

Genetic Engineering in Indian Agriculture

An Introductory Hand Book

Centre for Sustainable Agriculture

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FOREWORD

We at Centre for Sustainable Agriculture firmly believe that no technology is set in a social vacuum. All technologies are socio-politically shaped, with differential socio-political impacts in different settings (spatial and temporal), apart from other possible impacts. There is a political economy behind each technology that needs to be understood, so that informed choices can be made. We are aware that most technologies are driven by economic considerations and regulation of such technologies is also shaped by and tied to such money power.

Agricultural technologies, unlike many other technologies, have a major impact on human beings and other life forms. This is because of the huge magnitude of this human activity – farming is spread over a major part of this planet's land and is the primary occupation of millions of people, especially in the third world. Further, these technologies will impact each one of us as we are all consumers of food. Agricultural technologies also have the ability to leave lasting impacts, as the lesson from chemical pesticides has shown us. Fate of future generations can be sealed one way or the other by agricultural technologies deployed at any particular point of time. A closer look at agricultural technologies pushed as “modern science & technology” shows that science is certainly fallible and it is more than clear that decisions related to agricultural technologies should not be left to the so-called “experts” alone. Farming itself is a complex process with impacts spilling over onto communities and their very lives and livelihoods. Understanding of such a complex process cannot be left to reductionist science and its believers.

In the case of Genetic Engineering, more than any other agricultural technology, the need for utmost precaution is urgent and imperative. There is ample evidence to show that it is imprecise and unpredictable. What is worse, it is irreversible since it involves living organisms which are capable of procreation and further spread, unlike the chemical molecules used in pesticides. Its potential for contamination and bringing about evolutionary-level changes in eco-systems cannot be denied. The impacts of GE in farming will change the structure of the planet's food at the molecular level and there is no turning back.

It is also a technology that is being aggressively pushed with the enormous money power of large transnational corporations like Monsanto. There is a great hype created around the technology as “frontier science” and as the only alternative for the future. The reality on the ground is however different from the rosy picture that the industry promotes. There is growing rejection of GE as a technology the world over. Nearly a decade and a half later after the first GM crop, only 12 countries have opted for the technology in any significant manner. It is also interesting to note that in countries like the USA, where the technology has been promoted and adopted on a large scale, farming has to be propped up with huge subsidies, in spite of such ‘efficient’, ‘frontier’, ‘precise’ technologies. Many negative experiences are already available in India from Bt Cotton cultivation in the past six years.

We realize that India is a major battle-ground for the worldwide markets that the industry is eyeing. Within India, we find that policy-makers and scientists are blind to the full impacts of this technology and have an unscientific and irrational support for it. During the Green Revolution and introduction of Indian farmers to chemical farming, civil society groups and farmers' organizations had not intervened and did not present any alternate vision for agriculture. The same mistake cannot be allowed to be committed with the ‘Gene Revolution’. It is our duty and role to create an informed public debate on Genetic Engineering in agriculture and we have decided to come up with this Introductory Handbook as our contribution to this debate – a debate not just on GE in agriculture *per se* but on democratization of science & technology. We have freely borrowed from many authors/activists and are grateful to them for their material. We thank Hivos and Centre for World Solidarity for the financial and other support extended.

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1. WHAT IS GENETIC ENGINEERING?

Firstly, some basic information (in case you did not know) – all living organisms are made up of cells. Inside the cell is a nucleus which contains nearly all the genetic material of an organism. This genetic material is 'packaged' into organised structures called Chromosomes. DNA (De-oxy ribo Nucleic Acid), which has a double helix geometric structure lies in these chromosomes. Four chemical substances form the bases for the DNA – and genes are supposed to be made of definite sequences of these bases [guanine (G), thymine (T), cytosine (C) and adenine (A)] on the DNA, which in turn are supposed to code for production of particular proteins.

A plant starts its life as a single cell, an egg that has been fertilised by sperm. This first cell (Zygote) divides many times to form the tissues and organs characteristic of the species. As the development proceeds, cells differentiate themselves. For example, cells in the leaves become distinct from the cells in the root. Most of these differences can be attributed to changes in the kinds and amounts of proteins made in the cells, because many of the structures in cells are made of proteins and most of the processes that occur in cells are influenced by enzymes which are also proteins. Though several thousand different proteins are present in the cell, they vary in quantity; also, some proteins are found in all kinds of cells at all times in development whereas other proteins are in a particular tissue (or) at a specific time. Some proteins are made in response to environmental changes such as increase or decrease in temperature and this may or may not be present during the entire life of a particular plant. The most common way for a cell to control how much and which kinds of proteins are present is by controlling which genes are functioning.

The science and technology of isolating (a) gene(s) from the genome of one organism and inserting the same into the genome of another organism is termed as Genetic Engineering [GE]. Such insertion is done randomly and plants and seeds created thus are called Genetically Engineered Plants or Seeds [GE plants or seeds]. Such gene insertion would not normally happen within Nature.

The genes and thereby, characters are inherited from generation to generation. Exchange of genes happens only between sexually compatible, closely-related species. The modern techniques of the genetic engineering facilitate the removal of an individual group of genes from one species and insertion into another, without there being a need for sexual compatibility.

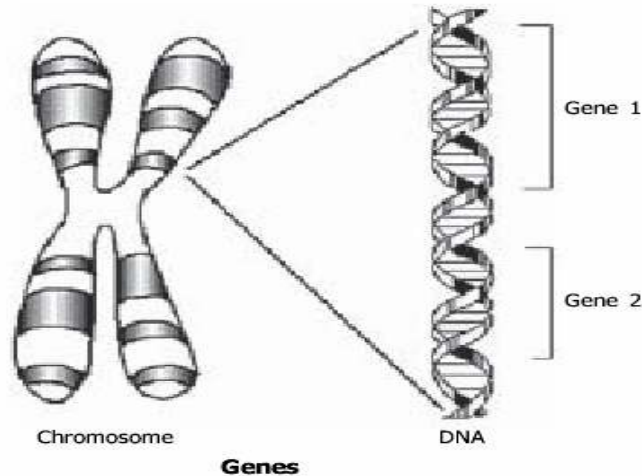
Genetic Engineering normally does not involve only one gene but a gene of interest accompanied by any necessary additional pieces of DNA which provide the insertion and control/regulatory sequences. These could be promoters, markers, terminators etc., all of which together with the gene of interest form the Gene Construct.

Genetic engineering can therefore be defined as the process of manipulating the pattern of protein in an organism by altering genes. New genes are added or existing genes are changed so that they are made at different times and/or different quantities. As the genetic code is similar in all species, genes taken from a firefly coding the luciferase, chemical responsible for glowing, can function in a tobacco plant, and so on. The transfer process involves cutting the desired gene out of a chromosome of a particular plant, animal or bacteria and putting that gene into a cell; the genetically modified cell is then regenerated to produce a 'transgenic' or genetically modified organism or GMO. The modified organism passes the new gene onto its progeny.

What is a genome? – the complete set of genetic material of an organism (all the DNA contained in an organism) or all of the hereditary material possessed by an organism, encoded in the DNA and/or RNA. This includes the genes as well as the non-coding sequences.

What is a Gene then? – There is no simple clear answer to this question. It is understood that DNA (De-Oxy ribo Nucleic Acid) codes for genetic information and that it is arranged in an

alphabet or a genetic code for the production of proteins. A gene is supposed to be a definite sequence of bases in the DNA chain, which code for the production of a particular protein. In the 1960s, this code was deciphered and genes were understood to be the code. A gene consists of many different parts which can be put together in different ways to produce different proteins.



What are Proteins? - Proteins are chemical substances which mediate the form and function of cells and organisms either by forming part of definite structures or by acting as biological catalysts in living processes. Proteins are chains of different amino acids, and the order of amino acids and length of the chain are unique for each kind of protein. Each unique amino acid sequence is specified by a code on a chromosome. The code is made up of DNA. Every cell has two full sets of genes which code for the proteins made in all of the tissues and organs that an individual plant will need during its life cycle. However, only those genes whose proteins are needed in a particular cell will be used by that cell. The other genes are inactive but may be active somewhere else in the plant. Whether a gene is active or not depends on complex interaction between the DNA and other molecules in the cell. Specifically, a typical gene can be divided into two parts. The first part is a stretch of DNA responsible for interacting with the cell or the environment and called the promoter. The second part actually contains the coding for the order of amino acids in the protein, and is called the coding sequence. When the gene is active, the promoter is interacting with the molecules in a way that allows the coding sequence to direct the synthesis of a specific protein. Proteins emerge as the biochemical products of gene expression. Throughout the life of an organism, production of different proteins is being switched on and off and this regulation of gene expression (protein production) is a vital function of a living organism. This regulation happens at the most basic level of a cell's development (elementary biochemical processes) as well as at the level of evolutionary changes in response to environmental change.

It is interesting to note that it is not the number of genes that determine the hierarchy of a living organism as a lower or higher organism, but the number of proteins that the genome of an organism encodes for. For instance, bacterial genomes encode something like 1000 proteins while mammalian genomes encode some tens of thousands of proteins. In the higher order organisms, some genes of the chromosomes encode proteins whose apparent sole function is to regulate the production of other proteins. It is also important to note that there is more to genes than a code for proteins.

To sum up again, Genetic Engineering involves a "cut and paste" job with some genes where they are cut from one organism and inserted into another.

2. ARE WE TALKING ABOUT ALL BIOTECHNOLOGY?

No. Biotechnology encompasses all technologies based on living forms – all biological technologies.

“Low end” biotechnology could encompass even things like vermi-compost and several bio-fertiliser/bio-pesticides that are used by farmers. But most biotechnology is usually understood to be at the molecular level. For instance, it could be irradiation that induces mutation, which is part of genetic modification (GM) technology.

There are also technologies like Marker Assisted Selection (MAS) used as part of conventional breeding where genetic markers (specified DNA fragments) are known to correspond with specific traits, for more precise breeding.

Genetic Engineering or transgenics is only one of the technologies under the broad umbrella of Biotechnology. This is also part of genetic modification. In this handbook, we restrict ourselves to the use of transgenic technology in agriculture (for the simple reason that we have not studied other gene technologies enough).

3. WHAT IS THE SCIENCE BEHIND GE AND IS IT RELIABLE?

Genetic Engineering rests on some reductionist and simplistic beliefs. It believes that characteristics of organisms can be traced back to particular genes, that such genes can be isolated and inserted into another living organism and that the characteristic would be expressed in the new organism as in the old organism, provided a few more DNA fragments are added. However, it is now known scientifically that genes and gene expression are not nearly as simple as the GE industry would like us to believe.

Complex regulatory networks control gene expression in a manner that is far from fully understood. Genetic Engineering cannot incorporate these complex regulatory networks. There are still many unanswered questions in the science behind GE. Neither the basic structure of DNA nor the genetic code offers a satisfactory explanation for the production of so many proteins from so few genes in the human genome, for instance.

GE assumes that genes act as isolated units within a system. This is simply not true. Gene position within the genome is crucial to the strict regulatory controls it is subjected to. Genes inserted at random into the genome are outside these regulatory controls, which means that they are unregulated.

The transgenic gene construct usually includes promoters as well, which initiate transcription of the DNA. However, these promoters are not part of the regulatory system of the cell. In most cases the cauliflower mosaic virus (CaMV35S) promoter is used, which keeps the inserted gene(s) switched on all the time, in every cell of the organism and it is this promoter which is now suspected to cause some serious health effects with GE.

The very process of GE is fairly disruptive. For many GMOs, the fate of the inserted genes in the organism can only be found out through painstaking analysis. For instance, a variable number of copies end up randomly peppered throughout the host genome. Or, in the gene uptake process, parts of the gene construct can get lost – it can be truncated, inverted, fragmented or scrambled.

Furthermore, inserted genes can be immediately or gradually 'silenced' by normal DNA management mechanisms of the host organism. Another concern about inserted genes is the extent to which they disrupt the integrity of the host genome or interfere with the normal expression of the host's genes. There could be 'insertion site' changes [mutations] or 'genome-wide' changes [mutations]. Sometimes, transgenes have been found to code for proteins of unknown functions. These are proteins that were never intended or tested.

Thus, the process of gene insertion can delete one or more of the host organism DNA's own natural genes, scramble them, turn them off or permanently turn them on. It can also change the expression levels of hundreds of genes. And growing the transformed cell into a GM plant through a process called tissue culture can create hundreds or thousands of additional mutations throughout the DNA.

Also, as mentioned earlier, as of now, scientists cannot direct transgene location in the host organism. Because of all these reasons, **GE becomes a very imprecise, unreliable and unpredictable technology.** One of the things that is predictable is that GE is unpredictable!

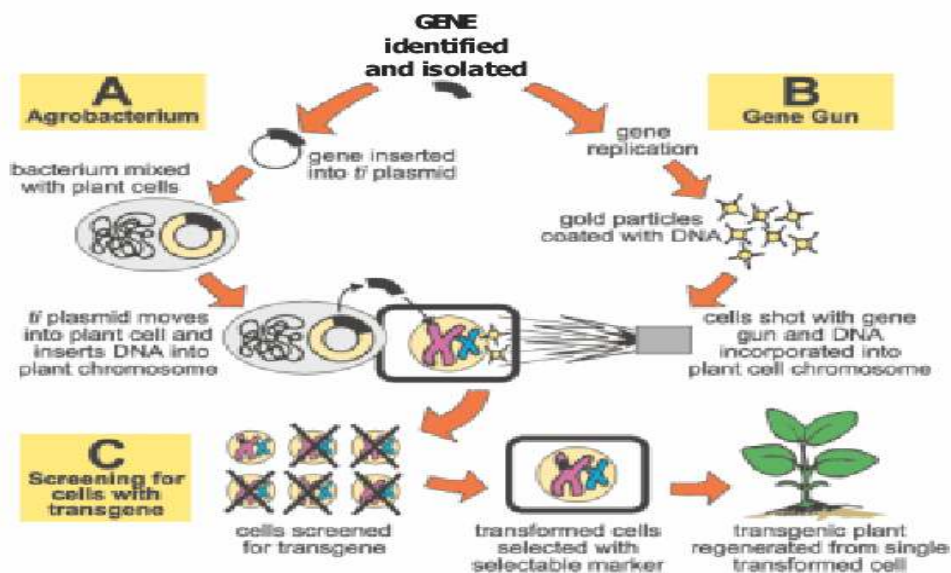
While the unreliability takes different forms, it has serious implications in case of changes in the nutritive quality or safety aspects of a food or when it leads to stress intolerance in a plant. The latter could even jeopardize the national food security of a country, if a country tries to build such food security based on GM food crops.

Very importantly, it is not mere genetic engineering that will ensure that a plant will have desired characteristics for specific functions of pest resistance or for increased drought tolerance or any other trait. The expression of the characteristic is heavily dependent on the internal and external environment that is present and provided. Mere presence of a gene is no guarantee for its expression. This is often ignored as a major critical factor and GE is presented as a miracle solution for all of world's farming problems, in a narrow framework of genetic determinism. Even if we assume for a minute that GE was not a hazardous technology, it is certainly not guaranteed to perform just because of the genetic engineering that has gone on. Farmers would have to provide the most suitable environment in any case. With that kind of careful environment management, many existing problems can be successfully addressed in any case, without genetic engineering.

How is Genetic Engineering done?

There are a couple of methods usually used for genetic engineering or recombinant-DNA (r-DNA) technology. First, the desired DNA is extracted by physical or chemical means (a whole collection of methods like blotting, washing, transfer, chemical methods are used to obtain intact DNA). The desired gene should then be inserted into the target organism. For this, usually, a microorganism (Agrobacterium species) is used as a carrier or vector to smuggle the gene of interest into the target organism. Ballistics is another method. A 'gene gun' allows the DNA containing the gene, coated on microscopic gold or tungsten particles, to be blasted into plant cells. Once inside the cell nucleus, natural processes are expected to allow incorporation of the foreign DNA into the plant's own DNA in its chromosomes.

