

# genetic safe food - the end of choice?

Greenpeace is an independent, campaigning organisation which uses non-violent creative confrontation to expose global environmental problems and to force solutions essential to a green and peaceful future.



Greenpeace believes that GMOs should not be released into the environment as there is no adequate scientific understanding of their impact on the environment and human health.

We campaign for creating a paradigm shift in agricultural production – to transform how politicians, industry, media and the public see agriculture and to replace the industrial agriculture of corporate control, monoculture, genetically engineered crops, and synthetic agrochemical inputs with sustainable farming that has low external inputs, enhances agro-diversity, protects biodiversity and helps meet local food and employment needs.

PUBLISHED BY: Greenpeace India Society, October, 2008 60, Wellington Street, Richmond Town, Bangalore – 560 025

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Printed on 100% post consumer recycled paper.

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# **FOREWORD**

#### ENGINEERING LIFE

NIKHIL DEY AND ARUNA ROY

"He thought he saw a banker's clerk descending from the bus: He looked again, and found it was a hippopotamus. "If this should stay to dine," he said, "there won't be much for us!"

> LEWIS CAROL - THE MAD GARDENER'S SONG "THROUGH THE LOOKING GLASS"

At a hearing at the Central Information Commission in Delhi in April 2007 an official from the Department of Biotechnology emphatically declared - "there is no safety Issue in approval of Genetically Modified (GM) crop trials; they have been extensively tested and have been found 100 per cent safe." And yet this senior government official was unwilling to provide the material evidence on the basis of which this assertion was made. Worse, he was most concerned about the commercial interest of the companies who work to develop these products for commercial release.

As scientific research knocks on the doors of creation, putting the law of nature to test, we have to realise how fundamentally the dominant norms of scientific research have changed. It is now assumed that only commercial interest can drive the desire for research. Patents and Intellectual Property Rights are therefore needed to protect these commercial interests. A huge part of the patent regime is dependent on secrecy. In the course of these changes, we have even forgotten the crucial dependence of scientific inquiry on the free flow of information. With frontier areas like genetic engineering changing the shape and form of life itself, we no longer can tell or comprehend from sight, sound, smell, and touch. Even labeling, as this report will tell you does not reveal all, What you see, may not be what it is.

This report makes an effort to put forth the important health and safety concerns arising from Genetic Engineering (GE) in agriculture. The challenge we all face is to make this comprehensible; first to ourselves as readers, and then to the millions of others who also need to consider the issues, questions and implications and then exercise an 'informed choice.'

There is the fear that the option of an informed choice may be threatened in the case of GM foods. The fact is that GE research in India is conducted by the companies themselves. They have already made it clear that they don't want to share information. It is appalling that the regulatory agencies are taking their side. Even the farmers growing crops in field trials have been unaware of the nature of the crop they are growing. All this goes to expose the hostile information regime of GM foods.

When one factors in the reality of field trials being allowed without adequate information, contamination due to lack of supervision, and knowledge, and the potential effects of dispersion of GM seeds within the general gene pool, we will perhaps understand that the choice is already being snatched away from us. The urgency is abundantly clear.

There are many who feel the doomsday scenario being painted by the critics is grossly unjustified. They would do well to consider the fact that the very same countries like Switzerland and Germany that he companies harbour companies that engage in this research have banned the commercial planting of GM foods and moving towards a ban on even imports. Even the US, which is the big GM food exporter, has had to withdraw its long grain rice due to GM contamination. Those responsible for granting clearances need to first grapple with the possibility (however remote) of a bad product entering the general gene pool – what is the worst case scenario? The truth is that those consequences are so mind boggling, they can hardly be articulated. The best we can have by going down the GM food path is more efficient food 'products' that the so called 'pests' of nature will eventfully find a way to invade. Our overconfident regulators who talk about 100 per cent safety need to be re oriented, because we will survive without the benefits of GM foods. But we may find it very difficult to survive the change unleashed by the tide of modification coming our way.

The world has grappled with containing the spread of nuclear technology because of its acknowledged Armageddon potential. It is time all of us started thinking of the strictest regulations for Genetic Engineering. In India, we need to begin with a ban on commercial GE products, along with a moratorium on field trials. Let this research be confined to the laboratories, and let's have it as transparent and open as possible. It will be good for research, good for science, and good for life. Read this report, and if you feel concerned enough, do exercise your informed choice - while you still have it!

NIKHIL DEY

MAZDOCH KISAN SHAKTI SANGATHAN

ARUNA ROY

# **PREFACE**

#### GOOD HEALTH COMES FROM GOOD FOOD

DR. MIRA SHIVA

Food is one the most important determinants of health, which is why our food must be nutritive and safe, our processes involving cultivation, storage conducted with safety as a priority and where equitable distribution is ensured.

Any 'added value' in foods should focus on nutrition and safety and not merely economic value and profits.

In the past, experts on agriculture, agriculture universities, and their extension services aggressively pushed pesticides into the agriculture market. These were touted as safe. Health authorities had a small role to play in warning against the health hazards posed by these pesticides. It was only after campaigns against these hazardous pesticides, specially the 'dirty dozen' highlighted health hazards and safety concerns, that the problems were grudgingly acknowledged.

Similarly, antibiotic usage in animals was considered to be safe until much later when humans who consumed these animal products were tested to have developed antibiotic resistance. Similarly, health problems in humans associated with animals that were given hormones such as Bovine Growth Hormone (BGH), oestrogens, in order to increase the size of their mammary glands have been observed. However, these were neither systematically monitored nor the findings made public once known.

