologies.

8.2. The Precautionary Principle

The '*Precautionary Principle'* (PP) is a regulatory provision to be taken into account while GE crops or their products, are permitted for release into the environment or placed on the market. The PP is not a new idea, and was probably rooted in the Chinese adage that says '*when in doubt do nothing'* (Kameswara Rao, 2006). PP is widely applied in industry, particularly biological industry, but never so rigidly as with GE crops.

The PP was good in intent. Currently in spite of voluminous scientific evidence and vast practical experience in cultivation of GE crops which have repeatedly confirmed the safety of the crops and products to the farmers, consumers or the environment, the activists and politicians presume risk and invoke PP to halt GE crop development and/or deployment at any stage. For example, the then MoEF has stated on February 9, 2010 in the *Bt* brinjal moratorium order, that '*it is my duty to adopt a cautious, precautionary principle-based approach and impose a moratorium on the release of Bt brinjal'* (Kameswara Rao, 2010a). He used PP as the most important concern to impose moratorium and to escape his responsibility of solving the problem on hand.

Kameswara Rao (2006) cited the following three international agreements often used as evidence of authentication of the PP as an essential instrument in making decisions on, a) the introduction of GEOs into the environment, b) importing GEOs or their products, and c) placing them on the market:

(a) The PP was originally proposed in the '*Rio Declaration on Environment and Development'* of the Earth Summit, 1992, in the context of protecting the environment from adverse industrial and developmental activities, long before GEOs came on the scene. Principle 15 of the Rio Declaration states that '*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation';*

(b) The international Agreement on the '*Application of Sanitary and Phytosanitary Measures*' of the World Trade Organization (WTO) of 1995 states in Article 5.7 that '*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time*'. This provision governs international trade practices, pre-dates GEOs, and is often interpreted as justification for PP by the activists. The WTO was conscious of the time factor and advised the Members to take decisions '*…within a reasonable period of time*', which is often ignored; and

(c) Articles 10.6 and 11.8 of the '*Cartagena Protocol on Biosafety*' (2000) state that '*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the Party of Import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism..., in order to avoid or minimize such potential adverse effects*'. The emphasis here is on conservation, sustainable use of biological diversity and human health. This provision also is used in support of PP by the activists.

The EU has taken the lead in making PP sacrosanct, under pressure from the influential European anti-tech lobbies. A '*Directive of the European Parliament and Commission*' (No. 8, 2001) states that '*The Precautionary Principle has been taken into account in drafting this directive and must be taken into account while implementing it*'. Article 4 of the directive states that '*Member States shall, in accordance with the Precautionary Principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment, which might arise from the deliberate release or the placing on the market of GMOs*'.

The EU policy is in stark contrast with that of the US and many other countries, which adopted the '*Precautionary Approach*' as a regulatory norm, which seeks to err on the side of safety by applying precaution informally but implicitly in regulatory decisions.

The EU is on the side of the activists who have weaponized PP and also demands that other countries take the same stand on crop protection, GE crops and food safety, all of which result in far higher costs than benefits.

An unscientific and irrational emphasis of the PP seriously impacts international trade, including that governed by the WTO agreements and also on national policy on GE technology in several developing countries. Above all, the PP encourages evasion of responsibility for the *status quo* (Brown, 2013) and no one takes the responsibility for the consequences of an undue application of PP.

Periodically, there have been several critiques on the application of PP to GE crop regulation which have emphasized the need to evaluate the depth and range of the impact of the application of PP to biosecurity issues related to the GEOs and to suggest guidelines for a more meaningful application of PP, if it is at all needed. CAST (2013), in a recent comprehensive review on the import of PP made the following observations:

(a) Notwithstanding its swift rise in the international arena, the PP has serious shortcomings and does not, at least in its current form, provide a coherent, rational, and defensible basis for risk management decisions as it is flawed;

(b) Without a workable definition and agreed-upon criteria for its application, the PP's employment to date, including in the food context, has been dictated more by political influences than scientific factors. For example, governments have exploited the PP's ambiguity and arbitrariness to adopt protectionist policies, and activist groups have used the PP to apply a double standard of higher scrutiny and demands for certain technologies of which they disapprove;

(c) Todate the PP's solution to the question of appropriate risk management is blunderbuss rather than nuanced, extreme rather than reasoned, biased rather than balanced, and arbitrary rather than principled;

(d) The problems with the PP are imposing real harms on society, by delaying beneficial technologies, disrupting world trade, and perhaps most importantly impeding economic, social, nutritional, and safety progress in developing nations;

(e) PP holds back technology, innovation, incomes, environmental improvements, and health benefits, while increasing trade disruptions, risks, and human suffering;

(f) As with many things in life, with PP too, the 'Goldilocks strategy' (not too little precaution, not too much, but just the right amount of application) is urgently needed;

(g) For the millions of people who are lacking adequate nutrition today, and the many millions more who will suffer as a result of the growing food demand-supply gap projected over the next few decades, the PP does more harm than good; and

(h) It is in the joint interests of governments, industry, NGOs, and the general public, to ensure that appropriate risk management is applied with all technologies to minimize unreasonable risks and injury.

Potrykus (2010b) stated that the '*the present regulation is based on the extreme interpretation of the precautionary principle'*. EU Commission's Chief Scientific adviser, Dr Anne Glover stated in July 2012 that '*GMOs are no riskier than their conventionally farmed equivalents*' and that '*the precautionary principle no longer applies*' (James, 2012).

8.3. Substantial Equivalence of GE Crops and Products to their Conventional Counterparts

The issue of 'Substantial Equivalence' of GE Crops and products to their conventional counterparts was reviewed by Kameswara Rao (2009c). The US Food and Drug Administration (FDA) routinely and stringently used the '*Principle of*

Substantial Equivalence' (SE) of new drugs and foods to similar drugs and foods, already in use for long, to assure the public of the safety of those marketed in the US. SE refers only to the product and not the process of its production. Once SE is established, the FDA requires no further regulatory review of new drugs and foods. On account of the high standards of FDA's regulatory oversight, most other countries generally approve drugs and pharmaceuticals on the basis of FDA's approval. However, GE crops and products suffer a different fate.

The principles of SE were outlined in the consensus documents of the OECD (2006) and further elaborated by the FAO and WHO. When testing standards and procedures in different countries were reasonably uniform, what is considered safe in one country should be considered so in other countries too. This will eliminate the need for repeating the same and every test in every country, saving time and expense. Such a situation does not exist.

In the context of modern agricultural biotechnology, anti-tech activists have repeatedly made SE an issue of serious concern, on the assumption that unintended compositional effects could be caused by genetic modification, making the GE crops and products unsafe as food and feed. Efforts are made in every country to demonstrate that a GE crop variety and its products are substantially equivalent to its conventional variety (isogenic) and its products, but for the new genes in the transgenic variety and the consequent expected products of the transgenes, which also have been shown to be safe.

Under the '*Provision for voluntary consultation*', the US biotech companies seek SE certification by FDA, of all GE varieties and their products they intend to market. The voluminous dossiers submitted by the product developers to FDA are usually confined to the comparative study of proteins, carbohydrates and other components of nutritional significance (Compositional Equivalence or Nutritional Equivalence analysis). The focus is on determining whether the new GE varieties and their products are toxic or allergenic. If some GE products contain miniscule quantities of a few additional components that are, a) broken down during food processing or digestion, and/or b) if they occur below acceptable independently determined threshold levels, the products are regarded as *'Generally Recognized As Safe'*(GRAS). If the new genes code for new fats, proteins or carbohydrates in the GE products, and were found to be toxic or allergenic or adversely affect the nutritional value of the product, additional appropriate and adequate testing is required before they are certified as SE or GRAS.

Products from GE soybean, potato, tomato, corn, and cotton now in the markets, have been tested extensively, much more than any conventional foods, and judged SE to their conventional counterparts and so are safe food and feed.

The policy of the FDA considered as lax by the activists did not result in any health concerns during 18 years of consumption of GE crops and foods by millions of people. Nevertheless, the FDA policy has been criticized on account of, a) the FDA itself has a mandatory process for approving transgenic animals, b) the US Environment Protection Agency (USEPA) and the USDA have a mandatory and open process for evaluating the biosafety of GE crops, and c) the data are provided by the product developers.

The objective of SE is to establish nutritional equivalence and safety (toxicity and allergenicity). In the application of SE, the comparison should only be between the GE variety and its isogenic, which is the basic variety into which a new gene was inserted, but not any and every variety of the same crop. It would lead to a difficult situation if SE has to be established for all products of a GE variety, including livestock feed, and worse if SE has to be established for different transgenic varieties of the same crop with the same transgene, as demanded by some activist groups. The certification is to the effect that the GE crop variety is SE to its isogenic, in genotype, marked characteristics and performance, but for the transgenes and their anticipated products and characteristics. If the isogenics were safe, the transgenics will be equally safe, provided that the newly introduced transgenes do not exercise any adverse effects by themselves or through altering the expression of any other genes of the isogenic in the new status which has not happened so far. Such an assurance requires scientific evaluation of the crop variety and its products, which involves additional effort, time and expense, escalating farmer and consumer costs.

The activists look down upon safety data provided by the product developers, even when gathered by different recognized private and public sector laboratories outside the companies, as has happened with the Indian *Bt* brinjal.