Usually a "gene construct" is used which comprises the gene of interest and any necessary additional pieces of DNA which provide the insertion, identification and control/regulatory sequences. Control sequences are necessary to trigger the expression of the gene of interest, i.e. the making of the protein which corresponds to it, since the gene of interest is in an alien setting. These include a Promoter and a Terminator in addition to a Marker gene (for most crops). Since gene insertion is a random process, for easy identification of cells with the inserted genes, markers are normally introduced into the gene construct. Normally-used marker is an antibiotic resistant gene. After the cells are cultured in a medium treated with antibiotic solution, the surviving cells, with antibiotic resistance, are selected as they are 'believed' to contain the entire gene construct transferred. Normally-used marker is kanamycin-resistant marker. It has to be noted that there are chances of antibiotic resistant genes escaping and getting integrated into other living organisms, especially microorganisms.



4. HOW IS GE DIFFERENT FROM OTHER BREEDING TECHNOLOGIES?

Species barriers are not usually crossed by any other breeding technology employed by agriculture scientists. For instance, in the case of Genetic Engineering, genes from a scorpion can be inserted into a Maize plant. Human genes have been inserted into rice plant. This is unnatural and such crossing of barriers could be across animal and plant kingdoms too.

Admittedly, there is genetic variation happening naturally in living organisms, mostly as a response to interaction with the external environment. Genetic variation inevitably gives rise to novelty in individual organisms. Novelty may survive and be inherited by later offspring. This process is called natural selection, in an evolutionary sense. Natural selection can be thought of as irreversible ecological change.

Natural selection is understood extremely poorly by thinking about it only in terms of genes “encoding” characteristics of individual organisms, as some proponents do. This is because most of the factors that determine the survival of organisms are external to them and are continually changing. What appears to be an individual’s genetic advantage in one ecological context may be a disadvantage in another context. The original genetic change in an individual organism is only a minor part of any event of natural selection. The ecological context of that original change, affected by all of the constellations of genes in other organisms and the way they interact, ends up being more important.

In nature, lasting genetic changes in eco-systems have happened mainly as a result of three sets of processes:

- I. mutation and recombination;
- II. horizontal (inter-species) gene transfer;
- III. natural selection due to environmental and ecological pressures.

Selective breeding, practised by humans for millennia, is a manipulation of the first set of processes. Genetic engineering is a manipulation and extension of the second set of processes. The natural selection processes are well understood and practiced by the farmers as part of regular farming activity. Among the existing variation, plants are selected to suit specific needs and situations. For example, India had more than 50,000 varieties of rice cultivated across the country in a variety of situations ranging from dry, hilly, waterlogged, saline conditions etc. Rice was available in different flavors, colors, sizes and suitable for different types of cooking. Modern breeding (which is now termed as conventional breeding) made the process of selection more systematic using statistical designs. From the days of selection from the naturally occurring variation, science has moved to creating variation and making selections. This variation is created by crossing wild species or plants having the desired characters. Irradiation techniques to induce mutations were also tried to create variation - for example, Sharbati Sonara in wheat. In genetic engineering, as mentioned earlier, genes which code for the desired characters from selected organisms are extracted and inserted into other organisms.

Conventional Breeding vs Genetic Engineering

In conventional breeding by reproduction, only individuals from the same species or related species can be mated to produce offspring. The offspring will have genes from both parents, but the genes are just different variants of the same genes coding for the same functions. A GMO, however, bypasses reproduction altogether, so completely new genes with new functions, as well as new combinations of genes can be introduced, which will interact with the organism’s own genes in unpredictable ways. A transgenic line results from gene insertion events in a single original cell, out of which the entire line is produced.

	Conventional Breeding	Genetic Engineering
Basis	<p>The selection is among the existing variation within the species of a particular genus.</p> <p>Sometimes variation is introduced by using irradiation techniques.</p> <p>For a particular trait, selection and transfer is between alternate alleles from the existing variability.</p>	<p>Genes are introduced and expected to express the trait they express in native species.</p>
Transfer	<p>Normally inter-species and intra-generic.</p> <p>Sexually compatible plants are crossed and plants expressing the desired trait are selected.</p>	<p>Normally inter-generic.</p>
Selection	<p>Based on the phenotype. Plants which express the desired trait are selected.</p> <p>Trait based selection takes genotype and environment interaction into account.</p>	<p>Based on the genotype. Cells which show the presence of genes are selected.</p> <p>Gene based selection ignores environment interaction.</p>

A few examples of Genetic Engineering will clearly demonstrate its unnatural nature and that it is very different from conventional breeding techniques.

- Pig genes in rice: Three kinds of pig genes are being put into the rice plant in Japan. These rice plants manage to survive the application of plant killing herbicides.
- Human genes in rice: Japanese researchers have inserted a gene from the human liver into rice to enable it to digest pesticides and industrial chemicals. The gene makes an enzyme, codenamed CPY2B6, which can break down harmful chemicals in the body. An American company called Applied Phytologics is producing rice genetically engineered with two human genes lactoferrin and lysozyme, to protect plants against fungal and animal pests. Ventria Bioscience in California is developing rice containing human genes to produce the proteins lactoferrin and lysozyme. This genetically engineered rice is meant for treatment of diarrhoea. Washington State University is testing Barley altered with human genes for lactoferrin, lysozyme, antitrypsin and antithrombin. Meristem Therapeutics company in France is field testing maize genetically engineered with human lactoferrin genes.
- Genes from the rabies virus have been inserted into tomatoes to produce an edible vaccine.
- Human genes to produce insulin and vaccines are being put into crops like corn, tomato and rice.

So, why the concern with GE and not other breeding techniques?

Any genetic change can have an effect at many levels. Most immediately a genetic change affects the molecular events inside a cell. This may show up as altered cellular metabolism or altered development of the embryo. The change may produce an organism with altered characteristics. It may respond differently with its environment. It may interact differently with

members of other species. Ultimately, the course of evolution can be affected by an apparently small genetic change.

When we do genetic engineering, we manipulate organisms at the most basic level - the information required for their construction and maintenance. This information, usually held in the form of DNA sequences, is replicated as new cells are formed in each generation. Some effects of genetic change can be seen straight away, but the final effect of any genetic change is very hard to predict because of the complexity of biological networks. On the other hand, the rapidity at which the molecular changes are happening through GE does not even allow for eco-systems to modify and adjust.

There is now increasing evidence with regard to the potentially hazardous nature of the popular genes used for Genetic Engineering. These include the many Bt genes extracted from a bacterium called as *Bacillus thuringiensis* as the genes of interest/desired trait genes for insect resistance, the *CaMV35S* (Cauliflower Mosaic Virus) used as the promoter, antibiotic-resistant marker genes like *nptII* and *aad* with antibiotic resistance to kanamycin, neomycin etc., as the selection agents and *Agrobacterium tumefaciens* as the vector. This evidence is in terms of their allergenicity, immunogenicity, toxicity etc.

While they are hazardous as individual particles too, the very process of insertion of the gene construct into the new organism would cause further hazards. Add to this the possible changes in the genetically engineered organism as it interacts with its environment over a period of time. We would have altered irretrievably and uncontrollably the very course of evolution of life at a rapid, human-induced pace. Therefore, the utmost precaution is advised with regard to GE.

5. DON'T GE CROPS ALLOW FOR LOWER USE OF AGRI-CHEMICALS?

Many GE crops are being brought in on the grounds that they will reduce the use of pesticides in farming and therefore be more environment-friendly. A closer examination of the situation will give a true picture of this claim by the GM proponents.

Most GE crops being grown in the world today (more than 80%) are engineered to tolerate the application of broad spectrum herbicides like glyphosate or glufosinate. This trait is called Herbicide Tolerance, which is especially in vogue in those countries where the landholdings are large and population in farming is low. With herbicide-tolerant GM crops like Roundup Ready Soy or Roundup Ready Corn [Roundup being the brand name of a Monsanto herbicide, which is the largest selling herbicide in the world], the use of chemicals in agriculture has increased, as evidence from the USA and other countries shows. This is logical, given that herbicide tolerant crops have been engineered for tolerating more use of agri-chemicals! Now, there are GE crops being engineered to tolerate two herbicides and not just one. It is also worth noting that Monsanto has a stranglehold over the technology – around 99% of all herbicide tolerant crops being grown worldwide have Monsanto's proprietary traits.

The other common trait for which genetic engineering is being promoted is that of insect tolerance – here, a plant which is genetically engineered produces its own pesticide against some select pests. These pests, upon feeding on the plant, are supposed to get killed by the toxin produced by the plant. The most common insect-tolerant crops worldwide are Bt Cotton and Bt Corn, which are made by creating a cotton or corn plant with a gene drawn from a soil bacterium called *Bacillus thuringiensis* (it is the name of this bacterium shortened into Bt that appears in the name of the GE crop and the actual gene inserted in most Bt Cotton hybrids in India is Cry1Ac). A Bt Cotton plant is supposed to produce its own toxin from this Bt gene inserted into it, to kill the American bollworm and the spotted bollworm. Bt Cotton proponents say that it is also effective against the pink bollworm. These three together constitute the bollworm complex.

What is interesting is that even the biotech industry agrees that pests will develop resistance to GM crops developed for insect resistance, as in the case of pests developing resistance to pesticides and this is true of Bt Cotton or Bt Corn. A new kind of genetically modified cotton is now being introduced with 2 genes (stacked traits) so that resistance buildup in the pest can be slowed down and this new Bt Cotton variety is expected to be effective against another pest too called the tobacco caterpillar.

GM soy, corn, and cotton have reportedly led to a 122-million pound increase in pesticide use since 1996, with a huge increase on herbicide-tolerant crops (138 million pounds) and a modest decrease on Bt crops (16 million pounds) [2005]. It is interesting to note that 'super-weeds' are getting created along with herbicide-tolerant GM crops which is leading to ever-increasing use of herbicides on these GM crops. Weed resistance is reported from more than 15 million acres in the USA now. While two decades of herbicide usage did not create as many resistant weeds, in the decade of herbicide-tolerant GM crops expanding, 30 new glyphosate resistant weeds have emerged.

In the case of insect-resistant GE crops, it is claimed that pesticide use will come down with the introduction of the technology. However, as per a Cornell University study from China released in 2006, Chinese Bt Cotton growers were net losers compared to their non-Bt Cotton counterparts. The amount of pesticides that these Bt Cotton growers were using, seven years after the official introduction of Bt Cotton into the country, was the same as the pesticide use before the advent of Bt Cotton. Though there was an initial decline in the pesticide use after the entry of Bt Cotton, the

pest ecology in cotton fields changed dramatically and secondary pests like myrid bugs have become a major problem now. Pesticide use went back to earlier levels because of this.

The experience with Bt Cotton in India points to similar trends – of newer pests and diseases appearing in the cotton fields requiring more chemicals for control in addition to the predicted problem of resistance building up in the targeted pest to Bt Cotton. In fact, the Indian growing conditions and lack of regulation are such that inefficacy and failure of the technology due to resistance build-up is predicted to happen much faster here, even as per official scientific studies.

It is also important to remember that four of the top ten seed companies in the world, trying to sell GE seeds, are also the world's biggest agri-chemical giants – Monsanto, Du Pont, Syngenta and Bayer. It is naïve to assume that they would want agro-chemical use to come down in reality, but would rather find ways of selling both seeds and chemicals if technologies like GE are available!

It is now clear that use of GE crops does not reduce the use of chemicals as promised by the biotech companies and it is just an empty promise. This is an expectable outcome since all that the GE technology is doing is to engineer plants to select weeds and insects for resistance.

6. WON'T GE CROPS INCREASE PRODUCTIVITY OF FOOD IN AGRICULTURE?

GE crops are being projected as ones that will solve the hunger and malnourishment problems of the world, especially in the continents of Africa and Asia and the technology is projected as the answer in all Malthusian projections of population growth outstripping food production growth figures.

It should be remembered that hunger and malnourishment, from what history shows us, are not a result of scarcities in production but mainly due to poverty and lack of political power. They result from distribution failures rather than production failures.

Secondly, majority of GM crops are not feeding the poor of the world but feeding the livestock in the diet of the rich or more and more, to produce agro-fuels to run the cars of the rich in the first world. They are also being used to produce highly processed food products for the global North. There is no evidence that they have been used to feed the hungry and the poor. What's more, food producing lands are being diverted to agro-fuel production with the use of GE seeds, amongst others. A third of Monsanto's seed sales in 2007 were from GM corn, pushed by the ethanol boom. All the above make it abundantly clear that GE seeds are not about hunger and malnourishment but about increasing markets for big agri-business.

Yield is a complex phenomenon that depends on numerous factors, including weather, availability of irrigation and moisture, soil productivity, farmers' management skills and level of pest/disease infestation. At the molecular level, yield is not a factor of any single gene but such properties as increased yields etc, are a combination of many different genes interacting with each other and the environment. Therefore, as a technology, Genetic Engineering has not been able to break the productivity barrier unlike the high-input-high-response hybrid seeds that were promoted as the miracle seeds during the Green Revolution.

In fact, in marketing seeds like Bt Cotton, farmers are being misled to believe that Bt Cotton will increase their yields – only when questioned did the companies clarify that what they mean by increased yields is the saving from any crop losses due to pest attacks. It follows logically that there should be no increase in yields if there is no pest (the targeted pest in the case of each insect-resistant plant) outbreak in any case in a given season!

There have been reduced yields recorded consistently with the use of Roundup Ready soybean and this phenomenon is being termed as “**yield drag**”, especially in the case of Herbicide Tolerant (HT) crops. It is now being understood that the presence of glyphosate in the root zone promotes growth of pathogens like Fusarium which in turn affect the plant's absorption of nutrients; it is also being surmised that the presence of glyphosate in the HT plants makes nutrients unavailable to the plant. Glyphosate hinders uptake of essential nutrients like manganese in Roundup Ready soya, both reducing yields and making plants more susceptible to disease. Even in the case of non-GM crops on which glyphosate has been used extensively, subsequent crops are more likely to be damaged by fungal diseases, as experience from Canada shows. On GM soya, worldwide data shows that there is around 5-10% yield drags or decreases than their non-GM counterparts.

In reality, even in the USA, the biggest promoter of GE technology, GM crops were found to be lower than or at best equivalent to non-GM crops when it comes to yields.

One study conducted in the U.S. demonstrated that Bt corn yields were anywhere from 12% less to the same as similar conventional varieties. Average cotton yields have stagnated since the adoption of Bt cotton in the U.S., Argentina, Australia and Colombia. While cotton yields have

increased in China, it is still questionable whether the increased productivity is attributable to Bt cotton. For example, Xinjiang, the Chinese province with the greatest cotton production and the highest average yield in the nation, grows mostly conventional non-GM cotton, and its positive yield performance is due to other production factors not related to Bt technology.

In India, the state of Gujarat contributes the single largest chunk to the production of total cotton in the country. In 2007, Gujarat's contribution to Indian cotton production was around 39%. The inclusion of Gujarat into national figures gives a skewed picture to overall cotton production analysis. In the past six years (the years of Bt Cotton introduction and cultivation in India), irrigated cotton increased by around 33% leading to increased yields in the state.