The Mad Cow Disease also known as Bovine Spongiform Encephalopathy, highlighted the fact that the "feed" given to animals, not only adversely affected the cattle but also humans once these animals entered the human food chain. Although the Mad Cow Disease was not supposed to affect human health, cases of Creutzfeld Jacob Syndrome, which resulted in the brain becoming sponge-like have been recorded in humans. Scientific information pertaining to the cause of the Mad Cow Disease was proved to be erroneous and thousands of cattle had to be killed.

Most doctors in the medical field know little or nothing about GM foods. The only information available to them is the "orchestrated" promotional information. Take drugs for instance, costly, irrational, and potentially hazardous drugs are promoted when safer and better alternatives exist.

Clearly, neglecting food safety has resulted in public health concerns in the past. As far as GMOs are concerned, the safety concerns have not been adequately addressed, neither at the field trial stage, nor later. Even when independent experts have highlighted GMO- related biosafety concerns, these have been vociferously denied. Efforts to de-legitimise the scientist-panels have failed. And it is the lack of transparency, which leads to suspicion.

Denial of information and secrecy related to GM food raises serious questions. The fact Mahyco claims that making biosafety test results available for review would violate the TRIPS is a sham. The 'urgency' to enforce the Draft National Biotechnology Regulatory Authority Bill, without addressing food safety and public health concerns further erodes peoples' confidence.

What is of graver concern is the fact that there are various short-term studies that have been conducted, but nothing is known of long-term consumption of products such as GM foods. The mysterious and unexplained deaths of sheep, which fed on remnants of Bt cotton harvested in Andhra Pradesh needs to be seriously investigated. And the various problems related to allergenicity, carcinogenicity, effects on the immune system, effects on the development of brain, pancreas, kidneys, and infertility, which have been recorded by respectable scientists in various experiments, although not acknowledged, need to be thoroughly examined.

The gene transfer between animals and plants, which is the basis of Genetically Modified food is unstable and irreversible. Mutations, complications that could result from Horizontal Gene Transfer, and the fact that living organisms have the capacity to multiply magnifies health concerns several times over. It is precisely for these already evident and potential problems related to public health, that several countries have already imposed moratoria on the cultivation of crops and import of products containing GM ingredients.

Food crises, the weak regulatory system, practically non-existent health ministry, low health literacy and a naïve and gullible people makes it easier for people in power to influence the market, the laws and acts, and actively promote GM foods without any sense of accountability. This needs to be urgently addressed.

It has taken a long time to recognise the impacts of pesticides, fertilisers, Mad Cow Disease, or even junk food on public health. We are not willing to be dished out hazardous GM foods, just to placate the interest of a vested few.

What people need is nutritive and safe food, and a knowledge of what is being forced down their throats so that consumers can make an informed decision. After all, "we are what we eat."

We reject it, to protect public health.

DR. MIRA SHIVA, M.D.

INITIATIVE FOR HEALTH, EQUITY & SOCIETY



### GMOs: IS OUR HEALTH AND SAFETY AT STAKE?

Whether it is referred to as Genetic Engineering, or recombinant DNA (rDNA) technology, it can be stated as 'Research involving the combinations of DNA molecules from different biological origins using any method that overcomes natural barriers in mating and recombination to yield molecules that propogated in some host cell, and the subsequent study of such molecules,' (EMBO, 1976)<sup>1</sup>

Genetic engineering is simply the artificial transfer of genes from one species to another – plant or animal. This results in a genetically 'modified' organism. The genetic make up or the genetic blue print of an organism is completely and permanently altered; with the objective of bringing about a certain function – for instance in plants, increasing resistance to viruses, developing a tolerance to herbicides, generating increased protein or other nutrient content.

Modification involves the isolation of genes from one type of organism and splicing them with the DNA of a dissimilar or distinctly different species altogether. Technically, it completely disrupts the DNA's natural sequence. Given that the transplanted gene is a foreign body, it cannot function without an artificial boost.

These foreign genes need an artificial boost and are equipped with very strong signals, called 'promoters' or 'enhancers'. These act independently of the host organism's cellular controls, uncorrelated with the other genes, in contrast to the harmonious coordination that exists among the host cell's genes. This aspect makes the nature and functioning of altered genes completely unpredictable and irreversible.

#### Why GM foods?

Promoters of GM foods suggest that GE is the next agricultural revolution, a step towards 'sustainable agriculture' with increased productivity achieved through improved crop varieties, reduced input costs as well as lower environmental hazards.

#### Herbicide tolerance

Plants can be engineered to generate certain chemicals that break down the action of herbicide molecules. These herbicide- resistant crops make weed elimination easier by a mass application of herbicides, which would otherwise also harm the crop species.

#### Pest and disease tolerance

Plants can be engineered to generate biotoxins to make them resistant to certain pests and thus reduce agro-chemical usage. They are also engineered to gain resistance over diseases like viral and fungal infections and reduce losses incurred during yield.

#### **Nutritional enhancement**

Plants are engineered to enhance nutritive value, like vitamin content. The process helps either in enhancing the production of a particular nutrient in the crop or produces a new nutrient in the plant making it a healthier supplement.

#### Abiotic stress tolerance

Plants are engineered to increase tolerance to salinity and drought conditions by altering their genetic structure.

#### **Edible vaccines**

Plants are engineered to produce specific proteins and enzymes that have medicinal value. Genes from different micro-organisms producing vaccines or antibiotic proteins are incorporated into the plant.

In a nutshell, GM foods are being promoted by the industry and its supporters as the panacea to the world's food problems. That there is no justification for most or all of these claims is now a matter of fact, as this report goes on to show.