At no time, transgenics can be wholly SE to their isogenics in their entire genotypes and this is not related to transgenic technology. Even to start with, members of the same population are not entirely genetically identical. In addition, mutations occur naturally and randomly, involving different genes. Lethal mutations are naturally eliminated. Mutations of the genes of the desired characteristics are eliminated in the process of selection, but those that do not affect the desired characteristics escape attention and accumulate. After a certain number of generations, a critical genetic analysis will contravene SE, although SE can be established for the genes of the desired characteristics. Such a situation would cause problems in some countries, where the regulatory authorities apply the principle of SE more in letter than in spirit, and a lot more strictly than in other countries.

The official consensus of the EU is that, SE should only be used to inform of basic safety assessments and so GE products require further confirmatory analysis by sophisticated methods. The EU safety regulations, based on this premise, are so stringent that they raised doubts whether any GE product will at all qualify to be considered safe. The *Codex Alimentarius* Commission sees SE as a starting point in the regulatory process rather than as the end point, which commits GE crops and products to further unwarranted testing.

Notwithstanding the care taken in developing procedures to establish SE, it has been criticized as vague, ill defined, flexible, malleable, open to interpretation, unscientific and arbitrary. In the debate on SE, activists often hold that:

(a) The focus of SE has been well known nutritionally significant components, occurring in significant quantities;

(b) The studies employed routine food safety testing methods which are not sensitive enough to detect all components and so are not detailed total critical analyses;

(c) That more sophisticated and deep analytical approaches may reveal chemical compounds hither to unexpected and unknown, which may make the GE products unsafe for human consumption; and

(d) In the US, SE data were generated not by independent entities but by the product developers themselves (and so suspect) and largely remained in the private domain, not easy for others to access for evaluation.

Collaborative efforts of bioinformaticists and molecular biologists have resulted in the '–o*mics*' series of analytical protocols. Some common examples are, a) Genomics (the study of genomes, with several subareas such as cognitive, comparative, functional and personal), b) Proteomics (analysis of the entire complement of proteins in an organism, with subareas of structural, functional, immunological and nutritional), c) Glycomics (study of the carbohydrate profiles), d) Metabolomics (chemical fingerprinting of residual small molecules), and e) Metabonomics (metabolic responses to pathophysiological stimuli or genetic modification) (Kameswara Rao and Seetharam, 2013). Transcriptomics, the study of the set of all RNA molecules, is actually a part of genomics.

The -omics protocols are complex, sophisticated and require technical expertise, extensive instrumentation and heavy time and financial inputs. The -omics protocols should be employed on a case by case basis, if other safety evaluations warrant the need for any study in the –omics series, as they are by no means routine studies. In a given case, some but not all of them, may be useful in evaluating SE beyond the routine compositional level. It is in fact comic that the activists demand that every GE crop product should be subjected to all the different –omics analyses, as there is no scientific basis for doing so and it is wholly unnecessary and waste of both time and money. There is a lot of literature demonstrating the lack of appreciable differences between GE and non-GE crops and products, confirming SE between them as established by other means. The following are some examples:

(a) Catchpole *et al.* (2005) demonstrated that, in metabolomic comparisons, apart from targeted changes, field grown GE potatoes and their traditional cultivars were SE to each other. The minor differences that were found between the GE and the non-GE varieties were of the same kind and magnitude of such differences among the non-GE varieties, that occur on account of natural variation in gene expression. None of these differences are significant in the context of the safety of the GE potatoes for human consumption.

(b) Batista *et al.* (2008) noted that the observed transcriptome alteration was greater in mutagenized plants than in transgenic plants;

(c) Chassy (2010) evaluated data from metabolomic studies on GE crops and counterparts and concluded that such studies may not be advantageous for safety assessment and that they would only increase the current regulatory burden on GE crops;

(d) Kogel *et al.* (2010) stated that cultivar specific differences in transcriptome and metabolome greatly exceed effects caused by transgene expression and that the impact of a low number of alleles on the global transcript and metabolite profile is stronger than transgene expression;

(e) Ricroch *et al*. (2011) reviewed the literature on –omic profiling techniques for safety evaluation of GE maize, potato, rice, soybean, tomato, wheat and tobacco in comparison with their non-GE counterparts and noted that in several studies more large effects due to the environment were observed on gene expression, protein, and metabolite levels, than in GE crops;

(f) Results from most studies involving comparative proteomics demonstrated essentially identical protein profiles in GE crops and controls (Gong and Wang, 2013). Furthermore, genetic modification caused less variation in GE crops than the natural variability derived from conventional breeding and genotypic variation; and

(g) Ricroch (2013) examined data from, i) 60 recent '-omics' comparisons between GE and non-GE crop lines, ii) 17 recent long-term animal feeding studies (longer than the classical 90-day subchronic toxicological tests), and iii) 16 multigenerational studies on animals. The '-omics' comparisons showed that the genetic modification has less impact on plant gene expression and composition than conventional plant breeding. Environmental factors (such as field location, sampling time, or agricultural practices) have a greater impact than transgenesis. None of these three sets of studies has raised new safety concerns about GE varieties. Therefore, there is no need to perform any such studies in a case-by-case approach, unless reasonable doubt still exists after conducting a 90-day feeding tests. Plant compositional analysis and '-omics' profiling do not indicate that toxicological tests should be mandatory.

There is a dire need for a uniform and harmonized international policy on SE as a measure of safety. On account of the concerns raised, the procedures to establish

SE should be re-examined, for re-defining the applicability of SE to GE crop plants and their products, laying emphasis on a reasonable application of the principle, addressing only those genes and their products that are relevant to the objectives of developing a particular transgenic variety or product.

So far, it has been established that GE crops and their counter parts are SE and that there is no evidence to consider GE crops as unsafe as food or feed. Nicolia *et al.* (2013) reviewed literature on GE crop safety during the last 10 years, to conclude that the scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops. Basing on a survey of 20 years of research, Herman and Price (2013) concluded that suspect unintended compositional effects that could be caused by genetic modification have not materialized on the basis of this substantial literature. Hence, compositional equivalence studies uniquely required for GE crops may no longer be justified on the basis of scientific uncertainty.

8.4. The *'Terminator Technology'*

'*Gene Use Restriction Technologies*' (GURTs) are a group of tools to regulate gene expression, in different ways. There are many conventional means to alter gene expression such as addition or deletion of genes, induced gene mutations, induced polyploidy, experimental hybridization and somatic hybridization, which are difficult to manipulate with precision. Modern protocols to develop GURTs, such as the patented *'Control of Plant Gene Expression'* (CPGE, US Patent No. 5,723,765, March 1998), RNA interference (iRNA, gene silencing) and the now well known rDNA technology, are more precise.

The obnoxious term *'Terminator gene/technology'* was widely and incessantly used by the anti-tech activists making the public believe that every GE crop contains the terminator gene. The term terminator gene, which is not a scientific term, was coined by the NGO, 'Erosion, Technology and Concentration' (ETC, earlier called 'Rural Advancement Foundation International', RAFI) to denigrate GURTs, which include several useful protocols. The unthinking scientific community has often used the term terminator technology adding credibility, which led the public to believe that MNC scientists have developed it to make enormous profits for their companies.

In another approach of CPGE, derogatively dubbed as the *'traitor technology'*, where the expression of a specific desirable transgenic trait is dependent upon spraying a specific proprietary chemical, sold separately, often by the same company. Another patented technology for *'reversible transgenic sterility'* (RTS), allows the farmer or breeder to restore the seed's fertility by applying an external chemical inducer. The issues related GURTs were discussed in detail by Kameswara Rao (2008).

The CPGE allows the crop to grow and set seed normally and the seed can be used as usual, but it would not germinate to give a new plant, as the development of the embryo was arrested. The scare spread is that GURTs threaten the livelihoods of millions of small farmers around the world, as they have to buy new seeds for each planting, reducing their self-sufficiency making them dependent on major seed and chemical companies.

Some scientists have contributed to the belief that all GE crops contain the 'terminator gene'. While explaining the gene construct in a transgenic, they inadvertently call the 'termination codon' (which signals the stop of the end of the reading frame) as the 'terminator (or termination) gene'.

CPGE gained all its notoriety as it was unfortunately first demonstrated in the context of arrest of the development of the embryo making the seed unusable to raise a crop from it. The anti-tech activists have conducted such massive fear campaigns against CPGE that made Governments of many countries prohibit its use in agriculture. In the face of vehement protests in India, Latin Amerca and south-east Asia, Convention on Biological Diversity (CBD) recommended a *de facto* moratorium on GURTs in 2000 and the Patent holders had agreed not to use CPGE in any crop.

There are several derivable benefits from the use of GURTs (Kameswara Rao, 2008). The major objective behind GURTs is bio-containment of transgenes in crops and trees, to the advantage of the farmer, the consumer, environment and biodiversity. It can be used to prevent of spread of seed borne pathogens from one generation to the other. CPGE can be used safely to prevent gene flow where the commercial product is not the embryo but the endosperm as in rice, wheat and corn. It can also be used where the crop is vegetatively propagated such as potato or grape vine. It is useful in producing seedless fruits of cucumber, melon and pumpkin or aubergines, where the seed is wholly formed of the embryo, but it is not the commercial product. CPGE would not be used when the seed formed wholly of the embryo and that seed is the commercial product, such as chickpea, groundnut, and soybean.

GURTs containing crops are not designed for the marginal and poor farmers in the developing countries who use their own or a local seed. GURTs are meant for farmers who are technologically savvy and can afford to buy hybrid GURTs-incorporated transgenic seed each season, to prevent gene flow from GE crops. For decades, farmers who have been using branded designer seed, GE or not, are fully aware that they cannot recycle the seed as the benefits of the technology rapidly dwindle with each generation.