Despite the hype that the biotech proponents make about Bt Cotton being the cause for increased yields in the state and in India, Gujarat's official assessment on Bt Cotton says: *"The productivity of cotton crop also increased due to increase of irrigation facility by massive water harvesting programme. On other hand, rainfall is also very good during past 3 years. Parameters like irrigation facility, good monsoon, use of drip, low pest pressure, black soil and farmers' experience are contributing in the success of cotton crop in the State".*

In other states like Madhya Pradesh, Andhra Pradesh, Karnataka and Tamil Nadu, yields have shown a very uneven trend over the past six years, belying the claims of Bt Cotton supporters that there has been a steady increase in yields with increased adoption of Bt Cotton. In a state like Madhya Pradesh, the 5-year average yields in the state before the advent of Bt Cotton have been higher than after the introduction of Bt Cotton!

In the USA, the USDA (United States Department of Agriculture) itself records that there is no economic gain or economic loss with some GM crops. Studies have shown that adoption of GE technology in most places is for the "convenience effect", especially in a particular socio-economic setup of large landholdings and only a small percentage of population dependent on farming.

In conclusion, there is no evidence of GE crops increasing productivity of food in agriculture. On the other hand, simple changes in management practices like in the case of System of Rice Intensification (or SRI or the Madagascar system of rice cultivation) have shown that yields of major food crops like paddy can be increased through lesser use of inputs like water without having to use GE or hybrid seeds.

Further, there is utmost caution needed in resorting to GE technology for improvements in food security since GE crops have shown themselves to be unpredictable and unstable, especially in stress conditions. In the era of climate change, it would be extremely unwise to resort to GM crops for increasing food production!

7. WON'T GE CROPS MEAN MORE NUTRITIOUS FOODS?

It is usually argued by the biotech proponents that GE crops will mean more nutritious foods in terms of protein/vitamin enriched or fortified foods. While one and a half decades of commercial cultivation of GM crops and scores of years of research has not given us any evidence of that, there is in fact evidence that GE crops might mean altered nutritional composition in several products.

One of the usual cases that GE proponents like to talk about to illustrate their claim is that of Golden Rice.

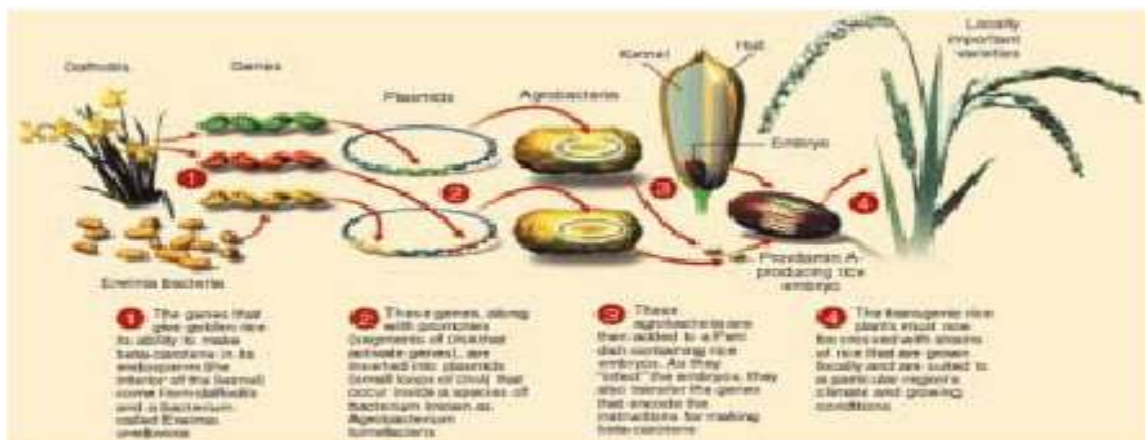
Golden Rice

Facing severe opposition against hazardous and profit driven efforts related to insect-resistant Bt plants, herbicide-tolerant plants and the highly-controversial terminator technology, biotech companies came up with a new *mantra* - 'Golden Rice'. This is Rice which is engineered with certain genes from daffodils (*Narcissus pseudonarcissus*) and bacteria (*Erwinia uredovora*), to modify the metabolic pathways to produce Betacarotene, which is a precursor to Vitamin A.

Naturally cultivated rice does not have the precursor chemical Beta Carotene or other carotenoids that the body converts into Vitamin A molecule called Retinol. Plants are usually rich in carotenoids but in rice crop, they reside in the greener parts of the plant [which are discarded] and not in the endosperm.

The technology was developed by a team of scientists led by Ingo Potrykus and Peter Bayer of the Institute of Plant Sciences, the Swiss Federal Institute of Technology, Zurich, Switzerland, and the Centre for Applied Biosciences, University of Freiburg, Germany, respectively. The research was sponsored by the Rockefeller Foundation (1991-2002), the European Union under a European Community Biotech Programme (1996-2000) and the Swiss Federal Office for Education and Science (1996-2000).

Vitamin A Deficiency (VAD) is one of the world's major nutritional problems. More than 100 million children in Asia and Africa do not get enough Vitamin A and it is a leading cause of blindness in these countries. An estimated two million children die each year indirectly as a result of persistent Vitamin A deficiency. Vitamin A is provided by liver, egg yolk, chicken, meat, milk, butter etc. Beta-carotene, the precursor of Vitamin A is provided by dark green leafy vegetables, spinach, carrot, pumpkin, mango, drumstick and many other leafy vegetables which are often considered as weeds by modern agriculture. The widespread Vitamin A deficiency is mainly because of reduction in food diversity and lack of economic access to foods rich in minerals and vitamins.



Will Golden Rice really mean more nutrition?

The appropriate gene coding for the required enzymes was identified in daffodils (*Narcissus pseudonarcissus*) and in a fungal agrobacterium (*Erwinia uredovara*). These genes were introduced into Taipei 309 Rice with the aid of *Agrobacterium tumefaciens*. One to three transgene copies were found in transformed plants. Ten plants harbouring all the four genes showed normal vegetative characteristics, were fully fertile and had yellow endosperm indicating carotenoid formation. One gram of rice grains from plants grown in the greenhouse from immature embryos injected with these new genes was found to contain 1.6 micrograms of carotenoid.

Given the figure of 1.6 micrograms of carotenoid per gram of rice, we can calculate the bio-availability of Vitamin A from this Golden rice. The daily cereal intake by pre-school children who are one to three years, and four to six years, is 124 and 185 grams respectively.

Currently, Indian Council of Agriculture Research [ICAR] is engaged in transferring the Golden Rice genes into Indian varieties/ hybrids and has been announcing that this will be available for Indians soon!

Given these carotenoid levels, the amount of carotene intake through Golden rice would therefore be 198 microgram/day and 296 microgram/day respectively for these age groups of children. The Vitamin A or Retinal Equivalent (RE) is 1/6th (according to WHO) and 1/4th (according to ICMR) of the total carotene intake. Assuming a Required Daily Intake (RDI) of 400 RE, Golden Rice consumption would contribute to only 8 to 12.5 % of the requirement for children in the one to three years' age group and 12.5 to 18.7 % for those in the four to six years age group. In adults, a similar calculation can be done for a daily cereal intake of 420 g for males and 345 g for females and RDI of 600 RE. The bioavailability of Vitamin A from Golden Rice works out to be 18 to 26% for males and 15 to 23% in females. Further, in these calculations, one has assumed that all the converted Vitamin A is available. This is not realistic since Vitamin A is fat or oil-soluble and not water-soluble. Therefore the loss of Vitamin A during cooking makes Golden Rice even more unfavourable.

The story of Golden Rice is a good illustration to show that GE crops which are supposed to be nutrient-enriched are not the solution that they are touted to be, especially in the face of sustainable solutions present in diverse cropping and food systems. Uncultivated foods (mostly greens) which went hand in hand with traditional farming practices are known for their nutritional properties; however, the push for intensive agriculture has eroded such affordable and nutritious options for the poor.

8. IS THERE SCIENTIFIC EVIDENCE THAT GMOs CAN ACTUALLY CAUSE HARM?

As mentioned earlier, the science behind GE is reductionist and unreliable. Gene regulation within a genome is not fully understood by modern science and for that reason, not replicable. GE however presumes that it is replicable and uses a variety of other materials like promoters, markers etc., to get a trait expressed. However, the unintended consequences are many. For instance, it has been found that with genetic engineering, there is coding for proteins of unknown functions that was discovered! The impacts of this are unknown.

There are three or four distinct possibilities emerging from the science and technology of GE and most of these are categorized under the framework of “biosafety” (the safety or impact implications from a GMO on human beings, on other living organisms, on the environment etc.).

There could be another set of possibilities on the agronomic front, on the actual performance of a GE crop vis-à-vis a conventional counterpart in terms of yields, pest incidence, crop economics and so on. Here in this section, we discuss mostly the bio-safety related aspects of GE crops.

A. Alterations to the toxicity or nutritional value of a cultivar

This means that a food that has been considered safe so far might have an altered constitution and impact due to changes induced, related to allergens, toxins, vitamins, anti-oxidants etc. Some GE foods are found to be missing on some vitamins that the non-GE counterparts had. Food safety and quality is therefore changed. However, testing does not capture these changes before the release of the GMO for commercial use since one does not even know all the right questions to ask, leave alone have testing designs and methodologies worked out for assessing such impacts!

It has to be remembered here that it is the interaction of human beings with nature, with careful breeding and selection that has resulted in a vast variety of cultivated and uncultivated foods that are available to us today with a variety of nutritional compositions. More importantly, this food has been made safe by careful work over centuries. GE however has the potential to make food that is safe to become unsafe.

The following are results from some studies taken up to assess the safety/toxicity of GM foods – it is worth noting that very little research of independent nature is available on a variety of potential impacts of GE crops, for transparent scientific review and funding is hard to come by for such research to take place.

1. In 1996, a major GE food disaster was narrowly averted when researchers in Nebraska in the USA learned that a Brazil nut gene spliced into soybeans could induce potentially fatal allergies in people sensitive to Brazil nuts. People with food allergies, whose symptoms can range from mild unpleasantness to sudden death, may likely be harmed by exposure to foreign proteins spliced into common food products.

2. In 1998, Hungary-born nutrition and toxicology scientist Dr Arpad Puzstai in the Rowett Research Institute in Scotland, UK, reported preliminary results from a 3-year, multi-centric study of rat-feeding tests with GM Potatoes. He and his team found unexpected and worrying changes in the size and weight of the body organs of rats fed with GM potatoes. Liver and heart sizes were getting smaller, and so was the brain. There were also indications that the rats’ immune systems were weakening. For reporting this on a TV show, he was sacked from his job and discredited by the scientific community. It is suspected that the damage to the gut lining of the rats fed with GM potato could be linked to the Cauliflower Mosaic Virus promoter used in almost all GM crops that are being developed!

3. Recently released reports from a secret study done for Monsanto in 1998 by Institute of Nutrition of the Russian Academy of Medical Sciences and suppressed for 8 years, showed that GM potatoes did considerable damage to the organs of the rats in the study. In comparison, the rats in the "control groups" which were fed on normal potatoes or on a non-potato diet were healthier and had much less organ and tissue damage. The potatoes used in the study were Monsanto GM New Leaf potatoes bred in 1995 from the Russet Burbank variety to be resistant to the Colorado Beetle. The GM event was registered as 082, and the potatoes are included in the Bt group of GM crops. They also contain an antibiotic resistance marker gene. The GM potatoes were the most dangerous of the feeds used in the trials and on the basis of this evidence, it was concluded that they cannot be used in the nourishment of people.

4. A 1999 study by Dr. Marc Lappe published in the Journal of Medicinal Food found that concentrations of beneficial phyto-estrogen compounds thought to protect against heart disease and cancer were lower in GE soybeans than in traditional strains. This has implications for food quality and nutrition with Genetic Engineering.

5. In a study taken up by a Russian scientist called Irina Ermakova [at the Institute of Higher Nervous Activity and Neurophysiology of the Russian Academy of Sciences, with preliminary results reported in 2005], most offspring of GM-Soy-fed rats died in addition to showing growth abnormalities when compared to the offspring of non-GM-soy-fed rats. Within three weeks, 25 of the 45 (55.6%) rats from the GM soy group died compared to only 3 of 33 (9%) from the non-GM soy group and 3 of 44 (6.8%) from the non-soy controls. The results indicate that conventional soy did not have a negative effect on the death rate, while a GM soy diet increased the death rate by a factor of eight. The soy she was testing was Monsanto's Roundup Ready variety, which has bacterial genes inserted in it to withstand applications of glyphosate [of Monsanto's brand called Roundup].



Further, in 2007, in a study done by Vavilov's Agrarian University in Russia, it was found that a herbicide resistant RoundUp Ready Monsanto soy approved for human consumption in the Russian Federation and in many other countries, induced serious changes in the morphology of viscera (liver, kidney, testis) of mice, in their histological and cell structures. GM-soy also is found to impact the size of litters, and the mortality of the young.

Photo: On top is a mouse fed with GM soya and at the bottom is one fed with non-GM soya, in this Russian study

6. Studies at the University of Urbino in Italy (2002 to 2005) showed that mice fed with GM Soy had misshapen nuclei in their liver cells, suggesting a possible response to an elevated level of toxins. These mice also had dramatic reductions in enzyme production in their pancreas. Published reports from the University of Urbino, Perugia and Pavia indicate that GM soya fed to young mice affected cells in the liver, pancreas and testes.

7. Cooked GM soy is reported to contain twice the amount of soy lectin, which can also block nutrient assimilation. The gene that is inserted into GM soy produces a protein that resembles known allergens.

8. The only human feeding trial on GM crops was done in Newcastle upon Tyne, England. Results published in Nature Biotechnology in January 2004 showed that when humans ate GM soy products, the gene that had been inserted into the soy transferred into the DNA of gut bacteria. This means that long after you decide to stop eating GM soy, your own gut bacteria may still be producing this potentially allergenic protein inside your digestive tract.

9. In 2003, Filipinos living next to a GM cornfield developed skin, respiratory, and intestinal symptoms and fever, while the corn was pollinating. The mysterious symptoms returned the following year, also during pollination, and blood tests on 39 of the Filipinos showed an immune response to the Bt toxin – this was the result of the GM corn.

10. In 2004, a Monsanto study report on a new type of GM Bt maize kept secret showed significant harm caused to rats fed on the variety, called MON 863. The study showed kidney abnormalities and unusually high levels of white blood cells.

11. In 2005, scientists at the Commonwealth Scientific and Industrial Research Organization [CSIRO] in Canberra, Australia tested a transgenic pea containing a normally harmless protein in bean (alpha-amylase inhibitor 1), and found that it caused inflammation in the lungs of mice and provoked sensitivities to other proteins in the diet.

The US Food and Drug Administration had data dating back to early 1990s showing that rats fed GM tomatoes with anti-sense gene to delay ripening (of Calgene company) had developed small lesions in their guts. Soon after, the regulatory systems in the USA were changed!

Some researchers warn that Antibiotic Resistant Marker [ARM] genes used in most GE crops might unexpectedly recombine with disease-causing bacteria or microbes in the environment or in the guts of animals or people who eat GE food. German researchers have found antibiotic resistant bacteria in the guts of bees feeding on gene-altered rapeseed (canola) plants.

There are other studies which have looked at the allergenicity, immunogenicity etc., of various Bt genes, of the cauliflower mosaic virus and so on and the findings reinforce the findings of some of the above studies.

B. Changes that have ecological impacts

There are different environmental impacts that could be expected from genetic engineering in agriculture which can be classified as impacts on the pest & disease ecology, on unintended beneficial organisms, on soil microbial activity, on pest and weed resistance and finally, biological contamination due to gene transfer.

a) Increased outcrossing is a very serious hazard, flowing out of GE. Gene flow from transgenic cultivars to non-transgenic cultivars is a distinct possibility. Accumulation of such transgenes in related and wild relatives results in many untested products and there could be a collective impact on eco-systems and food safety. Even physically, such GE crops cannot be segregated from non-GE crops in most growing conditions.

There is a possibility of reduction in biodiversity due to genetic displacement, given the advantage that the transgenic plant has over its eco-system on certain aspects.