#### Frankenfoods - an unappetising future

Whether the target is a plant or animal, genetic engineering disrupts the organism's natural genes, and renders it unstable in character and function. The modification process does not, however, take away its ability to reproduce, which essentially means the new mutant organism continues to reproduce and is thereby impossible to control once released in the environment.

#### Health ill-effects

Health risks are a primary concern with food crops. Innumerable concerns are being raised about the adverse effects these genetically engineered crops have on the health of people and animals alike. There is a growing body of evidence regarding these health risks, and none of these risks have yet been disproved.

There is no certainty that the new protein, which is formed when the new gene is introduced into a plant, will not adversely affect human health. For example, many scientists agree that hat the Cry 1Ac proteins have potential for undesired immune reactions in humans. Presently, the toxicity and allergenicity tests conducted in India rely on animal feeding tests for a maximum period of 90 days, using a synthetically derived protein instead of the protein extracted from the transgenic plant. Without assessing long-term impacts over generations, the behaviour of the transgene in the host plant can never be fully understood.

New genes can also create a large range of unseen side effects in the plant's metabolism and thereby also to the humans or animals subject to it. For example, the fact that Bt cotton, a non-food crop could have led to unexplained adverse effects on sheep and goats that fed on the stalks and cuttings, illustrates how a product supposed to have undergone thorough testing still resulted in an unforeseen disaster.<sup>2</sup>

#### Resistance

In the case of pest resistant transgenics, Bt cotton has shown that the resistance is limited to one class of pests, and that this toxin kills beneficial insects as well. The killing of non-target beneficial insects damages the field ecology and the natural pest-predator balance. Bt plants also induce faster resistance to the Bt toxin among insects due to indiscriminate use.<sup>3</sup> If this resistance were to spread, the insect resistant properties of GE crops would become ineffective, leading to the inevitable application of new, more toxic chemical pesticides and increased farmer expenditures on both the GM crops as well as pesticides.

#### Nutritional enhancement

Considering the risks to human health and the environment, the idea of nutritional enhancement via transgenic crops, like golden rice providing vitamin A, are unnecessarily complicated and unproven 'solutions' to a nutrition problem.

#### Impending dangers of pharma crops

Pharma crops are crops that are genetically modified to possess medical properties. Ironically, such crops pose a grave danger to the health and safety of all food crops. The antibodies and antigens being generated could go out of control due to the usual instabilities of GM crops, causing a new kind of health epidemic. Contamination threats from such GM crops would lead to huge economic losses.

#### **Economic losses**

Claims of huge economic gains from GM cultivation are as hollow as those surrounding their alleged pest resistance or nutritional benefits. In several cases across the globe, farmers have incurred heavy economic losses either directly because of the failure of the GM crop or because of the loss of market for their crops due to GM contamination. The United States Development Association (USDA)<sup>4</sup>, European Commission<sup>5</sup> and the United Nations FAO<sup>6</sup> have acknowledged that over the years GM crops have decreased yields.

Several studies and cases have been documented worldwide where GM crops have had reduced vields and farmers have lost profits.

A recent study of Roundup Ready Soya<sup>7</sup> in Kansas, USA revealed that the yield of GM soya was nine per cent less than a close conventional relative and proved that RR soya continues to suffer from a yield drag, as reported by several earlier studies. RR soya was found to have a 4-12 % yield drag. By one estimate, the stagnating soybean yields in the U.S. cost soybean farmers \$1.28 billion in lost revenues between 1995 and 2003.8

Corporate control The trade in seeds, food and crops is dominated by a handful of companies with the largest share held by Monsanto. This corporation has acquired or merged with more than 50 companies in the last few years. The other major corporations are Bayer Agro sciences, Syngenta, Dupont and BASF. In India, Monsanto is the largest company in the agribiotech sector, and has a joint venture with Mahyco. Mahyco Monsanto Biotech Limited, which markets the Bt cotton seeds, has licensed the Bt technology to more than 25 seed companies that sell cotton seeds. Non-Bt cotton seeds are hard to come by now, due to

"Punjab is reeling under toxic pressure, the state is in the grip of a severe environmental and health crises and the large-scale engineering food crops will only hasten this process. Research clearly indicates that GM techniques are nakedly anti-nature; endangering plant biodiversity; animals and humans. In addition, the possibility of emergence of antibiotic resistance bacteria and horizontal transmission of the gene to bacteria and other cells is grave. The succ ess of natural farming has proved beyond any doubt that neither chemicals nor GMOs are necessary for successful agriculture. It is very obvious that GMOs are being imposed on our farmers and people with an active connivance of our governments and agriculture scientists. We need to launch a massive awareness campaign to fight against this slavery."

DR. AMAR SINGH AZAD, ASSIT, PROFESSOR, COMMUNITY MEDICINE GGS MEDICAL COLLEGE FARIDKOT, PUNJAB



the market control exercised by Mahyco and its licensees. Adopting GM crops would place farmers and the food chain itself under the control of a handful of powerful Multinational Corporations.

#### A contamination nightmare

In crops, depending on the seed type, various kinds of pollinators – butterflies, bees, wind and water – ensure crosspollination; this results in the new mutant gene being transferred to a regular crop or a related wild species, leading to the uncontrollable spread of the unnatural mutant species. Once a GM crop is experimented upon, undergoes field trials or is commercially licensed, it rapidly contaminates other non-GM crops. Control is impossible, and eventually the entire crop species will effectively become genetically modified.

The fundamental problem with GM crops is segregation. Since there is no way of discerning a GM crop from a non GM crop, identification is impossible without laboratory tests.

This curtails the consumer's choice to eat GM free food, as the entire crop species – rice or brinjal, for example – will be genetically tainted. This also makes subsequent recall or elimination of the GM species completely impossible. GM food is neither visibly different nor is the labelling of GM food mandatory all over the world, so much so that even non-GM food could contain GM ingredients.