On the other hand, the seed companies know that it is not ethical and/or economical to jeopardize the interests of the small farmer who may recycle the seed season after season and the revenue loss to the companies from such ill advised use of seed is inconsequential.

In 2006, Australia, Canada and New Zealand backed a proposal to end the moratorium on CPGE, but this was rejected by the CBD. In December 2013, the Brazilian Congress was set to permit the use of GURTs for the controlled propagation of certain GE plants used for medicines and eucalyptus trees which feed paper mills, but activists pressurized again to get the Bill withdrawn from the agenda of the Congress in January 2014. The issue of GURTs in agriculture will come up for discussion at the next meeting of the CBD in October 2014 in Korea. Right now there is no GE crop that contains GURTs anywhere in the world.

8.5. Mandatory Labeling of GE Crops and Products

Mandatory labeling of GE crops and products has been a long standing and persistent demand of the activists. This highly contentious issue has been under serious discussion in several fora for a long time and several suggestions were made but none accepted.

Labeling is a consumer interest issue and currently most edible products are labeled as per their ingredients so that a consumer avoids what one does not want, for health or religious or ethical concerns. In practice, a product is rarely chosen entirely basing on the information provided on the labels.

Organic products are labeled as '*Organic*' for 'value addition' and 'assurance of safety' or even just to justify the higher cost. However, the implication of safety here is misleading as discussed in 8.7 on Organic farming *vs* GE crops, in this Chapter. Labeling a product as '*Contains GEO*' or '*Contains no GEO*' is fine if it is only a matter of information respecting the right of people to know what they are going to consume, but such labeling sounds as a warning signal and conveys a wrong impression that GE crops and their products are dangerous. Besides, labeling is quite impractical in the case of most crops and crop products, particularly in the developing countries. Even for organic foods often only the racks, shelves or packets are labeled. Such packages, once removed from the display, are often disconnected from the process of the product.

Currently, there are no mandatory regulations of labeling GE crops and products, though the EU block insists upon it. It is the long-standing policy of the USFDA that special labeling of a food is '*required if the absence of the information provided poses a special health or environmental risk*'. The USFDA does not require labeling of '*a food based on the specific genetic modification procedure used in the development of its input crops*'.

The American Medical Association stated that they saw no health purpose for labeling genetically modified foods as such (AMA, 2012).

The American Association for Advancement of Science (AAAS) has observed that '*There are several current efforts to require labeling of foods containing products derived from genetically modified crop plants. These efforts are not driven by evidence that GM foods are actually dangerous. These initiatives are driven by a variety of factors, ranging from the persistent perception that such foods are somehow "unnatural" and potentially dangerous, to the desire to gain competitive advantage by legislating attachment of a label meant to alarm. Another misconception used as a rationale for labeling is that GM crops are untested. Legally mandating such a label can only serve to mislead and falsely alarm consumers*' (AAAS, 2012).

In his *Bt* brinjal moratorium document, the MoEF was concerned about the need for labelling GE crops and products but recognized that it is fraught with problems (Kameswara Rao, 2010a). In countries with largely illiterate population and consumer indifference to labels (hardly anyone reads them), labeling GE crops and products is a waste of time and effort and results in only higher costs to the consumers.

The *Codex Alimentarius* Commission which has been seriously concerned about the issue of labeling of GE crops and products has not yet taken any official position in favour of labeling.

In November 2013, the '*Mandatory labeling of genetically engineered food initiative*' was rejected by 53.7 per cent in California and by 55 per cent in Washington State, in the USA (James, 2013). The remaining States have yet to vote and some of them are likely to support mandatory labeling, leading to a patchy policy situation, which would disrupt the supply chain of growers, markets and consumers in the US. In order to avoid such a problematic situation, the Coalition for Safe Affordable Food requested the USFDA for a Federal labeling solution for the whole of the US, overseen by the USFDA (Steever, 2014). Other countries would do well to put in place a uniform labeling policy, only when it becomes unavoidable.

8.6. Distance of Separation and Level of Detection of Transgenic Proteins

One common misconception is that there is rampant gene flow among all crops and so GE, conventional and organic crops cannot co-exist without 'contamination', the scare word of the activists. This led to two contentious issues, both causing enormous practical difficulties in the development of GE crops:

(a) One is the insistence of a physical Distance of Separation (DoS) between GE and non-GE crops, more particularly during field trials. If at all a DoS is necessary to assuage the fears of the organic and other farmers, it should be reasonable, practicable, crop based, and not a blanket regulation. In India the limit of DoS has gone too far with the Supreme Court stipulating a 200 meter separation during field trials for all crops and this is highly unreasonable.

(b) Second is the Level of Detection (LoD) of a transgenic protein in a crop sample to determine the level of GE component. The EU permits 0.9 per cent GE component while the other countries permit 1 to 5 per cent level of GE component in a non-GE or organic crop produce and in China there is no such restriction. The Indian Supreme Court stipulated a 0.01 per cent as the maximum level of transgenic protein for all crops. Besides being entirely unnecessary, this stipulation has practical difficulties since the protocols to detect at 0.01 per cent level exist in only sophisticated laboratories and there are no field detection kits. Besides, such a high level of detection is unnecessary in certain cases, as for example animal feed and non-food crops.

The Supreme Court directive on both these issues is a reflection of the failure of the Indian scientists and administrators in impressing upon the Supreme Court on reasonable DoS and LoD.

8.7. Organic Farming *vs* GE Crops

Right from the beginning of commercialization of GE crops, the Organic Lobby has been the most important, vehement and persistent of opponents of GE crops the world over. The opposition stems from several misconceptions, the more important being that gene flow through wind or vector borne pollen from a GE crop would 'contaminate' the neighbouring organic crop. The latest of such onslaughts is the charge that a GE crop affected organic certification of neighbouring Canola crop, which is now in the Supreme Court of Western Australia where an organic farmer is seeking financial damages from a GE Canola farmer (Beetles, 2014).

A number of international bodies accept that co-existence of GE, conventional and organic crops is possible and does not pose any serious risks of intermix. For example, a report of the European Commission (EC) concluded that *'conventional (non-GM) seed production in Europe with adventitious GM presence not exceeding 0.5%'* (against an acceptable threshold of 0.9 per cent) *'is feasible with few (maize) or no changes (sugar-beet and cotton) of current seed production practices'* (EC Report, 2006). Some Indian farmers have been cultivating *Bt* cotton organically with great satisfaction (Farmers's Forum, September 2010). Dawson (2014) stated that GEO and non-GEO farmers have a long successful history of co-existence, adopting many kinds of different cropping systems.

Organic farming, which is a cultivation practice and not a technology by itself, prohibits use of synthetic chemical pesticides and fertilizers, but extensively uses biopesticides (including several *Bt* formulations) and biofertilizers, which are chosen for the benefits from the natural chemical compounds contained in them and hence the claim of the organic lobby that their produce is pesticide free, is not true.

Nutrient content of crop produce depends upon crop health which is intricately linked to soil fertility, irrigation, control of pests and diseases and not essentially on the cultivation practice. Organic crops also deplete organic and mineral content of the soils and fertilizers have to be applied to maintain adequate levels of nutrients in the crop produce.

Proponents of the highly romanticized organic foods claim that they are a) more nutritious, b) safer because no pesticides are used on them, c) safer as no hormones, antibiotics or biotechnology are used in their production, d) 'more natural' because they are not irradiated, e) better for the environment, f) organic farming ensures food security and g) organic agriculture will save the family farm. Avery (2006) was emphatic that none of these projected benefits are real.

The nutritional superiority, safety and yields of organic foods have been questioned. Some important precautionary facts about organic foods are:

(a) A survey of 50 years of literature on the nutritional content of organic farm produce from January 1, 1958 to February 29, 2008, supported by the UK Food Standards Agency, showed that organic foods are no more nutritious than conventional foods (Dangour *et al.,* 2009);
(b) In the spring of 2011 occurred the *E. coli* O401 disaster in Europe, the source identified as organic sprouts (Miller, 2011). More than 40 people died and thousands were stricken, as a result of the contaminated foods, which were not being subject to regulatory safety checks, as organic foods are often exempt from farm-to-fork policies of Europe. Frequent recalls of organic foods in North America and Europe on outbreaks of infections traced to specific organic foods and farms that produced them, show that organic foods are not necessarily safer than conventional foods;
(c) Organic agriculture cannot feed the world (Connor, 2008), as organic yields are 15 to 34 per cent lower than conventional crop yields (Seufert *et al.*, Nature, 2012); and
(d) Organic foods are far more expensive than conventional foods, usually costing more than 50 per cent above the cost of conventional foods.

Lower yields from organic farming mean more land to obtain the same quantity of crop produce. Norman Borlaug wrote in comment on Avery's book (2006, back cover) that '*organic foods offer no real health or safety benefits. Organic farming's low yields and reliance on scarce organic fertilizers represents a potential threat to the world's forests, wetlands and grasslands*'.

There are two benefits that are likely to accrue from organic farming but both are conditional and not exclusive. One is that organic foods are free of synthetic chemical pesticide residues, provided all regulations governing pesticide application and organic cultivation are followed honestly. As per the US regulations on organic produce, *only the produce itself needs to be pesticide-free*, which means that before the harvest, the plants can be fumigated and treated with chemicals. Some years ago, complaints were made to the USDA on such practices on organic strawberries that contained chemical residues.