Biological and/or physical contamination of seed stocks is irreversible, in addition to contamination of wild/related species. It is actually contamination from field trials that resulted in tonnes of long grain rice in the USA having to be withdrawn from the international markets. This resulted in losses of millions of dollars to US rice farmers as country after country rejected imports from the country. There were 39 cases of crop contamination (of non-GM crops from GM crops) in 23 countries in 2007, and more than 200 in 57 countries over the last 10 years.

b) Similar are unintended effects on beneficial insects now captured as scientific evidence through studies. If our impact assessment mechanisms are broad enough, such impacts can be captured as both direct as well as indirect effects. Long-term exposure to Bt (Cry1Ab) pollen from two Bt maize types, MON 810 and Bt 11, has recently been found to cause adverse effects on larvae of the monarch butterfly, even though these strains of Bt maize contain less Bt in their pollen than Bt 176. Although no short-term effects (4-5 days) were noted, longer-term studies (2

years) found over 20% fewer monarch larvae reached the adult butterfly stage when exposed to naturally deposited Bt pollen. Numbers of beneficial ladybird beetles were found to be lower in Bt maize plots than in non-Bt maize. Ladybird beetles feed on many food sources including on aphids, pollen, European corn borer eggs and other pest eggs, so have several routes of exposure to the Bt toxin.

In 2007, a new study published in the Proceedings of the National Academy of Sciences, USA, done by Loyola University researchers shows that Bt toxin from pollen and agricultural wastes from Bt Corn fields entering adjacent water streams impedes the growth of caddis flies, a group of aquatic insects very closely related to the crop's pests. The researchers examined the transport of crop litter (pollen, leaves and cobs) in 12 streams near a heavily farmed region of Indiana and established that a pathway does exist for Bt toxin to enter into the streams. They further fed crop litter to the flies in a lab and found that the insects grew only half as much as those on a toxin-free diet. In addition, very high doses of pollen in the water were shown to kill as many as 43% of the caddis flies, the non-targeted insects.

c) There are alterations in soil organisms and their activity due to GE plants and their exudates/interactions with the soil biosphere around them. An Australian CSIRO study captures this. This might have implications for the subsequent crops grown on this soil including in terms of growth, plant physiological functions and in terms of diseases. *This is as yet an under-studied area in impact assessment.* According to the US Environmental Protection Agency's (EPA) scientific advisory panel, Bt proteins "are likely to be present in the rhizosphere soil not only throughout the growth of the crop, but perhaps long after the crop is harvested". The Panel drew attention to studies that showed Bt could persist in certain soil types for up to 234 days.

Horizontal gene transfer from GM crops to soil bacteria (beneficial or pathogenic) cannot be ruled out.

d) Pest ecology is found to be shifting quite dramatically in crops like Bt Cotton. GM crops meant to control a particular group of pests are changing the pest picture on a crop with secondary pests becoming a major problem. There is also resistance building up in the targeted pests creating what are being termed as 'super pests' – pests on which newer and newer actions have to be deployed to control them.

Data from China shows that use of Bt crops can exacerbate populations of other secondary pests, including aphids, lygus bug, whitefly, Carmine spider mite and thrips. Studies there have shown significant reductions in populations of the beneficial parasites *Microplitis* sp. (88.9% reduction) and *Camponotus chloridae* (79.2% reduction) in Bt cotton fields.

A Cornell University study in 2006 showed that in China secondary pests have become major pests, to the extent that pesticide use has shot up to the same levels as at the time of introduction of Bt Cotton.

Another recent study (2007) by the University of Neuchatel, Switzerland, researchers found that in Bt maize lines, there are higher amino acid levels compared to its non-GM counterpart, which made it much more susceptible to aphid infestation.

A University of Arizona study, published in 2008, documented the first case of field-evolved resistance in bollworms, targeted by Bt crops and this issue is no longer hypothetical. This is evolution in action, as per the researchers. Bt-resistant populations of *Helicoverpa zea* were found in more than a dozen crop fields in Mississippi and Arkansas between 2003 and 2006. A team of University of Arizona entomologists analysed published data from monitoring studies of six major pests of Bt crops in Australia, China, Spain and the US, collected from 1996 onwards and came up with these findings.

The researchers concluded that Bt Cotton and Bt Corn have generated one of the largest selections of insect resistance ever known! These findings confirm the worst fears of critics about GM crops.

e) Increasing adoption of herbicide resistant crops meant that weeds are developing faster and more potent resistance to herbicides, thus converting themselves into 'super weeds'.

The increased use of herbicides like glyphosate in turn pose their own problems – glyphosate is known to impact beneficial insects, invertebrates and fish; by destroying their habitat, glyphosate also impacts small mammals and birds. Further, glyphosate is linked to adverse health impacts. Glyphosate also affects plant nutrient fixation functions as has been discussed earlier.

Increased Horizontal Gene Transfer (HGT) is another potential from GM crops – this could potentially have health as well as environmental impacts. HGT involves transfer of genetic material between cells or genomes belonging to unrelated species by processes other than reproduction. HGT normally occurs in nature mediated by bacteria and viruses. GE is considered to speed up this process. Other routes of HGT are direct assimilation and integration of naked transgenic DNA by all kinds of cells, direct injection of transgenic DNA by insects with sharp mouthparts etc. HGT leads to unintended contamination with unpredictable consequences. For instance, in one study published in 1999 in Applied & Environmental Microbiology, it was reported that human consumption of biotech food resulted in transfer of antibiotic resistance gene present in the engineered DNA to bacteria normally present in human saliva and respiratory tract.

In 1999, a paper published in Microbiology Ecology reported that under field conditions, transfer of antibiotic resistance gene from biotech beetroot crop residue to soil bacteria was detected.

Similarly, in 2001, it was found that Agrobacterium, which was widely believed not to infect animals and hence not transfer engineered genes from plants to animals, mediated transfer of DNA in human cancer cells. The results of the University of Newcastle study wherein DNA fragments from RR soy were found in the intestines of human volunteers has been mentioned in the earlier section.

C. Changes that have implications for food security

At a larger level, GM crops pose serious implications to food security given their unpredictability and stress intolerance. This could mean unexpected crop failures, especially in the age of climate change. Therefore, instead of actually eliminating hunger and malnutrition, GE crops have the potential to wipe out existing food security.

Other reasons which threaten food security if such food crops are derived from genetic engineering are:

- newer pests and diseases emerging over crops
- possible impacts on soil microbial activity
- "yield drag" phenomenon with GE crops, especially herbicide-tolerant crops
- in countries like India where food security of people is closely linked their purchasing power (and not just about a community's or the country's ability to produce enough food), herbicide-tolerant crops will eliminate employment opportunities for the poorest in the villages and will cause further food insecurity
- food safety and altered nutrition with GM crops will also impact food security

It has to be understood that the hazards of GE mainly flow out of the transgene-induced instability. Such changes at the genomic level have the potential to create evolutionary level changes. It has also been found that larger the number of genes and longer the transgenic DNA cassette, the greater the instability.

It is now very clear that with genetic engineering, changes certainly happen from the molecular to the eco-systems level and that the notion of “substantial equivalence” with which the GE industry sought to equate GE with non-GE just is not true. It is also obvious that not all changes are immediately apparent or can be captured in tests designed with a narrow scope. We do not even know what questions to ask for many of these aspects to be studied!

The biggest hurdle in realistic and scientific safety assessment in the case of GE crops is that genetic sequences of the products being tested could be different than that which had been described by the biotech companies during regulatory approvals. What has been tested may not be what will exist after commercial cultivation begins! It is understood that this is probably because the inserted genes rearranged over time. In the case of Roundup Ready Soybean, for instance, a Brussels lab confirmed that the genetic sequences were different than what was originally listed. But the sequences discovered in Brussels didn't match those found by the French. This suggests that the inserted genes are unstable and can change in different ways. It also means that they are creating new proteins—ones that were never intended or tested.

Even the most stringent regulatory impact assessment regime will be flawed given that humankind does not have an understanding of the totality of the complex regulatory processes at the genetic level and given the very nature of instability induced due to GE.

It follows logically that unstable genes make accurate safety testing impossible.

9. WHAT IS THE SITUATION WITH REGARD TO GE, WORLDWIDE?

Even though there is growing evidence that GE is an imprecise, unpredictable and irreversible technology, it is continued to be projected as “frontier science” and as the only alternative to many of world’s farming problems. It is mostly the big corporations with transnational operations which are behind the push, supported by the American government and institutions like the WTO, built to support such corporations. GE has a careful image built around it with a lot of Public Relations resources that go in – that of being a precise science, an ecological alternative, as frontier science, equated with development, progress etc.

Public sector agriculture scientists believe in transgenics with the same kind of religious faith that made them support chemical farming during the Green Revolution (forgetting that it is the same corporations which gave us chemical farming and the accompanying farming disaster and are now great proponents of GE on ecological grounds!).

In India, many of our politicians like to ask us why we should not adopt GM crops like the rest of the world. ‘Why are there so many concerns being expressed here when there are no problems in the countries that have adopted it’, they would like to know.

However, one look at the reality with regard to GE worldwide will give us enough reasons to apply precaution with the technology, especially in our growing conditions.

CONSIDER THIS:

- ✦ More than twelve years after the first GM crop was allowed for commercial cultivation, only 14 countries of the world have opted for GM crop cultivation in any considerable way, in a world which consists of more than 200 countries! Even in these 14 countries, GE crops make up less than 3% of the total agricultural land in those countries on an average! Only four countries plant GM crops on more than 30% of their arable land – the USA, Argentina, Paraguay and Uruguay.
- ✦ Over 90% of the area planted to GM crops is found in just 5 countries located in North & South America: the US, Canada, Argentina, Brazil and Paraguay.
- ✦ One country alone, the United States, produces over 50% of the world’s GM crops; the U.S. and Argentina together grow over 70% of all GM crops.
- ✦ Even here, only a few crops dominate – cotton, maize/corn, soybean and canola constitute almost all sown GE crops. Biotech versions of rice, wheat, tomatoes, sweet corn, potatoes and popcorn have been soundly rejected as unacceptable in the world market place. North American farmers themselves are not keen on GM wheat.
- ✦ Most GM crops go into cattle feed and not human food. Half of US corn goes into cattle-feed and 98% of US soymeal consumption is by livestock, for instance.
- ✦ Only one trait – herbicide tolerance – is present in more than 80% of the GM crops sown in the world today. The herbicide that they are mostly designed to tolerate is Monsanto’s Roundup [Glyphosate, which has many documented negative impacts]. Next to this trait of herbicide tolerance is insect tolerance in the form of Bt Cotton and Bt Corn, which accounted for 19% of all GM crops.
- ✦ 90% of all GM crops worldwide are estimated to have Monsanto’s “traits”. Monsanto holds IPR rights over the technology and the product in most of these cases. Monsanto is

also known to play a key role in creating a regulatory and policy regime for GM crops in the USA and in other places too (directly or through the US government). One of the methods employed is of revolving doors.

- ✦ Globally only 6% of the total cropland has come under GM crops, around 15 years after this “frontier technology” was given a formal go-ahead.

In the USA: Let us also look at the situation in the USA, which is behind an aggressive push for GM crops world over. In India too, it is the American multinationals which are promoting GM crops through their Indian subsidiaries. Bilateral aid agencies like USAID, along with American NGOs like Rockefeller are also promoting consortiums in the South Asian region to push biotech crops here. For example, a pan-Asian project called ABSP II is supported by USAID and American universities in its bid to draw in public sector agriculture universities in India into GM food crops like Bt Brinjal so that the acceptability of the technology goes up. A new bilateral agreement called Indo-US Knowledge Initiative on Agriculture is also seeking to support research on transgenics and promote them through public sector research institutes.

In the USA, which still has the largest tracts of GM crops in the world, the major crops are cotton, wheat, soy and corn. It is interesting to note that over 75% of cotton, 47% of wheat, 40% of soy and 19% of corn are exported into world markets. In fact, in 2006, there were record exports of agricultural products from the USA. These export markets will be adversely affected if there is resistance to GM crops, understandably and therefore, there are great stakes for the USA to get more and more countries to accept transgenics.

It is also important to note that half of US corn goes into cattlefeed and Livestock feed is 98% of the US soy meal consumption. Therefore, the markets are really mostly in cattle feed and not food, whereas in the developing countries, they are talking about genetically engineering the major staple crops like rice meant for human consumption. Most of our political leaders are not aware of these details.

Another interesting aspect of the American biotech history is that so far, seventy distinct biotech events across 14 different crops and with ten traits have been approved for commercial cultivation in the USA. However, only soybean, corn, cotton and canola in that order are grown in a majority of GM crop land that too with two traits. The first two go mostly for cattlefeed and cotton is in any case a non-food fibre crop.

The American regulatory regime is quite suspect – it is known for its laxity, pro-corporate frameworks, lack of scientificity and lack of rigour in its safety assessment of GE crops. Several regulatory processes are voluntary on behalf of the companies and there is no independent research that feeds into decision-making. There is evidence that precautionary evidence is often overruled.

It is also important to note the socio-economic context of farming in the USA and clearly understand the differences that it holds to our situation. Today, only 2% of the US population (that is, around six million people) live or work on 2.1 million farms in the USA. A small farmer would still have hundreds of acres of farm land. In India, on the other hand, around six hundred million people continue to depend on farming for their livelihood and an overwhelming majority of them live off landholdings that are lesser than one hectare. In the USA, there is probably a need for agricultural technologies that do not depend on manual labour (this is not to say however, that such technologies are indeed desirable). It would be foolhardy to import such technologies into the Indian context, however, without understanding the socio-cultural implications.

What is most interesting to note is that despite GE, much farming in the USA requires huge subsidies from the State to prop it up. WTO and trade rules did not matter when it came to convenient interpretation and re-ordering of such trade rules to suit American interests. That is

not the case here in India, though. Farmers are already in an extremely vulnerable situation and no technology that increases the risk should be allowed in.

Monsanto, a key player: A discussion on GM crops worldwide and in India would be incomplete without sharing a few facts about Monsanto, the American multinational company, which has proven itself to be a key player in the global GM push. Monsanto is the biggest seed company in the whole world – there is a high concentration of the global seed industry in Monsanto's hands. It also holds more than 600 patents on technologies, traits, genes, seeds and plants. Such patents actively disallow others the use of this material (even if it is a critical question of survival).

In North America, powered by such patents and the legal backing that they provide, Monsanto has a Technology Agreement with each farmer who buys its seeds in North America. There is a separate department with around 75 employees to spy over and inspect farmers and ensure compliance with such technology agreements. Scores of farmers have been sued and jailed for violations. Monsanto has collected tens of thousands of dollars from such farmers as penalties for violations.

There is also evidence that Monsanto manipulates the markets in such a way that the best seed varieties from all subsidiaries are supplied only as GM versions and non-GM versions are pushed out of the markets. In Indonesia, Monsanto is known to have paid bribes to scores of regulators and officials for getting its Bt Cotton approved. It had to pay the US government around 1.5 million dollars in fine for such improper payments in Indonesia.

The case of Percy Schmeiser, a Canadian farmer, is well known, where his canola was found to be contaminated with Monsanto's GM traits even though he planted non-GM canola. Monsanto took him to the Supreme Court of Canada on charges of violations of its IPRs. Surprisingly, the Supreme Court of Canada agreed with the arguments of the company [rather than see that the farmer's right to remain GM free has been violated] that this contamination of non-GM was indeed a violation of Monsanto's patent!

Monsanto is known for suppressing important data from biosafety tests on its GM products from regulators and the public – in the case of a Bt Maize line, there was incriminating evidence about the safety of the product from such tests done by the company itself.