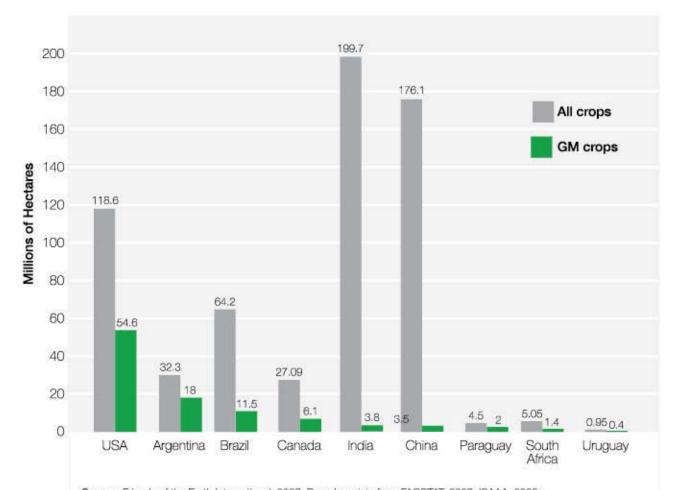
In other words, a country that chooses to be GM free may end up importing unlabelled food containing GM ingredients. While several countries have strict labelling, and have adopted liability regimes to prevent contamination, India has only enforced an import restriction with no liability for contamination. Even this is bogged down by regulatory inefficiencies as recently proved in the case of Doritos imported corn chips, which was found to contain GM corn, even though there was no indication to this effect on the package.<sup>9</sup>

#### False messiah

The final report of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), which was adopted by governments in April 2008 in Johannesburg clearly affirms that genetic engineering of crops will not play a substantial role in addressing the key problems of climate change, biodiversity loss, hunger and poverty. The future of farming lies in a biodiversity-and-labour-intensive agriculture that works with nature and the people, and not against them.

#### The Global GM scenario

The first engineered crops were sown in the United States for commercial use. Ten years later, genetically engineered crops were grown over 102 million hectares worldwide – an area nearly the size of France and Germany combined. Today, while there is no official estimate on the total spread of GM crops in the world, the industry estimates confirm that more than 91% of the GM crops are grown today in just three countries – the USA, Brazil and Argentina.<sup>10</sup>



Source: Friends of the Earth International, 2007. Based on data from FAOSTAT, 2007; ISAAA. 2006a. Notes 1: The table compares the total crop area harvested in 14 countries which have been classified by ISAAA in January 2007

as "Mega-biotech" countries - to the total hectares which are estimated to be planted to GM crops in each of the 14 countries. The 14 so-called "Mega-biotech" countries are U.S, Argentina, Brazil, Paraguay, Canada, India, China, South Adrica (SA), Uruguay, Australia, Mexico, Philippines, Romania and Spain.

Notes 2: Data from FAOSTAT is based on ProdSTAT, Crops, Subject: Area Harvested: Countries: USA, Argentina, Brazil, Paraguay, Canada, India, China, South Africa, Uruguay, Australia, Mexico, Philippines, Romania, Spain. Commodities: data on all crops includes the total harvested area in million ha of the following crop groups: cereals, fruits, fibres vegetal origin, oil crops, nuts, spices, stimulants, pulses, roots and tubers, selected fodder crops, sugar crops, tobacc and vegetables.

#### Safety first, say progressive nations

So far, the European Union has given its nod for only one food crop, which is also the largest food crop in the region - maize. The Mon 810 GM corn variety is spread roughly over 110,000 hectares and mostly in Spain. Several European nations have recently joined the league to completely ban this variety and have come forward to ban GM crops at a policy level. France, Hungary, Italy, Greece, Austria and Poland led the rest of the world by banning Mon 810, the only cultivated GM variety of corn in Europe. France joined the league in January 2008. 11 In May 2008, the French parliament rejected a bill that sought to allow genetically engineered crops, in line with a 2001 European Union Law.

Romania, which has been one of the most receptive markets, is moving towards a reversal of its stance. Austria banned Mon 810 and went a step further by banning the import of Mon 863, another controversial variety of corn. This variety has been at the centre of controversy since May 2004, when the French newspaper Le Monde reported on findings by Dr. Seralini and his team. 12 Despite the scientific controversy, the European Commission allowed GE maize to percolate into the market from January 2006 against the will of a majority of EU member states. The Austrian Government did a re-evaluation of Monsanto's safety documentation and found several loopholes, following which imports were banned. 13



Outside the European Union circle, Switzerland, already a GM-free country, extended its moratorium on GM crops till 2013. All 26 cantons (administrative regions) that make up Switzerland unanimously voted against GE crops and animals.

Mendocino, California became the first county in the United States to ban the production of GMOs in 2004 and was later joined by the Trinity and Marin counties.

From 2003, several states in Australia have enforced moratoria on the planting of GM food crops. New South Wales and Victoria have lifted GM bans, but South Australia and Western Australia have not relented. The Western Australian Government extended its moratorium on genetically engineered crops (food and fibre – especially canola and cotton) by another four years from 2008.

In 2005, a standing committee of the government of Prince Edward Island in Canada began work to assess a proposal to ban the production of GMOs in the province. PEI had already banned GM potato, the most cultivated crop in the country. More recently, in August 2008, Monsanto announced that it is pursuing a divestiture of its dairy product, POSILAC(R) bovine somatotropin. Monsanto also produces bovine growth hormone rBGH, a genetically engineered product to increase milk production in dairy cows. Global and consumer markets have rejected rBST, resulting in Monsanto's decision to get out of the rBST business in the U.S.