The second benefit relates to biodiversity enrichment. Tuck *et al.* (2014) reviewed 94 studies published in the last 30 years in Northern and Western Europe and North America with good data on species richness and found that organic farms harbored on an average of 30 per cent more species of birds, insects, and plants than conventional ones, with no sign of diminishing over time. Three fourths of the publications reviewed were heavily biased towards Europe and North America, and the organic farms in the tropics are almost entirely outside this review. Tuck *et al.* (2014) observed that the developed countries have had a strong tradition of intensive farming for centuries where the agricultural biodiversity evolved along with agricultural practices till the end of the World War II. Such a strong tradition was absent in the developing countries and so the positive effects organic farming on biodiversity in developing countries compared with conventional farming, may not be of the same magnitude as in the developed countries. Additionally, there is the influence of several factors such as the size of the farm, the crop and the species that constitute agricultural biodiversity on a given farm.

Biodiversity promontory effects, similar to those reported by Tuck *et al.* (2014), were found also on *Bt* cotton fields. In a study at 36 locations in 6 provinces in northern China with 10 to 20 field trials per location, a steady increase of various insects (including lady-birds and lacewings) and spiders in the *Bt* cotton fields was evident (Lu *et al.*, 2012). As these useful insects are the natural enemies of various cotton pests, this allows a better control of other pests not sensitive to *Bt* proteins.

Synthetic chemical pesticides are not target specific and every species on the farm is affected to some degree or the other, directly or indirectly. Lu *et al.* (2012) attributed the biodiversity promotory effects to the reduced use of broad-spectrum insecticides. Far lesser quantities of synthetic pesticides than before are now applied to *Bt* cotton fields. The common but not yet quantified experience indicates that a lot of biodiversity has reappeared on *Bt* cotton fields in India too.

There have been efforts to broaden the approach and reach of organic farming practices, and to make it more scientific than now. Two of these are more widely experimented as an extension of organic farming practices:

(a) *Integrated Pest Management (IPM)*: A package of diverse practices, both conventional and modern, to control the large number of pests and diseases of crops. IPM does not exclude crop GE or the judicious use of chemical inputs. It includes the use of biopesticides and cultivation practices that discourage pests and diseases. While transgenic technology focuses on one or two most important of pests or diseases of each crop, IPM seeks to address several of them simultaneously; and

(b) *Agroecology*: The application of ecological principles in the management of agricultural ecosystems for the production of food, fuel, fiber, and pharmaceuticals. The term Agroecology encompasses a broad range of approaches, and there is no unanimity in principles and practices even among its advocates. Both agroecology and organic farming are packages of agricultural practices and not technologies *per se*, promoted more from an emotional platform rather than on a solid science base.

Both IPM and agroecology, like organic farming, are the current favorite choices of the opponents of GE technology. In order to benefit from either of these practices, the farmers need expert guidance in their implementation.

Those who blindly believe in the projected benefits of organic foods and can afford them can certainly go for them. The claim that organic farming ensures present or future food security is entirely fallacious, and insisting that the whole world should go organic is absurd. Organic farming takes India to pre-Green Revolution times and if the whole of India goes organic it can feed only about a half of the present population. Organic farming cannot cater to the needs of increasing consumption and fast growing population anywhere in the world.

8.8. Impact of Differences in GE Crop Policy between Countries and States

Many conflicts arise from differing policies on GE crops within and between blocks of countries, independent countries or States within a country, which affect the developing countries more than the others. Some examples are:

(a) The opposition of the EU block of countries affects the development and deployment of GE crops in other countries. The threat of EU stopping import of crop produce, particularly from the developing countries, if they promote biotech crops, is an economic black mail which has been quite effective, particularly in the context of organic food exports (see 8.7 on Organic farming *vs* GE crops in this Chapter). The trade restrictions imposed by the EU on GE crop imports from US, Canada and Argentina, the leaders in commercialization of GE crops, have attracted censure under the WTO's regulations and the EU lost its case. The developing countries are not in a position to take issues to international arbitrators.

The burden some EU reporting procedures for farmers discourage a more rapid deployment of GE crops in Romania, Portugal, Czechia and Slovakia (James, 2013). EU's unrealistically stringent regulatory policies and its support to anti-tech activism, deter a wider adaptation of GE crops globally, as contextually discussed in the other sections of this chapter.

Despite well publicized opposition of the EU countries to GE technology, there has been extensive research on development and field trials of a large number of GE crops in the EU. The EU website shows that there are nearly

400 different GE crop Events in development in Europe, Spain leading the way developing about half of them. Kameswara Rao (2010a) discussed the details of crops in development in the EU countries and James (2013) has some updates. James (2013) reported that the hectarage under GE crops in the EU was up 15 per cent between 2012 and 2013. Five EU countries planted 148,013 hectares of biotech maize. Spain led the EU with a record 136,962 hectares of biotech maize, up 18 percent since 2012.

In 2010, the EU has approved cultivation of a GE potato (Amflora potato, containing over 90 per cent of amylopectin, for use as feed and in the industry). TC1504, a DuPont Pioneer's herbicide and pest tolerant gene stacked corn is only a step away from final approval for cultivation in the EU (The Wall Street Journal, February 11, 2014). Several GE crop products are imported into the EU. Once the EU approves an Event for import or cultivation, it is legal in all the EU countries, though different countries and countries may have anti-tech laws. Jonathan Harrington obtained the seed of MON 810 GE corn (approved by the EU for cultivation as a feed crop) from Spain and grew it in Wales where its cultivation was banned, but the administration of Wales failed to prosecute him (Kameswara Rao, 2010a).

The EU had spent Euro 300 million (Euro 200 million in the past decade), on GE crop research (European Union, 2010). EuropaBio (2012) estimated that regulatory delays in the past decade in adoption of GE crops have caused a cumulative loss of 44.6 years of time for the EU countries.

One does not understand the multifaceted policy of the EU on GE crops, 'pinching the baby and rocking the cradle' at the same time, apart from its helplessness in the face of opposing political pressures. Is EU's opposition to technology a strategy to prepare overseas markets for EU technology exports? EU's hypocrisy has embarrassed many European scientists and Heap recently made an appeal to the EU for a rethink of its policy (Heap, 2013).

The irony is that the European scientists have done extensive basic research and developed a large number of patented experimental protocols that paved way for crop GE technology. Subsequently EU policies have discouraged research and retarded deployment of GE crops both within and outside the block and even led to migration of EU GE researchers and companies to other countries.

Though there are some signs of softening of anti-GE policy, the EU block is still a real hurdle in the path of GE crops making a yet larger global presence.

(b) A few years ago the anti-GE lobby particularly from Europe forced Zambia, which was reeling under extreme famine conditions, to reject US food aid shipments on account of GE component (even at below an accepted threshold), preferring starvation deaths to GE crop consumption.

(c) Recently Bangladesh has started cultivation of *Bt* brinjal, while in India *Bt* brinjal is still languishing behind a moratorium since February 2010. Ironically, Bangladesh's *Bt* brinjal was processed largely basing on the Indian regulatory dossier. The Indian activists have gone to the absurd extent of asking the Government of India to use diplomatic channels to prevent Bangladesh from cultivating *Bt* brinjal, as they fear that *Bt* brinjal seed would be smuggled into the neighbouring State of West Bengal in India. The impact of this event is discussed in 8.9d of this Chapter.

(d) In India, the State of Kerala which is predominantly Leftist in political philosophy projects crop GE as an American technology that benefits only the American MNCs. The State is totally against GE crops, and GE technology is not on the agenda of modernizing agriculture, which Kerala needs much more direly than many other Indian States. Kerala imports most of agricultural produce it needs from the neighbouring States. Problems would arise when Kerala State moves to ban imports from the other States or worse if it insists that the other States too to go GE crop free. Kerala's anti-GE activists have been quite active in the other parts of India.

All political parties, except the Indian National Congress, have a stated anti-GE policy, not on the basis of informed decision but political expediency. What happens in different States depends upon the party/parties that run the Government of the day. The coalition Government at the Centre dithered for years, but woke up to some realities in recent times, as reflected in revalidation of permits granted earlier, for field trials of some GE crops with effect from March 2014.

8.9. Illegal Cultivation of GE Crops

Farmers will cultivate the crops they consider best for them. Most of the time farmers are not aware of any governmental restrictions on any crop and the rest of the time they do not care even if there are any, if they prefer a particular crop variety. Illegal cultivation of GE crops happens when farmers want to derive the benefits of technology, but were denied by the State and/or Central administration.

For about two years prior to the approval of *Bt* cotton for commercialization in India in 2002, there was a considerably extensive illegal cultivation of *Bt* cotton in Gujarat State, which was well documented (Scoones, 2005; Herring, 2007). The Government of India was set to destroy the illegal crop in 2001-02, but dropped the move when farmers and their organizations have opposed the move. Though this illegal hybrid was not in the regulatory pipe line, an earlier approval of Bollgard I *Bt* cotton by the Government would have discouraged this.

For two or three years now, there is a talk of illegal cultivation in some parts of India of, a) GE cotton with stacked genes for pest and herbicide tolerance in Gujarat, and b) the ring spot virus tolerant papaya in most parts of India; which is legal only in US, China and Japan. It is also believed that there is illegal *Bt* brinjal in some pockets in the country. While these reports were never officially confirmed, the threat of cultivation of illegal GE crops is real, on account of regulatory delays.

Vehement activism and political apathy have brought in a stalemate frustrating GE crop development and deployment in many countries, including India. Now the situation in India is that one can commercialize a GE crop without the regulatory process, so long as it is not promoted as GE.

Conflict in the policy of neighbouring countries and/or States may also promote illegal cultivation of GE crops. The following issues are pointers to such a possibility:

(a) In December 2006, we found that the farmers from in the Warangal District of Andhra Pradesh bought seed of some *Bt* cotton varieties from Nanded in Maharashtra and cultivated them a few years before they were approved for cultivation in Andhra Pradesh. The same story repeated when approval of Bollgard II was delayed in Andhra Pradesh.