In India, Monsanto's restrictive trade practices have been challenged by the Andhra Pradesh government with regard to the exorbitant seed prices charged by Bt Cotton companies as a result of the high amount of royalties that they are paying to Monsanto.

Monsanto and its subsidiaries also failed to compensate farmers for severe crop failure of Bt Cotton, even though the government ordered it to, within a voluntary agreement it had with the state government of Andhra Pradesh.

It has showcased its lack of accountability towards farmers in these numerous ways. Ironically, Indian GM regulators believe in and cite Monsanto's studies related to bio-safety as well as situation on the ground and use such data for decision-making on behalf of all of us!

To sum up, what is really interesting to note is that there is no large scale adoption of the technology as the industry would like everyone to believe. In fact, in most areas of Europe and elsewhere, consumers have been strongly and consistently rejecting any GE in their food and are forcing market players to put out only non-GE stuff on the market shelves. More and more countries are imposing fresh bans on GE crop cultivation. Activists are challenging biosafety of GE crops in courts and getting newer bans imposed. The reality with GE is that of growing rejection and resistance and declining acceptance, reflected as bans imposed by countries through legislations or through Courts or even if no such change is happening at the macro-level, by communities declaring themselves to be GE-Free and taking a pledge not to allow GE anywhere into their community.

In India too, more and more areas are declaring themselves GE-Free.

Uttaranchal state government has announced itself to be GE-Free. Kerala and Orissa state governments have announced that they will not allow GM food crop trials in their states.

Thousands of villages in Uttar Pradesh, Andhra Pradesh, Tamil Nadu, Maharashtra, Orissa and other states are also using their constitutional authority to declare themselves GE-Free.

Clearly, there are more GE-Free places in the world now than when GE first began. The picture worldwide, therefore, is one of declining acceptance and growing rejection. To move ahead on GE crops in such a situation, as Indian government wants to do, is a foolhardy step.

10. WHY ARE GROUPS FIGHTING GENETIC ENGINEERING IN INDIA?

There is utmost importance to be given to comprehensive assessment of agricultural technologies to be deployed in a country like India. Here, millions of lives and livelihoods are closely tied to agriculture and agricultural technologies deployed.

Agri-technologies have the potential to impact not just human beings but living organisms in general, in addition to changing the composition of our natural resources like soil, air and water. They have a vast impact spatially, given that a majority of our land area is under farming. They also leave their impacts temporally even to the extent of scores of years and to the extent of impacting our future generations. Therefore, any agricultural technology that is being deployed on a large scale requires a careful and comprehensive assessment for its impacts and understanding of its political economy (who is pushing it, for what reasons, with what differential impacts etc.) before it is blindly promoted as the only alternative – as is happening with transgenics at present.

To take a small example, thousands of agricultural workers are poisoned each year due to inhalation of agricultural pesticides for instance. Their very right to life is being violated by this technology. When pesticides were first introduced, they were promoted as being harmless for human beings. However, tough lessons have been learnt since then about the actual effects of pesticides. Genetic Engineering also will have a huge bearing on millions of people in the country – whether it is farmers or consumers.

GE in fact is more hazardous for a variety of reasons – this is a technology that is irreversible as it relates to living organisms capable of reproducing themselves and out-crossing into other organisms. This is not just about non-living chemical molecules expected to degrade somehow or the other. This is intentional 'contamination' in perpetuity, which cannot be recalled once released into the environment. The potential impacts can even be evolutionary in magnitude but brought in at such a rapid pace that the planet's eco-systems would have really no time to adapt. Therefore, with GE we are talking about a technology that makes changes inevitable from protein networks at the molecular level to evolutionary networks at the planetary level.

As discussed earlier, there are many hazards associated with the technology including implications on food safety and food security. After having built up national food security at a great expense to our natural resources and after marginalizing our many dryland pockets in the country, we cannot afford to erode such food security through the deployment of genetic engineering.

Most farmers in this country are into rainfed farming and are dependent on the vagaries of monsoon coupled with climate change. A shift to GE technology would mean increased risk to vulnerabilities of unpredictable results, crop failures, intolerance to extreme conditions, increased costs of cultivation and so on. This would mean increased vulnerabilities in their livelihoods and that too, with no public support systems to buffer the vulnerability (no social security or crop insurance for Indian farmers as in the case of the developed world).

There is no evidence whatsoever that transgenics are safe; there is certainly evidence that they pose serious hazards based on which a precautionary approach has to be adopted.

Other socio-political implications: In addition to environmental and human health implications from GE, there are many socio-political implications to the country in general and the farming community in particular flowing from transgenic agriculture:

- ☒ **GE crops de-skill farming communities:** There is now evidence to show that technologies like GE lead to de-skilling of farmers to the extent that their environmental learning is eroded and their own knowledge of their eco-systems discounted. It is once again the political economy of the technology which is a major cause for this. Seed-related decisions in farming should ideally be disconnected from money/market power driving such decisions but should be based on the local environment and resources that the farmer has to manage. This is a country which has witnessed enormous innovations from farmers over centuries. The varietal diversity developed by farmers to suit their own needs and tastes is seldom seen in the intensive agriculture models of the western world, for instance. Such innovation will be stifled by the rapid nature of market-driven technologies and the pace at which they are imposed on farmers.
- ☒ **GE crops displace agricultural employment:** most GE crops in the world today are created to be herbicide-resistant. In India, (de-) weeding is the most important agricultural activity that fetches employment for millions of farming women across the country. If this activity is replaced by chemicals due to the introduction of herbicide-tolerant GE crops, these employment opportunities would be lost to the women. This would have tremendous adverse impact on their livelihoods and the local economies, in addition to causing other problems related to chemical contamination.
- ☒ **GE crops erode farmers' self reliance:** Technologies such as GE would make farmers dependent on profit-seeking corporations who are only concerned about expanding and sustaining their markets. Local economies would be drained to fill the coffers of corporations, with ever increasing input costs for farmers (the technology is such that it will call for more and more inputs) and with output prices offering no guarantees at all. Majority of Indian farmers are small and marginal with very little support present in terms of institutional credit, market procurement etc. They will be clearly affected by the technology. While the economic viability is thus in question, this would also mean dependence on the choices made by the corporations which may not be based on farmers' actual needs.
- ☒ **GE crops are a threat to ecological alternatives in agriculture:** For those farmers who wish to be organic (in a certified or non-certified context) and for those who wish to use their own traditional seeds, GE poses a clear threat. Contamination from GE seeds used by others is inevitable either in a biological or a physical sense.
- ☒ **GE crops raise many unanswered ethical and moral questions:** GE also poses many ethical and moral questions. For instance, is meddling with nature to the extent of making inter-species genetic transfer acceptable, especially given the unknown nature of impacts? Should humankind be seeking control over nature in its pursuit of science & development, or should it take a cooperative approach? Does not GE violate inter-species and inter-generational equity principles by taking all the decision for the now and the present, for the so-called benefits of just human beings? GE, by bringing in genes from animals into plants (fish genes into tomatoes, for example), also confuses the socio-cultural and personal preferences related to vegetarianism and so on. It leaves very little choices to farmers or consumers. Is that ethical?
- ☒ **GE crops are violating democratic values:** More fundamentally, it is not clear how, where, when and why has it been decided that transgenic technology is needed in Indian farming. What processes have been adopted to consult the farmers and consumers to be affected by such policy decisions? Has it been compared with other safer, affordable alternatives?
- ☒ **GE crops threaten our trade security:** An overwhelming majority of countries in the world today have rejected or applied the precautionary principle on GM crops. There is widespread consumer rejection to genetic engineering, GMOs, products with GE ingredients and products developed from that process. This has serious implications on our trade security. Historically, agriculture has been a net foreign exchange earner in India. A major part of

Indian international trade even today, in a vastly liberalized environment, consists of agricultural commodities. Given the consumer rejection and suspicion that accompanies GE, we cannot afford to opt for the technology and jeopardize these trade opportunities.

- ☠ **GE crops' regulatory regime & enforcement is unreliable and even anti-farmer:** As the following sections would illustrate, GE regulation in this country is unscientific, lacks comprehensive assessments and is pro-industry rather than pro-farmer/pro-consumer. The enforcement is worse, with many instances of field trials of GE crops being taken up by companies without even obtaining prior informed consent of farmers in whose fields such trials are laid out. Regulatory regimes are imported from countries like the USA and dictated (directly/indirectly) by MNCs like Monsanto. They are the ones who propose testing protocols for various biosafety tests and the regulators just accept these, even if they don't conform to some research guidelines already laid down. There is no independent research taking place in the country for a variety of reasons including dearth of funds for such research. Most research is taken up by GM crop developers themselves who invest their R & D funds on it – they are hardly likely to come up with data that will point out problems or even to design studies that will capture long term or unpredictable results.
- ☠ **GE and IPRs go hand in hand:** Corporate control over our food chain will be complete when technologies are combined with exclusive marketing rights in the form of Intellectual Property Rights. There is rarely any research taken up in GE without being accompanied by IPRs. This in reality means control over communities and nature in the same breath. This was an opportunity that was not present during the Green Revolution which had 'open source technologies'. There is a clear oligopoly situation emerging with around five seed companies in the world controlling almost all the IPRs related to genes and process technologies. While Multi-National Companies are emerging as trait sellers, a hierarchy within the seed industry is emerging with Indian companies becoming seed sellers, which get into sub-licensing agreements, on payment of royalty, with MNCs like Monsanto.
- ☠ **GE crops cannot co-exist with other crops:** Many GE proponents try to offer co-existence as a choice – that both GM crops and non-GM crops can be allowed, left to the choice of individual farmers. However, given our kind of land distribution and land holding patterns, this is impossible. To remain non-GM in an area where GM crops have been allowed in, will be difficult both at a physical and a genetic level. Segregation would require various newer measures like isolation distances to be maintained to produce being sold/processed/stored/distributed strictly separately. Given our lack of infrastructure and the marginal landholdings, this is impossible. In reality, there would be no choices left to farmers - all of them would be forced to become GM farmers.

Add to all of this the binding commitments that India has made at the WTO due to which trade rules have gained precedence over any other internal regulatory laws/mechanisms. Countries like the USA have not shied away from using WTO's rules to question internal regulation related to food safety in countries. India has also faced such questioning on its GM regulation already.

Resistance against GE also stems from the fact that in countries like the USA, despite GE being promoted as an efficient and precise technology, the farming there has to be constantly propped up by huge subsidies. This in itself is an indicator of the lack of benefits of this technology to farmers and given its other hazards, there does not seem to be any reason why it should be introduced in India.

Civil society groups offering resistance to GE in agriculture also realize that India is a key battleground – in the South Asian region as well as in other developing countries, decisions that India will take for or against GE will have an impact in their decision-making too. Even in terms of market size for the technology, India is a key determinant for the future of GE in farming. For all the above reasons, almost all major farmers' organisations and CSOs of India have taken an emphatic stand saying "NO to GE" in agriculture in the country.

Terminator Technology and other Genetic Use Restriction Technologies (GURTs)

The story of Genetic Engineering is incomplete without making a mention of 'Terminator Technology'. Multinational seed giants, in their quest to get perpetual control over the seed and food industry, have developed a technology to 'Control Gene Expression' which makes a seed germinate only when treated with a chemical and otherwise remain sterile. This is popularly called as "Terminator Technology".

Facing deep resistance from third world farmers and farmers' movements the seed industry has kept this technology in abeyance. The Indian government has banned this technology and the new Seeds Bill and Protection of Plant Varieties and Farmers' Rights [PPVFR] Act (the *sui generis* legislation related to IPRs in India) incorporate this ban.

To produce terminator seeds, the genes must produce a toxin that will kill the seed late in its development. The way this is done is to take a promoter from a gene normally activated late in seed development and fuse this promoter to the coding sequence for a toxic protein that will kill the embryo late in seed development.

Why the Terminator?

The Terminator gene offers absolutely no agronomic advantage to the farmer. Its benefit is for the multinational seed companies which can use the technology to require farmers to re-purchase seed from the companies, season after season. The Terminator is just one example of how a company can load genetic modifications of a number of commercial characteristics into a plant or animal and then activate or deactivate them at the point of sale ... like buying a tractor with "value-added" accessories. Together, these genes can be called Tractor Genes.

"Gene Giant" companies want to tie these genetic modifications to their proprietary chemicals so that one is useless without the other. However, there are a number of potentially serious consequences that emanate from this Terminator technology. Now there are many more technologies like Terminator which control the gene expression at various stages. These are called Genetic Use Restriction Technologies (GURTs).

Resistance to GE in agriculture in India is also a resistance against Terminator Technology and GURTs.

11. HOW IS GE IN AGRICULTURE REGULATED IN INDIA?

Regulation of GE in agriculture rests mainly with the Ministry of Environment and Forests in the Central Government of India, through the 1989 Rules of the Environment Protection Act, 1986. In many other countries, regulation of GMOs happens through specially enacted gene technology legislations. Regulation just through rules has also meant that regulators are quite easily changing the rules frequently just by a simple gazette notification or as a decision noted in the minutes of their meetings!

The concerned EPA Rules have been brought into force in December 1989 “with a view to protecting the environment, nature and health in connection with the application of gene technology and microorganisms”.

As per the Rules, “Genetic Engineering” is defined as the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell, is inserted into said cell or organism. It shall also mean ‘the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material’.

Under these Rules, a Committee called Genetic Engineering Approval Committee [GEAC] has been set up under the Ministry of Environment & Forests, for approval of activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from the environmental angle. This Committee is also responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials. The Rules under 7(1) clearly mention that “No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee”.

Section (8) of the 1989 Rules clearly states that “Production in which genetically engineered organisms or cells or micro-organisms are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment”.

Thus, the Rules clearly lay down the authority of GEAC, including for allowing or disallowing GM imports into the country.

Other institutions have also been created through the 1989 Rules to help the GEAC regulate GE in agriculture [and in medical applications]. For all those institutions, including research agencies, which are handling micro-organisms/genetically engineered organisms, it is mandated that an Institutional Bio-Safety Committee [IBSC] is to be created, which includes a representative of the Department of Bio-Technology [DBT] under the Ministry of Science & Technology.

Under the Department of Biotechnology, there is a Review Committee on Genetic Manipulation [RCGM] set up to monitor the safety related aspects of ongoing research projects and activities related to GE. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines. While the Rules lay this Committee down as a “review” body, in reality, all research up to the stage of limited field trials is being approved by this panel.