#### **Current Situation in India**

Today, around 56 GM crops (41 food crops) are at different stages of trials in India at various private and public institutes. Bt cotton is the only crop that has been commercialised so far. An alarming number of crops are undergoing open field trials, which implies that the scope of contamination of non-GM varieties is magnified. Although contamination has been detected, vested interests have overruled it.

In 2006, unapproved and unregulated rice field trials were conducted following which rice exporters in India, fearing revenue losses, demanded a ban on GE rice field trials in six key rice producing (and exporting) states. The ban was granted in 2007, facilitated by a growing public resentment.

Today, India is poised to commercialise its first genetically engineered food crop, Bt brinjal, a widely cultivated vegetable in India, ranking fourth largest in terms of acreage. Bt brinjal, as the name suggests, contains a toxic gene from the bacterium Bacillus thuringenesis (Bt), which is injected into the plant so that the plant can produce pesticides and protect itself from the pest, Brinjal Fruit and Shoot Borer. While corporations claim this is in the long-term benefit of the farmers, there is no guarantee that pests will not, over a period, become immune to Bt Brinjal's biotoxin. Neither is there any evidence to prove that there will be no adverse effect on the health and safety of consumers or the environment. If it is indeed given a go ahead, it would open a Pandora's Box.

Okra, tomato, rice, mustard and a host of other food crops are in the GM pipeline. The most worrisome fact is that not a single study in the public domain has established the safety of these crops, either with respect to human health, or the environment. It wouldn't be far-fetched to say that after the Green Revolution, Genetic Engineering is the latest step in an agro-technological development paradigm that has led to large-scale reduction of biodiversity and depletion of natural resources (soil, water, habitats), all of which have long-term implications on the health of the environment and those dependent on it.

#### IS A GMO 'SUBSTANTIALLY EQUIVALENT' TO ITS NATURAL COUNTERPART?

Although the regulation of GE foodstuffs differs from country to country, the concept of 'substantial equivalence' forms the basis of regulatory assessments worldwide.

Essentially, the chemical composition of the GE food is compared to an equivalent non-GE variety – GE soybean would be compared to conventional non-GE soybean, for example. If there is no significant difference detected between the two, the GE variety is pronounced safe.

This principle has some serious short-comings. The first problem concerns what is actually compared between GE and non-GE food. The levels of some major and minor nutrients, known toxins and other anti-nutritional factors are measured. There is no standard list of what must be measured and there is no process to look for unexpected or unintended changes — one of the most important concerns over GE food safety.

The second problem is that the systems to detect allergenicity or toxicity of the GE product have serious limitations. Genetic engineering is designed to produce new proteins not normally present in the plant and these may cause allergies. The system of substantial equivalence obviously plays no role in testing the impacts of new proteins.

Another problem is that when any food safety testing is performed on GE crops, it is only short-term – over a few days or weeks. There is no long-term testing or testing for chronic effects of toxicity or nutritional changes.

Because of such gross limitations, the use of substantial equivalence as a criterion in GE food safety testing has been severely criticised <sup>14</sup> by institutions such as The Royal Society of London <sup>15</sup> and Royal Society of Canada. <sup>16</sup>



# HEALTH IMPACTS OF GENETICALLY ENGINEERED CROPS

According to the promoters of GM crops, the ability to genetically engineer seeds, the very nucleus of human survival, would theoretically give us an edge over natural events that determine whether or not a crop would fail in a given season. We would also be able to generate higher yields and reduce reliance on chemicals. In essence, GMOs are being projected as the panacea to the food crisis across the world, and policy makers in India are flashing the GM card in order to bridge the 'gap' between the demand and supply, with the promise of tackling the issue of food shortage.

#### Fallen for the trap?

In reality, the global shift away from GM is gaining momentum; countries are joining the league to ban genetically engineered foods in any form – field trials, commercialisation and even the imports of packaged foods. The Indian government, on the other hand, is in a GM trial frenzy and is looking to commercialise its first ever GE food crop, Bt brinjal.

Taking this into account, a closer look is needed at what implications GM food could have on the health of humans and animals before we 'progress' towards irreversible damage. It is a fact that most of the findings mentioned in this report have been a result of accidents, in the sense that the studies were conducted without the presumption of looking for any adverse health impacts while in contrast, statutory safety assessments have always been given a clean chit.

There is a paucity of accurate information, a direct result of the meagre scientific attention the issue has been accorded. What information exists has not been adequately collated. However, there have been sporadic studies conducted by independent scientists and the findings are rather disturbing.

#### Viscera and immune system

Dr. Arpad Pusztai (1998)<sup>17</sup>, of the Rowett Research, Institute, Scotland, found that potatoes modified by the insertion of snowdrop and jackbean genes that code for pesticidal toxins stunted the growth of rats and reduced their immune responses to injurious antigens. Rats subject to transgenic potatoes were observed to have had adverse effects in their vital organs including the kidney, thymus, and gastrocnemius muscle.

"In my opinion, naturally sown and grown foods are always the best. We don't want to tamper with nature and bring out unusual foods. At this point in time we are not sure of the harmful effects (if any) from long-term use of genetically modified foods. Moreover tilting the nutrient balance in modified foods might not be beneficial for our bodies."