(b) Bangladesh has recently permitted cultivation of *Bt* brinjal, as discussed in 8.8c of this Chapter. The activists are afraid that there would be smuggling of *Bt* brinjal seed from Bangladesh for cultivation in the neighbouring West Bengal in India. If this happens, farmers from Bihar and Orissa too will get *Bt* brinjal seed from West Bengal (or even from Bangladesh) and cultivate, as these three States suffer most extensive losses from brinjal stem and fruit borer (Kumar *et al.*, 2010); and

(c) The possibility of cultivation of illegal GE crops looms large in the Left dominated State of Kerala which has an official policy of 'no GMOs' (discussed in 8.8d of this Chapter). If the farmers find that they will benefit from GE crops that are legal in the neigbouring Tamil Nadu, they certainly will cultivate them illegally.

Scientists and product developers do not support illegal commercialization or cultivation of GE crops. The respective governments should recognize the safety and benefits of GE crops and the aspirations of the farmers, and facilitate legal cultivation after the mandatory regulatory oversight and not play politics of expediency and force the farmers to go into illegal activities. The scientist behind illegal *Bt* cotton in Gujarat was hailed as '*Bt* cotton Robin Hood' and there should be no opportunities for other Robin Hoods to emerge.

8.10. Costs of Regulatory Delays

The high time and financial costs of the current regulatory delays in the majority of countries have raised serious concerns (discussed in 2.3 of this Chapter). There are no issues of safety involved here, as the products in question have all been found as safe as their conventional counterparts. For example, Bangladesh is commercializing *Bt* brinjal while the same crop is languishing under a moratorium in India for four years. The unexplained delay in commercializing Golden Rice in India and the restrictions on open field trials, have imposed heavy time and financial costs. There are no appropriate estimates of these costs for many products in the developing countries. However, time and financial cost estimates have been made in a few cases, as below:

(a) EuropaBio (2012) has estimated that, i) The EC has caused about 50 years of undue delays in the EU to date, by breaking administrative timelines fixed in EU law regarding GE Authorizations; ii) € 9.6 billion of unnecessary costs to the EU economy is what a report published by the EC estimated when examining the impact of trade-related incidents with shipments sent back to the countries of origin, as a consequence of the slow pace of the GE authorization process in the EU, combined with a zero tolerance policy; and iii) € 443 million of lost income to EU farmers per year have been estimated to result from their lack of access to GE technology, as a minimum, the maximum estimate being € 929 million per year; and

(b) The Golden Rice technology is available since early 2000, and it comes without technology cost burden to the developing countries, but has not been introduced in any country because of governmental apathy in the face of anti-tech activism. The 'Real Option' model applied to the case of India shows that the annual perceived costs have to be at least US$199 million per year (US$ 2 billion for ten years). The delay in approval of the technology is an indicator of the economic power of the opposition towards Golden Rice resulting in about 1.4 million life years lost over the past decade in India (Wessler and Zilberman, 2014).

9. MANAGEMENT ISSUES

Crop husbandry, the careful management of the establishment, growth and harvesting of crops, whether conventional or modern, requires constant vigilance, course correction, monitoring the quality of inputs, crop specific cultivation practices, and farmer compliance of precautions and advice that goes with any technology. Managing these diverse issues is the responsibility of Agricultural Extension Services of the government's administrative and research departments, agricultural Universities, product developers and distributors. Failure at any one of these steps will affect the quality of the crop product and yield. In the developing countries most farmers are illiterate and hence there must be an official mechanism to ensure the quality of inputs such as the seed, fertilizers, pesticides, and appropriate irrigation. There may have been some window dressing action, but in practice there are no strictly adhered overall management practices. Management failures of the governments, extension services and the input suppliers are projected as the failures of technology, particularly in the context of GE crops. Some of the important policy and management issues, taken advantage by the activists, are discussed here.

9.1. Refugium

It is no one's contention that pests do not acquire resistance to the products of *Bt* genes that impart pest tolerance in GE crops. Experience has shown that the genes that impart resistance in pests are recessive, which is an advantage. In order to minimize the chances of development of resistance by the pests, it is strongly recommended that there should be about five rows of non-*Bt* plants (five to 10 per cent of the population in the crop field) around *Bt* crop fields, as a '*refugium*' (or '*refuge*').

The concept of refugium is not new. It was used when new synthetic chemical pesticides were introduced, in field trials to control spray drift and in regular cultivation to slow down development of pest resistance. When the majority of farmers was spraying synthetic chemical pesticides, the refugium was forgotten with time. In fact, the organic farmers too should plant a refugium, as there are chances of pest resistance to biopesticides, more importantly for *Bt* formulations that they use.

Bt cotton was shown to suppress cotton bollworm even in the neighboring non-*Bt* cotton fields in China (Wu *et al.*, 2008). Tabashnik *et al.* (2013) analyzed results of 77 studies from five continents reporting field monitoring data for pest resistance to *Bt* proteins in GE crops, from eight countries over two decades. Although most pest populations remained susceptible, reduced efficacy of *Bt* crops caused by field-evolved resistance was reported for some populations of 5 of 13 major pest species examined. In India, the pink bollworm (*Pectinophora gossypiella*) showed some resistance to *cry1Ac* protein but not the targeted pest, the American bollworm (*Helicoverpa armigera*). No pest resistance was reported from Bollgard II populations (*Bt* cotton with two stacked genes, *cry1Ac* and *cry2Ab*). Field outcomes showed that factors delaying development of resistance include, a) recessive inheritance of resistance, b) low initial frequency of resistance alleles, c) abundant refugia of non-*Bt* host plants and d) two stacked *Bt* genes. The analysis by Tabashnik *et al.* (2013) reemphasizes the benefits of refugia and the enhanced protection from stacked genes.

Planting a refugium is an essential precaution, which is largely ignored by *Bt* cotton farmers in India, as they do not want to lose that much of yield and there was no vigilance to ensure refugium. This is not good in the long run. Even without concrete data, the activists allege higher incidence of pest resistance in *Bt* cotton fields and project *Bt* technology, not the absence of management, as a failure.

The non-*Bt* seed for refugium is supplied in separate packets within the *Bt* seed containers and the farmers just do not use the former. It was suggested that the non-*Bt* seed be mixed with the *Bt* seed or plant an alternate crop as the refugium, since the cotton bollworm has several non-cotton hosts (polyphagous). Some believe that the standard patterns of sowing the refugium are better than the mixed bag.

The industry too did not like the suggestion and no efforts were made by the managers to follow this up (Kameswara Rao, 2010a).

9.2. Quality of Seed

There have been several controversies in India on the quality of *Bt* cotton seed sold to the farmers. In the long chain between the seed developer to the farmer, unscrupulous elements played mischievous roles that cheated the farmers and affected crop performance and yield. More the demand for Bollgard I or Bollgard II seed, greater were the problems. Black marketing, seed of earlier years with a poor percentage of germination, adulterated seed and spurious seed dominated some markets seriously affecting the farmers and the resultant crop failures were projected as the failure of technology. There are genetic and seed testing laboratories in different states. However mandatory seed testing and certification procedures to safeguard the farmers, should be established.

9.3. Cultivating Crops Under Unsuitable Conditions

Some years ago, the Department of Agriculture of Andhra Pradesh issued a missive asking its officers to discourage growing cotton in red soils under rain fed conditions, and this was largely ignored. *Bt* cotton with a much larger biomass requires even more water than non-*Bt* cotton. In the absence of adequate irrigation facilities, failure of monsoon caused crop losses, which were projected as a failure of technology, without taking into account similar losses in non-*Bt* cotton fields. Cultivation of cotton in regions less suitable to cotton may have been responsible for some farmer suicides attributed to failure of cotton crop (Bury, 2013). Cultivation of crops under unsuitable conditions is a serious negative factor and should be discouraged.

9.4. Public-Private Partnership

Public-private partnerships (PPP) involve '*a contract between a public sector authority and a private party, in which the private party provides a public service or project and assumes substantial financial, technical and operational risk in the project*' (NCPPP, 2010). PPPs should combine the efficiency of private firms with public faith in a public sector institution. The advantages expected from such a collaboration are, a) reduction of public capital investment, b) improvement of efficiency due to strong profit incentive, c) private entity is more accountable than government institutions, d) expedition of project completion by grouping multiple responsibilities into a single contract, e) availability of specialized and wide range of expertise, f) relief to the government from staffing issues, g) sharing of risk/ responsibility and h) Government's option to step in when private entities are misbehaving.

Many believe that PPPs will immensely help modern agriculture in the developing countries. The basic idea is equal partnerships between the public and private sector research organizations. A number of strategies are often proposed but rarely executed (Edmeades, 2012).

The private sector has been playing a very crucial role in agriculture, more particularly in GE crop technology, throughout the world, including the developing countries. *Bt* cotton and *Bt* brinjal in India are the contribution of the private sector. If *Bt* cotton were not introduced a decade ago by the private sector, India would not have had even a single commercialized agribiotech crop even today.

Genuity Smart Stax corn, which contains eight transgenes, six for above and below ground pest tolerance and two for herbicide tolerance, is an impressive example of private-private partnership (Kameswara Rao, 2009a). This amazing product is the result of collaboration between Monsanto and Dow Chemical companies, contributing four transgenes each.