There is an advisory committee in the DBT called the Recombinant DNA Advisory Committee [RDAC] which is supposed to recommend suitable and-appropriate safety regulations for India in

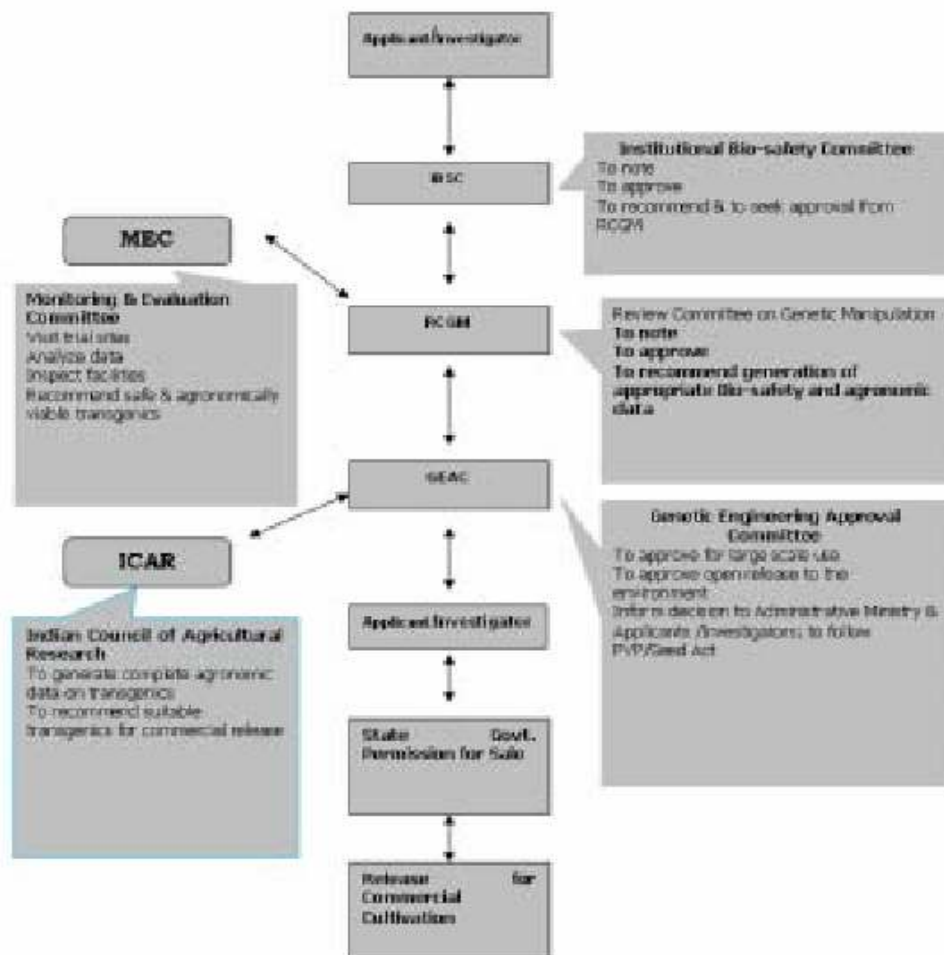
recombinant research, use and applications from time to time. From perusal of available information, it is not clear that this Committee meets regularly or performs its functions.

Though the 1989 Rules do not mention it specifically, there has been space created within the DBT to form a separate committee called the Monitoring & Evaluation Committee [MEC] to oversee field trials and to monitor the performance of GE crops. This committee is meant to undertake field visits for the purpose of collecting scientific information on the comparative agronomic advantage, if any, of the transgenic plants, to prepare formats for collecting scientific information in limited field trials, to suggest new experimental designs to RCGM etc.

The 1989 Rules also give some role to the state governments, though state governments are known to argue that GM-related decisions are all vested with the Central Government of India. Under the Rules, State Biotechnology Coordination Committees [SBCC] are to be set up with powers to inspect, investigate and to take punitive action in case of violations of statutory provisions. This Committee is supposed to review periodically the safety and control measures in various industries/institutions handling GMOs.

In addition, the Rules also provide for setting up of a District Level Biotechnology Committee [DLC] under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment.

SCHEMATIC REPRESENTATION OF REGULATORY APPROVAL PROCESSES IN INDIA



The Rules [under Section (13) "Grant of Approvals"] lay down that in connection with the granting of approval for production, unintended or deliberate releases, for food substances etc., terms and conditions shall be stipulated, including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee.

The Environment Protection Act 1986 also has a Penalties clause (15) which says that "whoever fails to comply with or contravenes any of the provisions of this Act, or the rules made or orders or directions issued thereunder, shall, in respect of each such failure or contravention, be punishable with imprisonment for a term which may extend to five years with fine which may extend to one lakh rupees, or with both, and in case the failure or contravention continues, with additional fine which may extend to five thousand rupees for every day during which such failure or contravention continues after the conviction for the first such failure or contravention".

Now, an additional condition for conducting field trials of any GE crop requires the crop developer to get prior approval from the Gram Panchayat and also inform all the concerned departments in the local administration in addition to the state government.

In addition to the 1989 Rules of the EPA, the other regulatory mechanism for GE products in India is through the Rules proposed under the Prevention of Food Adulteration Act [PFA] administered by the Ministry of Health & Family Welfare. These are Rules that pertain to labeling of GM foods and products. Section 37 (E) of the PFA Rules will, once notified, have a clause that prescribes the following: "Labelling of Genetically Modified Food:- Every package of genetically engineered or genetically modified food, in addition to other labelling requirements as prescribed under these rules, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material, whether imported or domestically produced shall indicate that the product has been subjected to genetic modification(s)".

Section 48 (F) of the PFA Rules will state: "Restriction on sale of Genetically Modified Food:- No person shall, except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) constituted under the Environment Protection Act, 1986, manufacture, import, transport, store, distribute or sell raw or processed food or any ingredient of food, food additives or any food product that may contain GM material in the country."

Through these Rules, GM crops and products approved by the GEAC (whether produced in the country or imported) will have to be compulsorily labeled as products that have been subjected to genetic modification. Failure to do so would amount to contravention of the PFA Act and its Rules.

However, though the draft rules have been put out in March 2006 and despite an Expert Committee giving a go-ahead to the rules after considering public feedback, these rules are yet to be notified. The ostensible reason is that the new Food Safety and Standards Act will look at GM food regulation in any case.

In addition to the EPA and the PFA/FSSA, there is a notification from the Commerce Ministry dated 7th April 2006, requiring the following compliance for all imports into the country (this is after applying the provisions of the EPA's 1989 Rules): "At the time of import, all consignments containing products which have been subjected to Genetic Modification will carry a declaration stating that the product is genetically modified. In case a consignment does not carry such a declaration and is later found to contain Genetically Modified material, the importer is liable to penal action under the Foreign Trade (Development & Regulation) Act, 1992".

Further, the Seeds Act of 1966 will also apply to GE seeds. As per this, state governments would have the authority to license the marketing of any kind of seeds, including GE seeds even if cleared for their bio-safety by the GEAC. State governments therefore have the authority to intervene through the SBCC right from the field trials stage (as per the 1989 Rules of the EPA) to oversee any environmental release of GMOs and can also use authority vested in them through other existing legislations for deciding on whether they would like to permit commercial cultivation or not. In any case, state governments have the constitutional powers to take their own decision on GE crops given that Agriculture is also a State subject.

What would also govern regulation within the industry is the Patents Act of 2005, since the technology and genes can be patented now in the country. In an ideal situation, what should also be governing India's regulation of GM crops are its commitments in international conventions like the Cartagena Protocol on Biosafety and the provisions therein – in reality, however, critical elements of the Cartagena Protocol are missing in their implementation in India.

While all the above are the stated laws and rules, the reality with regard to regulatory regime and its enforcement is very different from what is stated in the laws and Rules. The regulatory regime has been questioned time and again on some very fundamental flaws that it has.

1. To begin with, what constitutes bio-safety in the Indian regulation related to GMOs is highly questionable. For instance, a set of prescribed tests as per the OECD guidelines, imported from elsewhere, for testing related to toxicity, allergenicity etc. are prescribed to all GM crop developers to assess the biosafety of a GM crop and for decision-making related to its commercial release. However, the protocols for such testing, the kind of tests prescribed (both for health and environmental safety) are questionable on their scientificity and their real ability to capture medium/long term and unpredictable results. On top of that, it is the GM crop developer who does all the tests and brings back data with very little monitoring from others. There is no independent research that drives decision-making. Decision-making is based on such a narrow assessment of the technology, through data from questionable tests and with conflicting interests.
2. Elsewhere, like in Norway, impact assessment related to the technology is much broader than what falls under technical biosafety. The Gene Technology Act of Norway asks regulators to pose and obtain critical questions like: "is this ethically and socially justifiable?". Such impact assessment also goes beyond agronomic studies which are prescribed in India.
3. In India, open air trials happen parallel to biosafety testing; untested and uncleared products are being tried out in farmers' fields without adequate safety and these trials are often unethical.
4. It has been found that GM crop development and experimentation even in open air trials is happening without SBCCs and DLCs in place, which is a violation of the EPA Rules.
5. It has also been found that RCGM has always taken on an approval-giving role, with GEAC being sidelined. While RCGM might be constituted of scientists, it is the GEAC which is an inter-ministerial body, expected to look at impact assessment in a comprehensive manner, from health, environmental, trade, economic, legal, political and other perspectives. GEAC's functioning has been quite unsatisfactory, however. It is not even clear whether there are rules related to quorum etc., when decision-making takes place in the GEAC. Both RCGM and GEAC have acted in a thoroughly non-transparent fashion in the past decade or so of GM crop development and introduction in the country. It is not clear what their decision-making is based on.
6. It has been discovered that field trials are happening without any role for state governments. Worse, even farmers on whose lands such trials are laid out, are not being informed about what is being tried out. The local authorities, including the Panchayat are kept in the dark. What is shocking is that GEAC, which approves such trials, also does not have any knowledge on where trials are happening in the country! If trial locations are not known, the fate of monitoring can be understood.
7. All decision-making so far has been based on data produced by the companies themselves. No independent research has been taken up on any aspects related to GM crops. It is not

clear whether the regulators honestly expect the GM product developers to come back and report problems, if any. Such data produced by the companies is not peer-reviewed or put out in the public for scientific scrutiny.

8. There are other questionable dimensions to regulation too. Many GM crop developers themselves are sitting in the GEAC and RCGM as regulators, reflecting serious conflict of interest. They are being expected to take objective decisions on test protocols and findings!
9. Further, there is no scientific, broad based, multi-disciplinary monitoring or review of field trials or situation after commercial cultivation that feeds into decision-making. So far, reports that civil society has obtained on field trial monitoring show very clearly that such monitoring is missing. Further, many violations related to the scientific protocol prescribed as well as institutional mechanisms for monitoring and overseeing are reported.
10. It is also apparent that the Indian regulatory system does not know how to pick up early warnings from elsewhere or from the unfolding situation with regard to Bt Cotton as the first GM crop in the country. If early warnings are not picked up, invoking the precautionary principle enshrined in the Cartagena Protocol will be meaningless.
11. Even though Agriculture is a state subject too as per the Constitution of India, state governments have not been allowed any legislative space (other than in administration of the EPA Rules) to prohibit GM crop trials or sales if chose to.
12. In the entire regulatory regime, there is no routine oversight mechanism (an *ombudsman*, so to speak) to ensure that regulation is independent, scientific, rigorous, accountable, participatory and transparent.

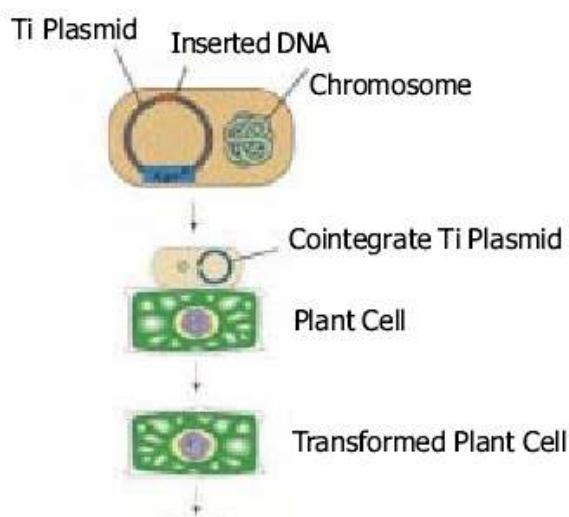
The proliferation of illegal Bt Cotton all over the country right from 2001 (before a formal approval for commercial cultivation has been given to any Bt Cotton hybrid in the country), the evidence of contamination of supply chain from field trials, of the many biosafety violations in field trials, of the absence of many institutions prescribed by the EPA, of the inability to follow up with scientific investigations on some early warnings from the ground and so on are all manifestations of the gross failure of regulatory enforcement the country. On top of that are questions related to the policy regime related to GM crops in the country. Most importantly, it is not clear when, by who, how and why [on what basis] it was decided that GM crops are needed by Indian farmers and that they will be a major thrust for the future of Indian agriculture.

12. WHAT HAS BEEN THE EXPERIENCE WITH GE CROPS IN INDIA?

The earlier section amply illustrates the experience with relation to regulation of GE crops in India. Now, let us look at the actual results obtained by farmers in the case of the only GM crop approved for commercial cultivation – Bt Cotton, approved by the regulators for the first time in 2002.

By 2007-08 Kharif season, 135 GM cotton hybrids were allowed into the Indian seed market, approved by GEAC and produced by around 25 companies. In the past year alone, more than 70 hybrids were approved. These hybrids have four “events” incorporated into them, including Monsanto’s proprietary Bollgard I and II traits into a majority of the approved hybrids. In addition to these, there are innumerable GM cotton hybrids which are “illegal”.

India’s experience with Bt Cotton in a visible, documented fashion began in 1998, when secret field trials were allowed by the DBT for some Monsanto-Mahyco’s Bt Cotton hybrids. These hybrids were developed by using imported Bt Cotton variety germplasm brought from the USA in 1995. In 2002, the first commercial cultivation approvals were accorded to three hybrids belonging to Monsanto-Mahyco.



Bt Cotton in India

The most popularly grown Bt Cotton hybrids in India consist of Monsanto’s proprietary brand “Bollgard”. This Bt Cotton consists of three genes mainly - Cry1Ac gene derived from the common soil microbe called *Bacillus thuringiensis* [Bt]; *nptII* gene as a marker gene; the *aad* gene which was also used as a marker. Cauliflower Mosaic Virus was used as the promoter.



Right from the beginning, a few things about the technology – its ramifications and its regulation were apparent in the country.

To begin with, the biosafety tests done on Bt Cotton are very questionable. The acute oral toxicity test accepted as part of regulatory clearance in India was done in 1993, years before Bt Cotton ever came into the country, in the USA, in Monsanto’s labs! Some tests have not been done and many others have unscientific protocols. Data from the studies is not in the public domain other

than as summary reports. The studies did not foresee the cotton growing conditions of India and prescribe tests to assess impacts to suit our conditions. For instance, there were no studies taken up on the impact on livestock like sheep or buffaloes in uncontrolled, open grazing conditions on cotton fields. The biosafety related to impacts on animals was only done on goats that too in controlled conditions of feeding Bt Cotton seed-based diet. This however, cannot be extrapolated to uncontrolled open grazing of green leaf material of Bt Cotton plants by animals in a situation when grazing lands are shrinking. As mentioned elsewhere, in any case, Genetic Engineering as a technology is such that no amount of biosafety testing can actually throw up expectable results in all growing conditions. In short, even though regulatory approval was given in 2002, there is really no reliable evidence to show that Bt Cotton is safe for the human health, livestock, on beneficial insects, on soil biota etc.

In India, Bt Cotton approval for field trials was given by DBT, a department which aggressively promotes this technology. This is also in violation of the rules of 1989 which provided that environmental release of genetically modified organisms could only be done by the GEAC under the Ministry of Environment. When challenged about this, the appellate authority upheld the validity of the permission saying that DBT had the authority to give permissions for experimentation and research because GEAC authorized DBT through an administrative decision in one of its meeting!

When the trials took place, it was in a secretive manner and state governments like Karnataka and Andhra Pradesh objected to such trials. It was discovered by several researchers later on that these trials were inadequately monitored, did not always follow the scientific protocol and most importantly, that cotton from the trial plots was allowed to contaminate the supply chain. This is a story that continues in India even now, for various food crop trials too.

In November 2001, it was discovered in Gujarat that though no approval has been accorded for Bt Cotton commercial cultivation, that a certain Bt Cotton hybrid called Navbharat 151 was being grown on thousands of acres! Starting from this episode, there has been a rapid proliferation of illegal Bt Cotton, backcrossed into scores of "farmers' hybrids" and of small enterprises/companies, all over the country. To this day, this has not been controlled.