DR. SHEELA KRISHNASWAMY
NUTRITION EXPERT AND MANAGING PARTNER & FOUNDER
NICHE BANGALORE



A group of scientists representing CRIIGEN (Committee for Independent Research and Genetic Engineering, University of Caen, France) found signs of toxicity in the liver and kidney of rats fed with Mon 863, a genetically engineered maize type of Monsanto. 18 There were also stark and observable weight gain differences between rats fed with Mon 863 and non-GE maize. There was a 3.3% decrease in weight for males and 3.7% increase for females. While it is not known whether the signs of toxicity are caused by the Bt protein, or from some changes in the plant's own DNA caused by genetic engineering, it is certain that it points to the unpredictable nature of GE technology. This result was a re-analysis of an earlier study done by Monsanto, which found no irregularities in the rats.

#### Allergic reactions

Allergic reactions can be caused either by a protein known for its allergenic properties introduced into a transgenic plant or due to unknown structural changes in a normal protein when expressed in a new environment of the transgenic plant.

Soybeans engineered with a Brazil-nut gene to improve nutritional quality, caused allergic reaction in people who consumed this soya. These transgenic soybeans were found to contain 2S albumin, a major Brazil-nut allergen. It also became evident that allergen from a food known to be allergenic can, by genetic engineering, be transferred into another food.<sup>19</sup>

Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) developed transgenic field peas with a gene from the common bean, Phaseolus vulgaris so as to make it resistant to bruchid beetles such as the cowpea weevil. The gene inserted was intended to produce an alphaamylase inhibitor, a protein that affects the digestion enzymes and causes the weevil to starve to death. After a decade of research, mice, which were being fed with these peas, were detected with lung inflammation<sup>20</sup>. Interestingly, these effects were not observed with beans that naturally produce this protein.

#### Vulnerability

A report by the Royal Society recognised that food allergies are far more common in children than adults, stating that: "food allergies occur in one to two per cent of adults and six to eight per cent of children" and, therefore, children would be most vulnerable to any allergens that may have gone undetected in GE food. The Royal Society also recognised that babies and infants are

vulnerable to harmful effects from nutritional changes in their diet. Any changes in the composition of foods made from GE crops could be important when given to infants over a long period of time, especially if it is a food such as infant formula, which is used as complete food nutrition for infants. This view has been reiterated by the British Medical Association.<sup>21</sup>

## Horizontal gene transfer (HGT) and antibiotic resistance to microbes

A myth promoted by the proponents of GE technology is that the components of the transgene get destroyed in the digestive tract itself and thus challenges the base of horizontal gene transfer (HGT). (HGT is a process in which an unrelated organism incorporates genetic material from another organism) This myth has been disproved by several independent studies. Mercer et al. reported that such transfer could start in the mouth itself.22 A plasmid of a genetically engineered cell has been found to have a 6 to 25% chance of surviving intact after 60 minutes of exposure to human saliva and insert itself into the genes of bacteria in the mouth. As a matter of fact, plasmid DNA and GM-DNA were found in micro-organisms that naturally live in the intestines and saliva in man. Experimental researches in mice showed that ingested foreign DNA can persist in fragmented forms in the gastrointestinal tract, penetrate the intestinal wall, and reach the nuclei of leukocytes, spleen and liver cells.23

However there is little information about the potential effects of exposing the bacteria that live in and on human beings to the antibiotic resistance genes in GE food. Concerns have been raised that if these bacteria do develop antibiotic resistance, then they may then pass these genes onto bacteria that could cause disease. It is to be noted that the European Union (EU) has previously recommended the phasing out of any antibiotic genes in genetically engineered plants because of concerns relating to human health and antibiotic resistance.<sup>24</sup>

#### Food and pharmaceuticals contamination

Even if the allergenic potential of a GE crop is recognised by the regulatory authorities, it can still end up in human food. Aventis' StarLink, an insect resistant GE corn grown in the USA, approved only for animal feed and industrial purposes (as there were concerns that the Cry9C protein in the engineered corn could cause allergies) was detected in corn taco shells and other corn-based foods even in Japan and Korea in September, 2000. Although over 300 corn

products were withdrawn from the market, there is no guarantee that it was completely sieved out of the market. There was no way of tracing how the corn was introduced into the food market – it may have been inadvertently mixed with other corn at a mill, a conventional crop may have crosspollinated with a StarLink crop, or it may have been sold for human consumption! The episode raises questions about regulatory authorities' ability to control GE crops.

A relatively new trend emerging in the field of genetic engineering is the emergence of pharma crops or crops engineered with hazardous bacterial and viral sequences to produce vaccines and pharmaceuticals. These pharma crops include those expressing specific proteins like cytokines, known to suppress the immune system, and central nervous system toxicity, as well as signalling proteins like interferon alpha, reported to cause dementia, neurotoxicity and mood and cognitive disorders. Some contain viral sequences such as the 'spike' protein gene, the pig coronavirus, in the same family as the SARS virus. 25, 26 Going with the tradition of contamination caused by genetically engineered crops, these vaccines and pharmaceuticals are in the most likelihood bound to get mixed up with normal food crops.

In 2001, the US company, ProdiGene ran field trials of a GM maize which contained genes to produce an experimental vaccine against a pig disease, transmissible gastroenteritis virus (TGEV). In 2002, seeds from a GE corn pharm crop of ProdiGene containing a pig vaccine were left in fields in Iowa and Nebraska and grew the following year amongst normal soybean crops<sup>27</sup>. 28. Action was taken by the U.S. Government to prevent the crops reaching the food chain. Over 155 acres of corn that was surrounding the soybeans in lowa was destroyed in case it had crosspollinated with ProdiGene's pharm crop.29 A staggering 13,600 tonnes of harvested soybeans that were mixed with the pharm maize (or corn) crop had to be withheld from entering the food chain.