While PPPs are fewer and far in between in the developing countries, there are some examples:

(a) The Cornell University and United States Agency for International Development (USAID) have facilitated cost free transfer of technology to the Indian public sector institutions to develop *Bt* brinjal varieties, which are now locked up in a moratorium along with *Bt* brinjal hybrids of the private sector, since February 2010. The moratorium is wholly based on political considerations and not for any proven biosafety risks (see 7.3 in this chapter). The *Bt* technology involving the use of the *Cry 1Ac* gene, the same as used in *Bt* cotton, originated from Monsanto. Philippines and Bangladesh are also parties to a similar facilitation by the Cornell University and USAID. While in Bangladesh saplings of *Bt* brinjal were distributed on January 22, 2014 to the farmers for commercial cultivation, it is caught up in activist initiated litigation in the Philippines. Significantly, both Philippines and Bangladesh have used the Indian dossier of biosafety of *Bt* brinjal, along with their own tests.

(b) The Golden Rice Humanitarian Board facilitates cost free technology transfer to the public sector institutions in India, Bangladesh and Philippines, to breed local varieties of Golden Rice for commercial cultivation. Golden Rice, which provides adequate quantities of β-carotene that is converted into vitamin A in our body, is basically a Syngenta product. In a decade there has been no visible progress due to inept handling by the governments and public sector establishments, both reeling under activist pressure (Kameswara Rao, 2010a). Potrykus (2010) and Dubock (2013) attribute this delay exclusively to the regulatory regime in different receiving countries, based on an extreme interpretation of the Precautionary Principle (discussed in 8.2 in this Chapter), without any scientific justification.

(c) The high phytase maize developed by the Chinese Academy of Agricultural Sciences and *Bt* rice developed by the Huazhong Agricultural University were licensed to Origin Agritech Limited (Chandrasekhara Rao, Chapter 1 in this volume), in an effort to utilize the services of the private sector to promote public sector products.

(d) The '*Droughtgard*' maize hybrids of Monsanto (Event MON87460) are drought tolerant transgenics approved for sale for food and feed in the US and European countries, and are being processed for release in South Africa, Kenya and Uganda (Edmeades, 2012). The International Maize and Wheat Improvement Centre (CIMMYT) in Mexico is promoting PPPs to develop drought tolerant varieties of maize for the African countries (Drought Tolerant Maize for Africa, DTMA and Water Efficient Maize for Africa, WEMA) through the mediation of the African Agricultural Technology Foundation which will ensure regulatory compliance of Droughtgard Event incorporated in to the local varieties suitable to the target countries. The Droughtgard technology is royalty free to five African countries (Edmeades, 2012). Similarly, the Gates Foundation supports Improved Maize for African Soils (IMAS) using royalty free transgenic Event from the Pioneer Hi-Bred to develop locally suitable varieties for increased nitrogen efficiency.

The private sector, particularly the MNCs, has the state of-the-art technological infrastructure, a very competent scientific force, financial strength, sense of time and a determination to produce. Besides, the private sector has a fiscal responsibility. On the other hand, the public sector largely lacks in most of these important prerequisites for a successful PPP. In spite of over a decade's effort and enormous expense, the public sector has not produced even a single marketed GE product in the developing countries.

Cost free technology received through benevolent organizations does not constitute PPP. For PPPs to be productive and benefit the private sector component as well and just not draw from it, a lot of committed effort is needed on the part of the governments, managers of agriculture and the public sector scientific institutions (Kameswara Rao, 2013a; Kameswara Rao and Seetharam, 2013). The current political climate and attitudes in India and other developing countries are not conducive to successful PPP. If the past experience is an indicator, there is hardly any scope for benefits from PPP in the near future. Public sector partnerships with the private sector are very much needed in developing countries, to promote adoption of new tools, technologies and opening business opportunities without much loss of time.

9.5. Revamping Education and Training in Modern Biotechnology

In India, biotechnology education was hyped up to self-destructive levels. Parents and students drew an unrealistic comparison with information technology (IT) and aspired for jobs and salaries on par with IT, resulting in an unprecedented rush to biotechnology courses at the expense of basic sciences. A very large number of institutions saw an opportunity to make quick money and fanned the dream. The job opportunities in biotechnology and more particularly in agricultural biotechnology are limited and demand expertise in diverse areas, which the current education system largely failed to provide. Kameswara Rao and Seetharam (2013) discussed the status of biotechnology education and training in India and observed that there is a crisis in the management of education and training in modern biotechnology (MBT), seriously affecting the country's efforts in terms of developing man power, because of a wide gap between the competence of the academia and the needs of the industry. This also affected the future of thousands of youngsters merely stamped for biotechnology with no matching skills to handle the jobs they aspire. As a consequence of such lopsided educational management, India is a decade behind the rest of the world in deriving benefits from the technology, endangering the country's future growth in terms of manpower generation, industrial development and services. Kameswara Rao and Seetharam (2013) made several recommendations to remedy the situation and to provide for a more purposeful education and training in MBT, among which the following require an urgent attention:

(a) All undergraduate (UG) programmes in biotechnology and bioinformatics should be discontinued with immediate effect, encouraging UG courses with a combination of i) botany or zoology, ii) microbiology, iii) chemistry and iv) computer applications;
(b) Postgraduate (PG) courses in botany, zoology, microbiology, genetics and biochemistry should be updated to provide a more holistic and competitive biology education;
(c) The intake of the PG courses should be drastically reduced to maintain standards; and
(d) Well structured and organized post-degree training programmes run by national research institutions will bridge the academia-industry divide.

Traditionally, the A, B and C of agriculture were agronomy, botany and chemistry. The basic botany courses also used to contain a considerable component of agricultural botany. Unfortunately, over time, most of botany and chemistry went out of courses in agriculture, which now largely focus on agronomy and the traditional botany courses left out agricultural botany. There are departments of basic sciences in the agricultural institutions, but these receive only a step motherly attention from the administrators. The consequence is that most agricultural scientists are unfamiliar with such important aspects as plant and crop reproductive biology, which is basic to answering the activist objections to GE crops such as gene flow and impact on biodiversity. It would go a long way if the traditional universities introduce a postgraduate course in agricultural botany and biotechnology, in collaboration with agricultural universities and if agricultural universities pay more attention to agricultural botany.

9.6. Public Awareness

The public is not averse to technology but robust public education programmes are essential to convince the public on the benefits and safety of technology and to counter vehement anti-tech campaigns. It is difficult to define the term 'public', because everyone is a part of the public in one context or the other. Different programmes have to be designed to address groups of farmers, consumers, politicians, judiciary, media, students and even regulators and some scientists.

The scientists, product developers and governments, have all neglected the very important aspect of educating the public on the benefits of GE crops in most parts of the world and this has led to the success of anti-tech activism (Kameswara Rao, 2013a). It is not in the public knowledge that a) GE crops and foods undergo rigorous testing for efficacy and safety as per mandatory regulations, b) conventional crops and foods do not undergo any safety evaluation, c) GE crops offer a wide range of well demonstrated socio-economic benefits to the farmers and consumers, and d) the activists mix up issues to project management problems as the short comings of technology. Activists took advantage of this overall ignorance to hijack public sentiment with the acquiescence of the media. Public education programmes are the immediate need and all those concerned should be alive to it.

The media are the key to the success of public education programmes. The media and most of the politicians who influence decision making, are as ignorant as the man on the street on technology issues and do not verify the veracity of what is being fed to them by the activists. What is now projected as public opinion is only the publicized opinion of the activists, chronicling misery divorced from facts.

10. SOCIO-ECONOMIC IMPACT OF GE CROPS

The product developers ensure the stability and efficacy of the new genes in a transgenic crop, as well as its agronomic performance, while the regulatory regime ensures biosafety and environmental safety, before commercializing a GE crop. Along with this evidence that is needed to build up stakeholder confidence, data on the socio-economic impact of the new crop are also needed to be assured of a positive risk-benefit ratio. While most of the socio-economic impact of GE crops is beneficial, activists raise some issues projecting the technology in bad light.

10.1. Socio-economic Benefits from GE Crops

The socio-economic benefits of the GE crops in cultivation in different countries and that of *Bt* cotton in India are now well established beyond any reasonable doubt. There is extensive information on the socio-economic benefits of GE crops (Brookes and Barfoot, 2012; James, 2013) and the Indian *Bt* cotton gathered from real time performance of over 10 years of cultivation (James, 2013; Mayee and Choudhary, 2013; Chandrasekhara Rao, Chapter 1 in this volume).

In the case of GE crops which have not yet gone into commercialization, the assessments of socio-economic impact are forecasts based on field trial data (*Ex-Ante* analysis), rather than on actual results of large scale cultivation. Several *ex-ante* analyses of *Bt* brinjal have appeared (Kolady and Lesser, 2005, 2006, 2008; Krishna and Qaim, 2007), but were not taken seriously by the activists and the MoEF at the time imposing moratorium on *Bt* brinjal. There is a comprehensive *ex-ante* analysis of the economic benefits of *Bt* brinjal in India by Kumar *et al*. (2010) which concluded that, a) the adaption of *Bt* brinjal significantly reduces insecticide application and losses from the brinjal shoot and fruit borer (SFB), enhancing the marketable yield by over 200 per cent with consumer benefits up to 60 per cent, b) the economic gain to the country would be between 30,000 and 1,19,000 tones, depending upon the level of adoption, with a financial benefit of Rs. 577 crore, 1,167 crore and 2,387 crore, at 15 per cent, 30 per cent and 60 per cent adoption levels, respectively, and c) West Bengal, Orissa and Bihar, which suffer the maximum damage from the SFB, would gain the most benefits. This study by a public sector institution, ICAR, supported by the Ministry of Environment and Forests, was ignored by the MoEF.