From the first year onwards (2002), the genetically modified cotton started showing results that belied the hype and promise that the industry made around it. In Andhra Pradesh, the state agriculture minister admitted in the legislative assembly that the performance of Bt Cotton was less than satisfactory and an official survey conducted by the agriculture department with hundreds of Bt Cotton farmers showed that non-Bt Cotton gave the farmers better yields and profits. In the year 2004 again, the Andhra Pradesh government had to officially order M/s Mahyco to pay compensation to the tune of four crores of rupees to Bt Cotton farmers who lost their crop, which the company refused to. The losses were estimated only in a small part of Warangal district whereas reports of failure emerged from several districts of the state.

In 2005, Madhya Pradesh government had to deal with complaints of failures from the Nimad belt where large scale wilting of the Bt Cotton crop was reported. In 2005 and 2006, there are widespread reports in the media about Bt Cotton being the cause of scores of farmers committing suicides after the crop failed.

Bt Cotton was sold aggressively by the biotech industry and civil society reports show that no other seed (of any crop) has ever been marketed like the way Bt Cotton has been. Lies, lack of ethics and huge investments in advertising were all part of the marketing of Bt Cotton in India. A published paper from Washington University after studying the Bt Cotton seed choices of farmers in a district like Warangal in Andhra Pradesh concluded that farmers' decisions about their seeds were irrational, like a fad and were not based on their 'environmental learning'.

Civil society reports from almost all the states indicate that Bt Cotton does not result in better yields or net margins for farmers, compared to non-Bt Cotton. Studies also show that compared

to non-chemical cotton cultivation like NPM cotton or organic cotton, Bt Cotton has little benefits to offer to farmers. This is something that Maharashtra state has officially registered. Andhra Pradesh and Gujarat state governments have officially acknowledged that any increases in cotton productivity in the states are not connected to Bt Cotton.

There are more sucking pests reported on Bt Cotton than on non-Bt Cotton, requiring the spraying of pesticides to control these pests. Other pests like mealy bug and stem borer are also now seen and reported on Bt Cotton. Further, there are newer and newer diseases being reported on Bt Cotton, almost unknown on cotton crop before. These diseases include Tobacco Streak Virus, Bronze Wilt and so on. The disease incidence on Bt cotton is higher also because of the higher presence of sucking pests which act as vectors for the diseases.

The advisory for farmers brought out by Acharya N G Ranga Agriculture University in Andhra Pradesh, called *Vyavasaya Panchangam*, cautions farmers that Bt Cotton is more susceptible to sucking pests and other pests and diseases than non-Bt Cotton.

In states like Punjab, farmers are experiencing that the wheat yields, on lands where they have harvested Bt Cotton before sowing wheat, are coming down. There are also many reports about increased incidence of diseases and affected growth in crops like paddy, maize, chilli etc., grown on lands where Bt Cotton has been grown. There are many indications that soils are being adversely affected by growing Bt Cotton. However, no official investigations have been taken up into the issue despite repeated reports submitted to the regulators. In fact, farmers who had opted for Bt Cotton for successive years are reporting that their cotton yields are falling too, as each year passes by.

It is noticed everywhere that chemical fertilizer application has gone up on Bt Cotton compared to normal cotton. In fact, higher dosages of chemical fertilizers are now being recommended on Bt Cotton by agriculture scientists (the *Vyavasaya Panchangam*, for example, informs farmers that Bt Cotton requires more fertilizer application).

There are also widespread reports of Bt Cotton's effects on human health. A preliminary investigation taken up by Jana Swasthya Abhiyan in Madhya Pradesh, India in 2005 found that farm workers handling Bt cotton developed allergic reactions. Twenty-three patients, including 10 severe cases, suffered allergic symptoms within about five hours of gathering, lifting and even touching the cotton, according to this study. "Farmers' skin turned red, swelling occurred, eyes reddened and breathlessness was experienced. Some victims suffered a burning sensation in the eyes, watering, itching, swelling of eyelashes, sneezing and running noses." Those who covered their bodies remained unaffected. Once again, the official agencies are choosing to turn a blind eye to this problem being reported.

It is also observed consistently that Bt Cotton's stress tolerance is very low, compared to non-Bt Cotton. Therefore, with the slightest change in the weather – whether it is excess heat or excess rain – it the Bt Cotton crop which is affected first and the most. There is wilting reported soon after such weather changes. Non-Bt Cotton is known to withstand such abiotic stress more than the genetically modified counterparts as many fact finding reports have shown. This stress intolerance is noted by several official reports.

The most alarming phenomenon observed with Bt Cotton is inexplicable deaths of animals that have grazed on Bt Cotton fields after the harvest of cotton. In Andhra Pradesh and Maharashtra, there have been sporadic reports of such animal deaths from 2003 to 2005, as area under Bt Cotton kept increasing. In 2006, around 12000 sheep are estimated to have died due to toxicity after grazing on Bt Cotton in Warangal district alone. In 2007 and 2008, such reports emerged from districts like Adilabad, Medak and Khammam, in addition to Buldana and Yavatmal of Maharashtra. Elsewhere too, farmers and livestock rearers are reporting that animals don't prefer eating Bt Cotton based feed/fodder.

The other aspect to Bt Cotton cultivation in the past six years is that of seed pricing. Because of the exorbitant royalty charges that local seed companies had to pay to Monsanto-Mahyco, the

technology-holder, farmers ended up paying four times the usual seed price for Bt Cotton. This meant a huge burden on the debt-ridden Indian cotton farmers.

All in all, the story of Bt Cotton in India from six years of its legal commercial cultivation is that of adverse economics for farmers (including exorbitantly priced seeds, ostensibly for paying royalties to Monsanto, the technology-holder), of changed pest ecology in cotton fields, increased incidence of diseases (all of which require more pesticides used for controlling these pests and diseases), of effects on soil health, of stress intolerance and unpredictability related to crop performance, of more resources used by farmers as part of their risk insurance mechanisms (more irrigation, more fertilizers etc., when it comes to Bt Cotton cultivation), adverse effects on human health and the inexplicable phenomenon of toxicity in animals after grazing on Bt Cotton fields.

Civil society reports on various experiences on the ground have been discounted consistently as “unscientific”. Decision-making had proven itself to be biased towards the industry rather than towards safeguarding the interests of farmers and consumers. There are valuable lessons to be learnt from this experience of Bt Cotton, which should be incorporated into any decision-making related to other GM crops in the country. The Bt Cotton experience shows that there has never been a more deserving case for applying the precautionary principle in the case of any technology.

13. WHAT ABOUT GE IMPORTS INTO INDIA?

The Environment Protection Act's 1989 Rules have been formulated with a view to protecting the environment, nature and health with the application of gene technology, as the preamble indicates. The Rules apply to Genetically Engineered Organisms as well as to any substances/products/food stuffs of which such GE cells/organisms/tissues form part of. Strictly speaking, all GE products and foods imported into India should have the prior approval of GEAC. And GEAC, ideally speaking, should be giving such approvals after impact assessments done in India. However, in reality, that has not been the case.

GM imports especially in the form of soybean oil have remained unchecked and unregulated over the years. In the countries of origin for this product (soy oil), there is no segregation of GM and non-GM soy. Majority of the production is from GM soy in the USA, Brazil and Argentina, from whom we import.

Groups like Greenpeace have tested some imported products on supermarket shelves way back in 2001 and found that some products of companies like Nestle like potato chips, baby foods etc., contained GM products/ingredients not approved by the GEAC nor labeled as having been evolved out of genetic modification.

Some GE foods have found their way into the country through the route of food aid. After the Orissa cyclone for instance, some of the food aid in the relief supplies was found to be GM-contaminated. It was only the alertness of civil society groups that discovered this. Later on, when American NGOs like CARE and CRS sought to bring in some potentially-GM-contaminated food aid, the GEAC rejected some consignments, on the belief that these consignments are StarLink-corn-contaminated.

In 2006, GEAC decided to allow imports of Roundup Ready soy products – Refined Soybean Vegetable Oil and Crude De-gummed Soybean Oil) as a one-time permission to the importers' association (and not individual importing firms) after ascertaining some matters related to the herbicide residues through laboratory analysis. It is important to note here that many studies related to adverse effects of GM soy were actually with Roundup Ready soy!

In 2006, the Ministry of Commerce, through the Director General of Foreign Trade [DGFT] put out a notification in April (Notification No. 2(RE-2006) / 2004-2009, dated 7th April, 2006) stating that *"at the time of import, all consignments containing products which have been subjected to genetic modification will carry a declaration stating that the product is genetically modified. In case a consignment does not carry such a declaration and is later found to contain Genetically Modified material, the importer is liable to penal action under the Foreign Trade Act, 1992"*. For a few months subsequently, an exemption was made for soybean oil imports. This notification also reiterated the need to obtain GEAC's approval prior to importing.

On 10th July 2007, the DGFT issued another notification stating that "import of GM rice is restricted. Import of rice in India is permitted only if the exporter is able to furnish a certificate from the competent government authorities from country of export that the exported rice is GM Free".

While these Commerce Ministry notifications do exist as part of regulatory requirements, preliminary investigations reveal that these rules are not always being adhered to.

Meanwhile, through a notification in September 2007, GEAC unexpectedly exempted processed food products from regulatory approvals from its side. This was justified on the grounds that the new Food Safety and Standards Act (FSSA) will look after GM food products from a food safety angle and that GEAC's mandate is to ensure 'environmental safety'.

The FSSA, to be implemented by the Health Ministry of Government of India, expressly states under Section 22 that no person shall manufacture, distribute, sell or import any novel food or genetically modified articles of food; Clause 25 says that no person shall import into India any unsafe food. Further, the Food Authority under this Act is supposed to set up a scientific panel on genetically modified organisms and foods. However, while of this might be part of this new law, at the time of writing of this handbook, regulation of GM foods is nobody's baby. The FSSA's implementation could take more time, especially related to GM crops and foods.

At the time of writing of this handbook, India is being flooded with many products imported from countries like the USA which do not have a system of segregation or labeling, where GM and non-GM products are mixed up. Products to watch out for in India now, for suspected GM contamination, are products with corn, canola, soya and cottonseed ingredients, from GM producing countries like some infant formula, breakfast cereals, mayonnaise, crackers and chips, salad dressings, sauces, edible oils, pop corn, sweet corn kernel, bread crumbs, corn syrup etc. If you thought that purchasing such imported products in supermarkets is the fashionable thing to do, think again – these could be GM-contaminated and these products have not been tested or certified in India for their safety.

14. WHAT IS THE CURRENT STATUS WITH REGARD TO GE CROPS IN INDIA?

Pipeline crops

Experimentation with GE crops is at different stages for different crops in different institutions that are dabbling with it. Other than Bt Brinjal (or eggplant), no other food crop has reached a stage of large scale field trials as yet.

In 2007-08, Bt Brinjal was allowed the first year large scale trials inside some public sector agricultural research campuses, coordinated by the Indian Institute of Vegetable Research. In allowing for these large scale trials, GEAC violated its own rules that require biosafety to be cleared first before large scale trials are allowed.

During Kharif 2006 and Rabi 2006-07, thirteen genetically modified crops were taken up for field trials. These crops include cotton, brinjal, cabbage, castor, cauliflower, corn/maize, groundnut, okra/bhindi, potato, rice, tomato, mustard and sorghum.

As per the information available on official websites (www.igmoris.nic.in) in 2007, permissions were provided for open air trials of GM potato, Bt rice (Mahyco), Bt Okra (Mahyco), Bt Brinjal (Sungro Seeds and University of Agricultural Sciences, Dharwad) in addition to many cotton trials.

What is alarming to note is that open air field trials as multi-locational trials are allowed in farmers' fields all over the country, without biosafety having been cleared and without monitoring capacities or ability to prevent contamination. All these field trials are essentially of untested and unknown products, happening without the knowledge of farming communities. Trials are often found to violate prescribed guidelines and norms and are also found to be unscientific.

Most experimentation on GM crops is happening through public sector institutions like agricultural universities. As per reports available, around 45 universities are engaged in GMO research across the country. An almost equal number of private companies are also engaged in GM crop development. Most of the GM crops being experimented upon have been modified for pest and disease resistance.

The immediate threats are from Bt Brinjal, Bt Rice, Bt Tomato, GM Potato, Bt Cauliflower and Bt Cabbage, most probably in that order.

Bt Brinjal

Bt Brinjal is a transgenic brinjal created out of inserting a gene [Cry 1Ac] from the soil bacterium *Bacillus thuringiensis* into Brinjal. This is claimed to give the Brinjal plant resistance against lepidopteran insects like the Brinjal Fruit and Shoot Borer (*Leucinodes orbonalis*) and Fruit Borer (*Helicoverpa armigera*). Bt Brinjal is being developed in India by M/s Mahyco [Maharashtra Hybrid Seeds Company] as well as universities like Tamil Nadu Agriculture University and University of Agricultural Sciences, Dharwad. In addition, Sungro Seeds of Mahyco is involved in the development of Bt Brinjal. It is the first food crop in India to have reached large scale field trials stage. The transformation work on Bt Brinjal started in Year 2000. Mahyco has sub-licensed the technology, as part of the USAID-supported, Cornell University-led ABSPII project [consortium of public and private sector institutions] to Tamil Nadu Agricultural University (TNAU), The University of Agricultural Sciences, Dharwad and The Indian Institute of Vegetable Research, Varanasi (IIVR). This transfer of technology was apparently free-of-cost, with the public sector institutes allowed to develop, breed and distribute their own Bt Brinjal varieties on a cost-to-cost basis.

In addition to Mahyco, the National Research Center for Biotechnology at the Indian Agricultural Research Institute (IARI) is also experimenting with Bt Brinjal. They developed a Bt eggplant using a Cry1Ab gene that is claimed to control 70 percent of the fruit borer attack. This institute had taken up agronomic trials in a controlled environment in 1998/99, 1999/2000, and 2000/2001. In 2003 they were permitted to conduct field trials in five locations - Delhi, Karnal, Pune, Tamil Nadu Agricultural University and the Indian Institute of Horticultural Research. Another company called Bejo Sheetal company, based in Jalna, Maharashtra, is also working on Bt Brinjal.

India is the Centre of Origin for Brinjal or Eggplant. Brinjal has been cultivated in India for the last 4000 years or so and has many historical references in various languages. It is grown all over the country, year-round and is one of the most popular vegetables of India.

While the company claims to have completed biosafety testing of Bt Brinjal and reports that everything is fine with the transgenic crop, civil society groups have pointed out many concerns with Bt Brinjal. One of the biggest concerns is that safety of Bt Brinjal is highly questionable for its potential impacts on human health and other organisms. Further, to be dabbling with genetic engineering in a crop like brinjal for which we are the centre of origin and diversity will pose a huge threat to the existing diversity. Furthermore, all decisions related to Bt Brinjal are being made based on the company's data rather than any independent research.

15. ISN'T THERE A SUPREME COURT CASE ABOUT GE IN INDIA?

A Public Interest Litigation has been filed in the Supreme Court by Aruna Rodrigues and three other petitioners in 2005, based on which the Supreme Court had ordered the stoppage of any further field trials of any GM crops in the country in September 2006. After presenting hundreds of pages of evidence of numerous adverse effects of GE as a technology, the following are the grounds on which the petitioners are arguing their case with the Court:

- A failure to take into account existing overwhelming scientific evidence that cast doubts on the safety of the technology would be arbitrary and unreasonable.
- The use of the technology of genetic engineering and the release of genetically modified organisms into the environment would clearly require the application of precautionary principle which mandates that every possible precaution must be taken to ensure that no harmful effects are caused to human and animal health and environment due to the use of new and unknown technologies and organisms.
- That GMOs slated for release must undergo proper biosafety tests by independent and scientifically competent bodies in a transparent manner keeping the public informed. That any release of GMOs into the environment without the requisite scientific testing for biosafety concerns would be unconstitutional.
- Since India is a signatory to the CBD and since its provisions are not in conflict, but in fact in aid of the domestic laws and interests of the citizens of the country, India is bound by the CBD provisions.
- That India is a signatory and is bound by the provisions of Cartagena Protocol, the binding international agreement on the matter of Biosafety. The central principle enshrined in the Cartagena Protocol is the Precautionary Principle that stipulates that a lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party from taking an appropriate decision, to avoid/ minimise potential adverse effects.
- India's signing of the Cartagena Protocol and its consequent commitment to the provisions of the Protocol require the country to put a sound safety protocol in place – a protocol that is credible, independent, scientifically sound, transparent and constitutes comprehensive, long term impact assessment including of socio-economic impacts, with public participation in assessment and decision-making.
- To ensure the effective functioning of the Protocol, and a meaningful employment of the precautionary principle it is important that a labelling mechanism of GM food and GM products are put in place.
- It also requires that the import of any biological organism, food or animal feed is prohibited unless they have been tested and certified and labelled to be GM free.