#### Mutations

Pleiotropic effects may occur when new genes are inserted into plants to give them 'desirable' traits. The impacts are unknown and tricky to trace. Mutations found at transgene insertion sites include deletions and rearrangements of host chromosomal DNA and introduction of superfluous DNA. Ancillary procedures associated with plant transformation, including tissue culture and infection with A. turnefaciens, can also result in mutations.<sup>30</sup>

#### THE BT COTTON MYSTERY

In 2006, a survey led by the Centre for Sustainable Agriculture, a civil society group, based in Hyderabad revealed that 1,600 sheep died in Warangal District, Andhra Pradhesh after grazing on remnants of leaves and stubbles of Bt cotton in the fields for a week.<sup>32</sup>

However, the GEAC dismissed the findings and gave a clean chit, permitting its further spread. The GEAC concluded that the deaths might have been due to high content of nitrates/nitrites, residues of hydrocyanide (HCN) and organophosphates, which are common constituents of pesticides used in cotton cultivation. The GEAC's purportedly based its conclusions on two reports – one from the Directorate of Animal Husbandry in Hyderabad and the other from the Indian Veterinary Research Institute, Izatnagar, Uttar Pradesh and a letter from the Andhra Pradesh Government.

Two years later, Dr P.M. Bhargava, the Supreme Court nominee to the GEAC found that the reports of the two institutes and also the State Government's letter contradicted the GEAC's version. For instance, the State Government's letter to the GEAC stated that the samples were "negative for HCN, nitrates, nitrites, alkaloids and glycocide." Even the report from the Veterinary Research Institute, U.P. had clearly stated that the Bt cotton samples did not show the presence of these chemicals. 34

#### 'Crystal clear'?

Genetic engineering technology for insect resistant crops depends mainly on the inserting genes from various Bacillus thuringiensis bacteria, which produce crystalline (Cry) delta endotoxins known as Bt that confer crops resistance to insects. The technology is based on the assumption that the protein is specific to lepidopteran insect pests. However, there are ample evidences, which show that several toxin-related, organisms related and environmental factors can modulate the toxicity and consequently the specificity of a Cry-protein. Some scientists have demonstrated that recombinant Cry1Ac protoxin from Bt is a potent systemic and mucosal immunogen, as potent as cholera toxin that could cause immune reactions on mere inhalation and contact with mucous.31

"I haven't heard much about genetically modified foods in India. I don't think they can catch on so easily in India, and I am of the opinion that they should not be permitted either. As an athlete, we stick to natural foods and a healthy diet, which if at all, could be substantiated with supplements. I would never experiment with such 'promising' foods nor recommend them to my young students. There is no short-cut to success."

NISHA MILLET EX-OLYMPIAN (SYDNEY, 2000)



Most of the GE crops implicated in impacts on human and animal health had Cry proteins as the component. Cry1Ac is being used in the Bt Brinjal, which is awaiting a green signal for commercialisation.

#### Indian Regulatory System: Public Safety vs. Commercial Interest

On the global front, the International Regulatory Systems on Biotechnology are increasingly becoming conscious about the safety of GM crops. The Indian Regulatory System on the other hand, seems to be blinded by the myopic gains of vested interests.

The Genetic Engineering Approval Committee has a history of non-regulation contamination and de-regulation even before Bt cotton was approved in 2002. There is extensive documentation on the contamination mishaps that have happened during field trials of various GM food crops in the past years. According to the existing guidelines, complete bio-safety assessments are not a prerequisite before field testing.

These vital assessments are conducted simultaneously – during or after the field trial stage, but before they go for large-scale field trials. It has also been found that even when large-scale field trials are approved, the safety tests are not complete and are conducted simultaneously in order to cut costs, and expedite the approval processes.

The tests that are conducted by the corporation – outsourced or in its labs – are kept secret and not open to public comment. With poor monitoring during field trials and denial of information on safety, there is no way to keep our food clean from GE contamination.

The GEAC has never in its 19-year-history issued guidelines regarding the regulation of imports of GM food products. The Food Safety and Standards Authority (FSSA), a body constituted to safeguard the health and safety of citizens, is still on paper, while imports of GM contaminated food floods supermarkets across the country.

With the present understanding and expertise, scientists are struggling to explain the unintended and unexpected effects these crops could have on the consumers – human and animal, aside from effects on the environment. It would be preposterous to permit the commercialisation of GE crops with our limited knowledge, and allow corporations and governments alike to experiment on the population.



#### A PUBLIC HEALTH PERSPECTIVE ON GENETICALLY MODIFIED CROPS

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Principles of Bio-ethics require consideration of Beneficence (benefit to the users/public good), Non-malfeasance (non-harm), Autonomy (freedom of the users to decide) and Justice (considerations of equal benefits and risks). It is on one or more of these grounds that the proponents of the use of genetically engineered crops argue their case. However, from the perspective of health of any population, genetically engineered crops do not, at least, as yet, pass the test of any of these principles.

Ethical Public Health requires convincing data on the benefits and the safety of GE foods and medicinal plants for human health. Studies in animals provide enough prima facie indications that the negative effects are probable, and therefore there should be no concession on studies on the issue of collecting and analysing data for negative effects. Demonstration of the survival of the engineered genes through the digestive tract and their horizontal transfer to cells of the human body, increased mutations etc. magnifies the potential risk. Documentation of allergic reactions, auto-immune diseases, lowered resistance to infections and organ toxicities in animals as well as humans point to the potential risks. Within a history of abysmal research, there is enough evidence to prove its harmful effects on human health, which has often been suppressed. The now widely-known case of asbestos is illustrative, in that the data was revealed only in recent years, almost 100 years after it the information was available with the industry, and despite the negative health impacts, workers and communities dealing with asbestos continue to be permitted to use this toxic mineral.