10.2. GE Crops and Food Security in India

The Rome Declaration on World Food Security at the World Food Summit described food security as existing *'when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life'* (FAO, 1996). In November 2009, the Summit recognized *'the fundamental right of everyone to be free from hunger'* (FAO, 2009). The parties to the Summit pledged their commitment to *'reduce the number of the world's one billion hungry and chronically under-nourished people by half, by no later than 2015'*. In this context,*'the need of the poor countries for development of economic and policy tools required to boost their agricultural production and productivity'* becomes paramount (FAO, 2009). In the absence of any tangible progress and the year 2015 being so close, nothing of this can be achieved.

In 2011, 165 million children under five were stunted and 33 per cent of the children in Southeast Asia were under weight (Hunger Report, 2013). Globally, 870 million people are still chronically undernourished today (von Grebmer *et al*., 2013). Four hundred million Indians now live on less than the government-defined poverty line of Rs. 32/day (US$ 0.60). Another 200 million are classified as above the poverty line, but cannot afford to buy adequate quantities of appropriate food on account of high inflation and runaway food prices.

The Indian National Food Security Act, 2013 (the Right to Food Act, that became a Law retroactively from July 5, 2013), aims to provide heavily subsidized food grains to approximately two thirds of India's 1.2 billion people. It is set to provide rice at Rs. 3, wheat at Rs. 2 and coarse grains at Re. 1, per kg and five kg/person/month. This involves enormous financial costs and the Government has allocated Rs. 88,500 crore for the food subsidy segment in the Vote on Account for 2014-15. It should be remembered that budget is not money. The implementation of the provisions of the Food Security Bill would also require production of over 65 million tones of food grains a year, in addition to meeting the current demand, increased demand on account of increased consumption and rapidly growing population (Kameswara Rao, 2013a). The current 80 million tones of surplus food grain stock would not go far. India, in the face of stagnant agricultural production and having failed to modernize its agriculture, has a very serious problem in enhancing food production to meet with the future needs. There is no way to achieve this under the conventional agricultural practices and much less, through the highly touted organic farming (discussed in 8.7 in this Chapter). New technologies are the only option.

Rosegrant *et al.* (2014) investigated the role of agricultural technologies in addressing hunger using a comprehensive process-based modeling. This *ex-ante* analysis involved evaluation of yield and food impact through 2050 of a broad range of agricultural technologies under varying assumptions of climate change for maize, rice and wheat. While there was no specific reference to GE crop technology, heat-tolerant varieties, no-till, nitrogen-use efficiency, and precision agriculture are identified as technological practices with particularly great potential for yield improvement in large parts of the world. The greatest yield benefits were to be found in Africa South of Sahara, South Asia, and areas of Latin America. When multiple technologies are combined, food prices can be reduced by almost 50 percent leading to 12 percent decrease in the number of malnourished children and 40 percent reduction in number of people at risk of hunger (Rosegrant *et al.*, 2014). Taking these technologies forward will require institutional, policy and investment advances in many areas.

The following are basic criteria in ensuring food security (Kameswara Rao, 2013a): a) *Availability* of sufficient quantities of food on a consistent basis; b) *Accessibility* to appropriate diverse foods for a nutritious diet within reach in sufficient quantities; c) *Affordability,* having sufficient resources to purchase what is accessible; and d) *Knowledge* of basic nutrition and care. All these criteria are beyond the reach of the poor in India and most developing countries.

In the context of ensuring food security three issues are of crucial importance: a) Production of food grains to the tune of several times the present production levels; b) Nutritional security should be addressed along with increasing food grain production, as *nutritional security is an essential component of food security*, and c) Affordability levels have to be enhanced since mere availability of nutritious food grains is not enough as large sections of the population are hungry because they cannot afford to buy the food that is now available. Subsidies are not the real answer, as most subsidies are politically motivated and with a highly porous distribution system hardly any benefits would reach the target population.

GE crops would certainly ensure food security in India (Kameswara Rao, 2013a), but the Indian Food Security Bill is only a half measure as it does not address protein (pulses), edible oil and other nutritional requirements. The issues related to nutritional security through GE crops are separately discussed by Basavaprabhu Patil and Kameswara Rao (Chapter 12 in this volume). The Indian Bill leaves out large sections of the population which cannot purchase food grains even at the subsidized rates.

James (2013) projected that GE crops helped alleviate poverty of more than 65 million people, who are some of the poorest in the world and that GE crops contribute to the alleviation of poverty and hunger. However, in terms of the magnitude of the problem this is a miniscule.

The activists have always contested the projection that GE crops ensure food security, as they rightly recognize that poverty is the major issue behind hunger, and not necessarily the availability of sufficient quantities of food grains, which are there right now, provided one can afford to buy them.

Yield is a quantitative trait and there are no genes yet for use in GE crops. Pests, diseases, drought and other stresses severely reduce crop yield and so are a threat to food security. The higher harvests from the current GE crops accrue from preventing loss due to pests, pathogens and drought and not from yield enhancing gene *per se*. We need more GE crops that stem yield losses from diverse sources.

A serious lapse in the current situation is that GE varieties of the two most important staples, rice and wheat, are yet to be commercialized. More importantly, the millets, pulses and oil seeds which are the crops that benefit the poor in the developing countries have not been addressed. Market forces are one cause for this neglect which should actually be remedied by the public sector institutions. Some efforts to develop improved varieties of the dry land crops are discussed by Chandrasekhara Rao (Chapter 12 in this volume). While GE technology takes care of pre-harvest crop losses, the enormous post-harvest losses on account of seed borne insects and fungi are totally ignored.

GE crops will certainly increase harvests, increase farm incomes, reduce poverty, but only to an extent. GE crops are the most important but not the only means of ensuring food security.

10.3. Presumed Negative Impact of GE Crops on Rural Livelihoods

GE crops have been shown to be scale neutral and have benefited farmers of all sizes of land holding in India, China, Argentina and Brazil (James, 2013). The developing countries need GE crops much more than ever to contribute to their food security, primarily by containing the huge pre-harvest losses from pests, diseases and weeds. Nevertheless, the activists project GE crop technology as a threat to rural livelihoods on account of far lesser number of pesticide sprayings and almost complete elimination of manual weeding. China, Brazil and Argentina also have similar concerns about the welfare of the agricultural labour, yet cultivate several pest and herbicide tolerant GE crops (James, 2013).

Manual pesticide spraying is usually wasteful and affects the health of the farm labour. Manual weeding is laborious, largely inefficient and expensive. There is actually an acute shortage of farm labour and not employment opportunities. This unorganized sector acutely suffers from the seasonal underpaid employment that leaves them without income for half of a year. Realizing this, a good proportion of farm labour often migrates to other States for better wages, or seeks better employment opportunities elsewhere, which also contribute to shortage of rural farm labour. Opposition to GE crops is only in the interests of big landlords who want to retain the low paid labour force as their permanent slaves, also the reason behind lukewarm efforts in improving rural education, as education may draw people away from seeking rural livelihoods.

10.4. Farmer Suicides are not Related to GE Crop Failure

The activists and the media widely publicized the charge that failure of *Bt* cotton is responsible for the suicide of thousands of Indian farmers, inflaming public sentiment. However, research reveals that there is no link between the suicides and the increasing degree of adoption of *Bt* cotton (Gruere *et al*., 2008; Sheridan, 2009; Gruere and Sengupta, 2011; Bury, 2013). On the contrary, in most areas where a lot of *Bt* cotton is cultivated the number of suicides appear to have decreased (Bury, 2013).

11. NEXT GENERATION CROP GENETIC IMPROVEMENT TECHNOLOGIES AND RETHINK ON REGULATORY SYSTEMS

11.1. Next Generation Crop Genetic Improvement Technologies

The GE technology is very precise and efficient and has been shown to be safe to the consumers and profitable to the farmers. Yet, the mindless opposition to it based in non-scientific concerns brought in un-surmountable regulatory hurdles and it is becoming increasingly difficult in almost all the countries to bring in new products to commercialization. Non-scientists who have reservations about technology and its safety can probably be convinced, but perplexing situations arise when scientists question the technology or its regulatory processes. For example, the GEAC disapproved transgenic Events of groundnut '*because of the presence of gratuitous gene such as GUS, in the food crops',* ignoring the wide and safe use of GUS as a reporter in genetic transformation protocols (Kameswara Rao, 2010b).

The choice of experimental protocols is the prerogative of the scientists and cannot be dictated from outside. Yet, in the face of onslaught from the activists and insensitive government bodies imposing more and more restrictive regulatory oversight, scientists are almost apologetic about transgenic technology and have been making amends to its protocols. There is no scientific evidence of development of resistance by humans to antibiotics from consuming GE products with antibiotic resistance marker genes (ARMGs). To assuage such fears, the ARMGs have been replaced or even marker-free protocols were developed (Laing *et al.,* 2010). For example, in the gene construct of the current version of Golden Rice (GR2), the hygromycin marker was replaced by mannose phosphate isomerase. In response to the criticism that the phytoene synthase gene in GR1 was taken from the daffodil plant which contains toxic chemicals, this gene was replaced in GR2, sourcing it from corn.