Based on the above arguments, the petition prayed for the following from the Court:

- Direct the Union of India not to allow any release of GMOs into the environment by way of import, manufacture, use or any other manner unless the following precautions are taken.
- A protocol for all the required bio-safety tests of the GMOs proposed to be released is prepared by the GEAC after processes of public notice and public hearing.

- The GMO has been subjected to all the required bio-safety tests, prepared on the basis of the required Biosafety.
- Tests are prescribed and taken up on the basis of the above protocol, by agencies of independent expert bodies, and results of which have been made public.
- Direct the Union of India to ban the import of any biological organism, food or animal feed unless they have been certified and labelled to be GM free, by the exporting country.
- Direct the Union of India to put in place rules to ensure that it shall be compulsory for any dealer or grower selling GMOs to label them as such.
- Pass such other and further orders as the Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

As the case unfolded from 2005 onwards, there have been several interim orders passed by the Supreme Court.

- In May 2006, the Court ordered that only GEAC is the competent authority for giving GE-related approvals (before this, the RCGM of the DBT was giving permissions for field trials, in violation of the EPA). However, things did not change even after the Court's orders and GEAC continued to put its rubber stamp on approvals that were being given by the DBT, in a serious manifestation of objectionable conflict of interest.
- In September 2006, following a landmark order from the Supreme Court in this case, further approvals for field trials came to a halt in the country.
- In October 2006, the Court allowed field trials of GM Mustard by Delhi University subject to precautions laid down.
- On 8th May 2007, the Supreme Court allowed GEAC to permit ongoing field trials with some conditions: that there will be an isolation distance of 200 meters maintained from the GM field trial, that there will be a scientist designated for each trial who will be responsible for all aspects related to the trial and that prior to bringing out the GM material from the greenhouse for the open air trial, a validated event specific contamination test protocol at an LOD of at least 0.01% would be put in place to detect and confirm that there has been no contamination.
- On February 13th 2008, when the petitioners put in a contempt petition with evidence of GEAC overstepping the Court's orders for giving approvals, the Court allowed GEAC to consider applications for open air field trials and asked GEAC to invite Dr Pushpa Bhargava, noted molecular biologist and Dr M S Swaminathan, agriculture scientist to its meetings when applications are considered and before granting approvals. The GEAC was permitted to consider any application presented to it in accordance with law and take appropriate decisions after considering all aspects, including biosafety aspects. The GEAC was asked to consider apprehension expressed by experts that open air field trials may cause damage to the environment and cause contamination. The Court also ordered GEAC to publish the guidelines for granting approval if any on its website.

At the time of writing this handbook, the regulators in India are re-casting many guidelines including the ones on open air field trials, on toxicology and allergenicity testing and the FSSAI is reported to be setting up mechanisms for the implementation of the new law under the Health Ministry.

16. ARE THERE ALTERNATIVES TO GE IN AGRICULTURE?

Most GE-introduced traits in farming today relate to insect resistance and herbicide tolerance. It is also touted as a solution to the world's hunger and malnourishment problems (higher productivity/nutrient-enhanced foods) in addition to solving some environmental problems (drought-resistance/salinity resistance etc.). Let us look at the reality of the problems and their sustainable solutions.

Pest management which rests on understanding insects and their life cycles, insect incidence and its connection to other factors like monocropping, use of chemical fertilizers etc., rather than targeting only one pest in a manner that the technology becomes ineffective soon because the pest develops resistance [as in the case of GE and pesticides before that], is obviously the only sustainable solution. If such knowledge about insects in crop ecology is in the hands of farmers in a manner that they use nature's processes and locally available products to control pests, it is obviously more sustainable. There are thousands of farmers who manage their crop pests through these sustainable means and in Andhra Pradesh, women's self help groups have taken up such a Community Managed Sustainable Agriculture (CMSA) approach in around seven hundred thousand acres in 2007. Their efforts are supported with financial and other resources from the Rural Development department of Andhra Pradesh.

Coming to herbicide tolerance, it is in any case not a trait that developing countries like India should look for. Manual removal of weeds is the greatest source of employment and income for millions of farming women in the country. Promoting weedicides through herbicide-resistant crops jeopardizes their livelihoods, in addition to causing other environmental problems. Weeds are also an important source of greens for food in certain communities and also fodder for livestock. Weeds are also valuable bio-mass that is needed for increasing the soil productivity through ecological means. In some cases, they have medicinal value too. Ecological farming methods have a way of using such weeds for mulching and composting which allows for recycling of nutrients in a sustainable fashion.

On productivity increases through GE in agriculture, it has been proven time and again that GE will not lead to increased productivity. On the other hand, approaches like System of Rice Intensification [SRI] have been proven to increase yields in crops like paddy, that too with lesser use of inputs like water. This approach did not require GE to be brought in for increase in productivity!

Fortified food through GE is also a promise being hyped up by the GE industry. Golden Rice or Vitamin-A-enhanced rice is one such GE product that is being showcased to support GE in farming. However, for each such GE product, there are native, uncultivated foods available with farming communities. In fact, the systematic erosion and replacement of such uncultivated foods from the diets of the poor is a major reason for many health problems in rural India. There are also traditional varieties with high nutrient content that can be promoted to increase the nutritional status of the poor. These include many minor millets. At another level, fortified food is also being developed through conventional breeding, without the use of GE.

Traditional germplasm collections in various parts of the country have varieties which are drought/salinity-tolerant. These need to be revived rather than resorting to GE solutions to the problem. In fact, the answers lie in selecting the right crops and not just the right varieties within crops for issues like this. The best risk insurance for farmers comes from agro-diversity based farming.

17. WHAT CAN YOU DO?

All of us are consumers of food. As a consumer, begin by resolving that you will reject any GM foods, even if they are allowed based on the current faulty regulatory regime. When you purchase your food items, including packaged products, vegetables, rice etc., insist to know that it is GE-Free. Watch out especially for vegetables, rice and products containing soy, corn, cottonseed, canola etc. Reject food from GM-producing countries, especially ones which don't segregate GM from non-GM. Go organic. Support farmers who are into ecological farming by purchasing their produce.

If you are a farmer, resolve that you will not plant any GM seeds on your farm. Try and build seed banks for your community to fall back on. Ensure a diversity of crops and varieties of high quality in these Seeds Banks.

Educate your neighboring farmers and consumers and ensure that they take informed decisions related to GE in our farming and food.

Along with others, create GE-Free Zones/Communities/Villages/SHGs/Districts etc. Do not wait for the government to take a policy level decision on this. Pro-actively take a decision where it concerns you and your local resources. It is the constitutional right of Panchayats to resolve to remain GE-Free, after getting engaged in the debate.

Please get in touch with your local councilors, legislators, Members of Parliament and ensure that they are aware of the ramifications of this irreversible technology. Create an informed public debate wherever you are, whenever you get an opportunity. Get them to reject the technology, after understanding the full implications of the technology for farmers and consumers of the country and after sharing all relevant information. Get political parties to take a stand and base your voting decisions keeping their stand in mind.

Try and influence your state government to have a sustainable vision for agriculture and to take a pro-farmer decision on this matter. Get them to announce the state as a GE-Free state.

Watch out for secret and unscientific field trials happening around you. Guidelines by GEAC for field trials require Panchayat's consent before a trial begins. Ensure that Panchayats are aware of this. If your district or state does not have the required institutions for overseeing GE-related matters as required under the EPA, build pressure until such institutions are created. Educate them about the various implications of GE once they are formed.

Encourage media representatives to keep themselves informed on the matter and to create an informed public debate on the technology. Ask them to be the watchdogs for regulatory enforcement.

Annexure: Crops being genetically engineered in India

The following is a list of crops that have reached field trials' stage as per a website operated by members associated with DBT and Biotech Consortium India Ltd (<http://igmoris.nic.in>), followed by another table which lists out all the crops being genetically engineered in India, as per a USDA report in 2003.

Transgenic crops under field trials

S.No.	Crop	Organization	Transgene
1.	Brinjal	IARI, New Delhi	<i>σy1Ab</i>
2.	Cotton	Ankur Seeds P.Ltd., Nagpur	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Ajeet Seeds, Aurangabad	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Bioseeds Ltd, Hyderabad	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Emergent Genetics Ltd., Hyderabad	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Ganga Kaveri Pvt. Ltd., Hyderabad	<i>σy1Ac</i>
		JK Agri Genetics, Hyderabad	<i>σy1Ac</i>
		Krishidhan Seeds, Jalna	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Mahyco, Mumbai <i>cry1Ac; σy1Ac & cry2Ab</i>	
		Metahelix, Bangalore	<i>σy1Ac</i>
		Nandhi Seeds Ltd, Hyderabad	<i>σy1Ac</i>
		Nath Seeds, Aurangabad	GFM <i>cry1Aa</i>
		Nuziveedu Seeds, Hyderabad	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Namdari Seeds Ltd, Bangalore	GFM <i>cry1Aa</i>
		Pravardhan Seeds, Hyderabad	<i>σy1Ac</i>
		Prabhat Agri Biotech Ltd., Hyd.	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Rasi Seeds Ltd., Attur	<i>σy1Ac; σy1Ac & σy2Ab</i>
		Safal Seeds Ltd, Jalna	GFM <i>cry1Aa</i>
		Syngenta India Ltd., Pune	<i>Vp-3a</i>
		Tulsi Seeds, Guntur	<i>σy1Ac; σy1Ac & σy2Ab</i>

S.No	Crop	Organization	Transgene
		Univ. Agri. Sciences, Dharwad	<i>cry1Ab</i>
		Vibha Seeds Ltd, Hyderabad	<i>cry1Ac</i>
		Vikki's Agrotech, Hyderabad	<i>cry1Ac</i>
		Vikram Seeds Ltd, Ahmedabad	<i>cry1Ac</i>
		Zuari Agrotech Ltd, Bangalore ,	GFM <i>cry1Aa</i>
3.	Cauliflower	Mahyco, Mumbai	<i>cry1Ac</i>
		Sungrow Seeds Ltd, New Delhi	<i>cry1Ac</i>
4.	Cabbage	Sungrow Seeds Ltd, New Delhi	<i>cry1Ac</i>
5.	Chickpea	ICRISAT, Hyderabad	<i>cry1Ac</i> and <i>cry1Ab</i>
6.	Groundnut	ICRISAT, Hyderabad	<i>IPCVcp: IPCV replicase gene</i>
7.	Maize	Monsanto, Mumbai CP4 EPSPS	
8.	Mustard	IARI, New Delhi NRCWS, Jabalpur <i>bar</i> ; <i>bar</i> ase & <i>bar</i> star TERI, New Delhi <i>Ssu-maize Psy</i> ; <i>Ssu-tpCrtI</i> UDSC, New Delhi <i>bar</i> ; <i>bar</i> ase & <i>bar</i> star	<i>CoDA</i> , <i>Osmotin</i>
9.	Okra	Mahyco, Mumbai <i>cry1Ac</i>	
10.	Pigeonpea	ICRISAT, Hyderabad Mahyco, Mumbai	<i>cry1Ab + SBTI</i> <i>cry1Ac</i>
11.	Potato	CPRI, Simla NCPGR, New Delhi	<i>cry1Ab</i> <i>Ama-1 gene</i>
12.	Rice	Directorate of Rice Research, Hyderabad	Bacterial blight resistant Hyderabad Xa-21, <i>cry1Ab</i> , <i>gna</i> gene, Sheath blight resistant
		Osmania University , Hyderabad	<i>gna</i> gene
		IARI, New Delhi <i>BL</i> and <i>chitinase</i> genes	<i>cry1Ac</i> and <i>cry1B-cry1Aa</i>
		Mahyco, Mumbai	<i>cry1Ac</i>
		MKU, Madurai <i>Chitinase</i>	<i>b-1, 3-glucanase</i> , <i>Osmotin</i>
		MSSRF, Chennai	Gene (s) from mangrove
		TNAU, Coimbatore	<i>Chitinase</i>
13.	Sorghum	Mahyco, Mumbai	<i>cry1Ac</i>
14.	Tomato	Mahyco, Mumbai	<i>cry1Ac</i>
		NCPGR, New Delhi	<i>GMDC</i>

As per the IGMORIS website,

Transgenic crops under development and field trials in 2006

S.No.	Crop	Organization	Transgene
1.	Brinjal	IARI, New Delhi	<i>cry1Aa and cry1Aabc</i>
		Sungro Seeds Ltd, New Delhi	<i>cry1Ac</i>
		Mahyco, Mumbai	<i>cry1Ac</i>
2.	Cabbage	M/s. Nunhems India Pvt. Ltd., Gurgaon	<i>cry1Ba and cry1Ca</i>
3.	Castor	Directorate of Oilseeds Research (DOR), Rajendranagar, Hyderabad	<i>cry1Aa and cry1Ec</i>
4.	Cauliflower	Sungro Seeds Ltd, New Delhi,	<i>cry1Ac, cry1Ba and cry1Ca</i>
		M/s. Nunhems India Pvt. Ltd., Gurgaon	<i>cry1Ac, cry1Ba and cry1Ca</i>
5.	Corn	Monsanto, Mumbai	<i>cry1Ab gene (Mon 810 event)</i>
6.	Groundnut	ICRISAT, Hyderabad	<i>chitinase gene from rice (Rchit)</i>
7.	Okra	Mahyco, Mumbai	<i>cry1Ac, cry2Ab</i>
9.	Potato	Central Potato Research Institute (CPRI), Shimla	<i>RB gene derived from Solanum bulbocastanum</i>
10.	Rice	IARI, New Delhi	<i>cry1B-cry1Aa fusion gene</i>
		Tamil Nadu Agricultural University	<i>rice chitinase (chi11) or tobacco osmotin gene</i>
		Mahyco, Mumbai	<i>cry1Ac, cry2Ab</i>
11.	Tomato	IARI, New Delhi	<i>antisense replicase gene of tomato leaf curl virus</i>
		Mahyco, Mumbai	<i>cry1Ac</i>

For more information,

1. Visit: www.indiaqminfo.org
 2. Visit: www.gmwatch.org
 3. Visit: www.biosafety-info.net
 4. Visit: <http://www.centerforfoodsafety.org>
 5. Visit: <http://www.foei.org/en/campaigns/gmo>
 6. Visit: <http://www.i-sis.org.uk/index.php>
 7. Visit: <http://www.seedsofdeception.com/Public/Home/index.cfm>
 8. Visit: www.greenpeace.org
- ⇒ You could also send an email to: csa@csa-india.org
- ⇒ Call CSA [Centre for Sustainable Agriculture] at: +91-40-27017735
- ⇒ Write to: Centre for Sustainable Agriculture, 12-13-445, Street No. 1, Tarnaka, Secunderabad 500017, INDIA.

For official websites of Government of India:

1. http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html
2. <http://www.igmoris.nic.in/>
3. <http://dbtbiosafety.nic.in/>