Scientists have also been developing technologies as alternatives to transgenic technology that is being criticized on the basis of the presence of 'foreign DNA' in the GE crops and their products. Schaart and Visser (2009) discussed four classes of 15 novel plant breeding techniques, such as agroinfiltration, virus induced gene silencing, reverse breeding, accelerated breeding, grafting, cisgenesis, intragenesis and oligonucleotide-mediated mutation induction, that lead to end products (plants or plant parts) without the genes that are 'foreign' to the species. The use of programmable DNA binding proteins resulted in unprecedented advances in gene targeting and genome editing, which allow researchers to specifically alter genes, reprogram epigenetic markers and generate site specific deletions, which will help in enhancing crop quality, yield, tolerance to biotic and abiotic stress conditions (Fichtner *et al*., 2014). The ultimate result will be precise designing of the desired traits. These are the 'Next Generation Crop Genetic Improvement Technologies' (NGCGITs). As the term 'second generation technologies' is already in use for GE crops and products with stacked genes and those with transgenic nutritional and/ or pharmaceutical traits, a different term is needed for the novel techniques to avoid confusion.

Schaart and Visser (2009) compared the consequences of NGCGITs, for the environment and food and feed safety, to a baseline reflecting the 'natural situation' in its full band width to show that the base and developed varieties are identical in all respects. Now the hope is that, in an atmosphere of biosafety evaluation of a product, and not the process as at present, the products of at least some of the NGCGITs which do not leave 'foreign' genes in the product need not necessarily go through the whole battery of regulatory regime, thus saving time and expense, and making the products cheaper to the farmer and the consumer. One cannot be sure, as there is already a view that gene silencing need to be regulated if the RNAs were taken from another organism.

Supporting the use of NGCGITs, Heap (2013) has raised the following issues: a) Some of the NGCGITs induce epigenetic modifications and leave the resultant crops free of genes 'foreign' to the species, with the result they are often genetically or otherwise indistinguishable from the crops produced by conventional breeding and hence, they are not genetically modified in the now understood sense, even to the extent of raising the question 'are these GM crops?'; b) A GE classification of NGCGITs raises regulatory hurdles and associated costs, which could put the commercial use of NGCGITs beyond the reach of smaller companies and public sector researchers; c) The NGCGITs have potential to improve crop resistance to disease and to increase yields and nutritional content, but classified as GE would restrict their application to high value crops, as is happening now and it would be perverse if the costs of regulation yet again lock up the promise of the agricultural innovation within a few large companies; and d) Expert groups have concluded that many of the NGCGITs do not constitute genetic modification in the way the term is usually used and so the plants they produce should not be regulated as GE organisms.

Researchers and plant breeders need to know the status of NGCGITs before they commit to use them. Expert advisory groups of the European Food Safety Authority have already judged that hazards are similar for conventionally bred plants and those produced by *cis* genetics, and that targeted mutagenesis is also likely to minimize unintended effects associated with the disruption of genes or regulatory elements in the modified genome (Heap, 2013). Confirmation by the EU that targeted techniques which leave no 'foreign' DNA behind do not fall under the scope of GE legislation would give considerable support to agricultural innovation. In common with other innovation sectors, the objective must be to regulate the product and not the technology that produces it. By making better use of all crop improvement techniques and so reducing dependence on food and animal feed imports, the EU can help improve land use elsewhere, and allow more of the agriculture in developing countries to be used for their local needs (Heap, 2013).

11.2. Secondary Agriculture

'Secondary agriculture' is more conceptual than definitive and so is difficult to precisely define. It includes all food and non-food bioresource-based products for human, animal and industrial use. Some examples of secondary agriculture are, vitamins from grains, oil from rice bran, starched sugar from corn, milk and protein from soybean, essential oils, industrial chemicals, biofuel from sugarcane and ligno-cellulosic biomass, fiber board from rice straw, high value animal by products, in addition to medicinal plants and herbal products not yet fully capitalized in India (Verma, 2008). Most of this now involves modern biotechnological processes.

Agriculture is the foundation of rural economy of developing countries. With near self-sufficiency in primary agriculture (grains, sugar cane, fruits, vegetables and milk, etc.), countries such as India should now focus attention on Secondary Agriculture. Secondary agriculture takes crop produce into diverse derived products facilitating better returns to farmers from their harvest and revitalizes the rural sector by creating more jobs.

Realizing that secondary agriculture has an unlimited potential in enhancing the value of primary agriculture two to three-fold, the Indian Planning Commission has constituted the Technical Advisory Committee on Secondary Agriculture (TACSA) to address issues and find workable solutions that can serve as catalysts to fuel activities in this area. The TACSA has published a status and projection report (Verma, 2008) and proposed that a sum equivalent to US $2 billion be invested by the Government of India to jump-start activities in secondary agriculture.

Many of the GE crops now in cultivation (soybean, corn, potato) are feeders for secondary agriculture and there will be more of them in the near future. It is necessary to examine the prospects of current and future GE crops in promoting secondary agriculture.

11.3. The Need for a Rethink on the Current Regulatory Systems

Marginalizing science and subduing scientists by questioning on ideological and/ or political grounds, threaten the integrity, openness and usefulness of science. Scientists have for long mutely suffered the consequence of activism against biotech crop technology and the indifference of governments that preferred political opportunism in frequently raising the bar of regulatory standards. During the past few years, several scientists have expressed their concern about the lack of appropriate, science-based and cost/time-effective regulatory systems which continue to be the major constraint to adoption of GE crops (Potrykus, 2010a; Dubock, 2013; James, 2013). The need for a rethink and shift in regulatory policy is highlighted by the following:

(a) '*Unjustified and impractical legal requirements are stopping genetically engineered crops from saving millions from starvation and under nutrition*' (Potrykus, 2010a);
(b) '*The cause of 10-yr delay suffered by Golden Rice is exclusively GE-regulation. GE-regulation is also responsible for the fact that no public institution can deliver public good GE-product, which gives a de facto monopoly in favour of a few potent industries*' (Potrykus, 2010b);

(c) '*Unscientific, excessive, stultifying regulation, nationally and internationally, is a major reason for the failure of biotechnology to achieve its potential to bring greater food security to the poor*' (Miller, 2012);

(d) 'Sustainable intensification' is simultaneously raising yields, increasing the efficiency of input utilization and reducing the negative environmental effects of food production. Cantley and Kershen (2013) stated that '*sustainable intensive agriculture will not occur if developing countries formulate or implement non-scientific regulatory structures that impede, delay, disrupt or discourage scientific creativity, agricultural investment and farmer adoption of agricultural biotechnology*';

(e) Heap (2013) raised several issues on the present regulatory policy and made a fervent appeal to the EU '*to rethink its stance on GM crops, as the historical attitudes and actions of the EU have constrained the use of GM crops, both at home and in the developing countries*'. The other issues raised by Heap (2013) are: ' i) *An EU regulatory position not based on sound science could create damaging knock on effect for developing countries which may depend on the EU for export markets or look to it for leadership in managing bioscience innovation';* ii) *The EU must recalibrate its broader approach to GM crop regulation to make it transparent, predictable and fit the purpose by taking account of the extensive evidence of safe use of GM corps around the world',* and iii) *'There is an ever greater requirement for consistent, harmonized evidence based policy worldwide to enable synchronous technology development and trade'*; and

(f) '*A fast-track approval system in Brazil facilitated rapid adoption of biotech crops. The lack of appropriate, science-based and cost/time-effective regulatory systems continues to be the major constraint to adoption. A responsible, rigorous but not onerous, regulation is needed, particularly for small and poor developing countries, which are completely 'locked out' because of the high cost of developing and gaining approval of a biotech crop*' (James, 2013).

A uniform globally accepted regulatory regime would make GE crops and products approved in one country acceptable in other countries without wasting time and money on repeating the whole regulatory process several times.

12. CONCLUSIONS

A number of conclusions were contextually drawn in different sections of this chapter. The following are the other important considerations, some of which are taken from Kameswara Rao (2013a):

(a) The efficacy, safety and benefits from GE crops have been well established, as well as their crucial role in enhancing agricultural production contributing to food security;

(b) The current regulatory regimes in different countries are similar and scientifically sound, notwithstanding the noises made by the activists. The technical expertise of the product developers and biosecurity evaluators is also not in question;

(c) It would serve the cause well if the existing regulatory regimes in different countries are reviewed to develop a more uniform regulatory regime for all the countries that adopt GE crop technology;

(d) In India, about 95 per cent of cotton area is under *Bt* cotton and India, with only one GE crop occupies the fourth position in global GE crop hectarage, demonstrating that the issue of *Bt* cotton in India is no longer an open question;

(e) The Government of India should fast track both *Bt* brinjal and Golden Rice and encourage the process of commercialization of several other GE crops in development but held up at different stages due to regulatory hurdles;

(f) Research organizations, industry and others should be prepared to take legal action against criminal activities of the activists in preventing GE crop development and against false charges against technology, scientists and institutions;

(g) The product developers should device mechanisms to periodically monitor the performance of their products and provide improved alternatives when needed;

(h) Democratic governments need to respect legitimate public opinion, but should not allow ignorance and prejudice to dictate policy;

(i) The scientific establishments should educate and lead public opinion and the governments should not pander to vested interest with an eye on single issue voters;

(j) The government should respect the combined global and national scientific wisdom in evaluating GE products, and the decisions on their acceptance or rejection should not be allowed to be hijacked by the vested interest that uses junk science pursuing inept politics;

(k) Untangling biosecurity issues, from the mix up of political, economic, societal and ethical issues, projected as biosecurity issues by the activists, is the most urgent and important step the governments needs to take; and

(l) There is a distinct shift in public response in favour of GE crops. All those involved in GE crop development should provide the public, the media and the judiciary, with appropriate and adequate information on the efficacy, safety and benefits of GE crops. This is better done in collaboration with Genetic Literacy Project, Council for Biotechnology Information and ISAAA. It is essential that the activist propaganda is countered as soon as it emerges.

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