Benefits, in terms of human health are also not to be expected from GE crops, given the experience of the 'Green Revolution'. In the 1960s and 70s, the High Yield Variety (HYV) seed technology was propagated with the stated rationale of increasing food production to deal with the problem of widespread malnutrition. Despite significant increases in production of the cereals – wheat and rice, the consumption of cereals per capita in the country continued to decline steadily! The focus on these crops led to reduced production of the hardier and cheaper cereals, pulses and oilseeds, i.e. the major sources of staple food, calories and proteins of the vast majority of poorer sections. Thus, four decades later, we still continue to be faced with the problem of moderate to severe nutritional deficiencies in over 50% of the country's children and chronic energy deficiency in 40% of adults! This means a deficiency in the quantity of basic staple food that the poorer sections are able to consume. However, it is amply clear today that the issue is not of production of food, it is the limited 'access' to food based on low employment and incomes levels leading to low purchasing power, increasing prices of food items and the changing Items, food and otherwise, that people are spending on.

Now, once again we are being promised technology to increase agricultural production. Only this time, the purpose of human health is cited in only a few cases. Increasing production per unit land cultivated by GE as well as creating resistance to common plant diseases, are the primary benefits cited. If it improves agricultural incomes, this benefit to farmer's can indirectly translate into better health due to increased purchasing power. However, we have to factor in the reality of Indian agriculture that is related to socio-economic disparity, macro-economic policies and the influence of globalisation on farmers' investment and income. That the currently widely pervasive agricultural distress, as expressed starkly through the phenomenon of farmers' suicides, can be mitigated by such technological solutions alone is a naïve hope.

The principle of autonomy is seriously undermined by the very nature of the technology of GE crops. Crops grown in one field, even for research purposes, are likely to cross-fertilise plants in the neighbouring fields and thereby over time contaminate the entire production of a given species, even by farmers not desirous of using GE seeds. When these products are used for food, it will be impossible for a consumer to ensure food that is non-contaminated by GE products.

'Justice' is clearly going to be absent in a situation where the right to decide and to control seed production is taken away from farmers and consumers, industry gains a monopoly and its profits become the primary purpose. Choices made about what can be classified as safe is itself about a thin line between justifying some 'acceptable' negative effects for the sake of greater gains. Who decides what is acceptable levels of negative effect has been shown to change the operative conclusion from the same set of data. Analyses of past decisions by the Food and Drug Authority of the USA have shown that what had classified as 'acceptable risk' by the industry was well above the levels acceptable to public health analysts.

Therefore, concern with safety to human health of GE crops and medicinal plants/ herbs places the onus on the researchers, industry and government to provide convincing evidence of benefits and no negative effects. This requires making study methodology and findings available in the public domain to allow for scientific peer review as well as independent civil society analysis. Further, it requires that the introduction of GE crops be allowed only after such social consensus is achieved.

"India and the developing are already struggling with rampant communicable diseases and emerging progressive load of non-communicable diseases. It is ludicrous for national agricultural and commerce policy makers to act at cross-purposes with human and animal health. With the scientific data available (and worse, what is not yet available!) it doesn't require much to appreciate that plunging headlong into the GMO venture amounts to creating a voluntary Frankenstein. The Precautionary Approach accepted by most countries in the UNCED Treaty regarding human health is to be followed in letter and spirit. We urge on behalf of those representing the medical field and consumers that the policy makers not rush into permitting GMOs and certainly not permit uncontrolled field trials, which will systematically wipe out biodiversity and destroy the national genetic pool."

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# THE GE REGULATORY SYSTEM IN INDIA: PAST IMPERFECT, FUTURE TENSE

India's tryst with regulations to control Genetically Modified Organisms (GMOs) started with the publishing of the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms or Cells in 1989. These Rules are embedded in the Environmental Protection Act, 1986.

These were followed by the Department of Biotechnology's (DBT's) Recombinant DNA Safety Guidelines in 1990, which were then revised, expanded and published in 1994 by the DBT as the Revised Guidelines for Safety in Biotechnology.

These three documents cover all the four main sectors of biotechnology: medicine/pharmacy, agriculture, industry and environment. Four years later, the agricultural biosafety guidelines were separated out, expanded, revised and published by the DBT in August 1998 as the Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts.

The Director General of Foreign Trade (DGFT) Notification dated April 7, 2006 under The Foreign Trade Regulation Act, 1992 is another significant act. The notification bans the entry of all GM food, feed or any other raw material with GM ingredients without the permission of the Genetic Engineering Approval Committee (GEAC).

These rules also define the competent authorities and composition of such authorities for handling various aspects of the rules. Presently, there are six competent authorities – the Genetic Engineering Approval Committee (GEAC), the Review Committee on Genetic Manipulation (RCGM), the Institutional Bio-safety Committees (IBSC), the State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC) and the Recombinant DNA Advisory Committee (RDAC).

While the first five committees are involved in the approval and monitoring of GM research in the country, the RDAC or the Recombinant DNA Advisory Committee plays an advisory role in the direction of research in the country.

#### Regulatory system - reform and shortfalls

A major change in the regulatory system was brought about by the Supreme Court's intervention. In an order dated May 1, 2006, the Supreme Court took away the powers of the RCGM, which permitted small-scale (less than an acre) open air field trials since it amounted to an environmental release. The power was transferred to the GEAC, which has the mandate to permit the open air release of GMOs.

The regulatory system is inherently flawed, given that it permits the release of GMOs, which endanger the health of human beings and all other life forms and the environment.

- It fails to accept that once let out into the fields, GM crops cannot be traced back or checked.
- It fails to see the importance of the Precautionary Principle and the need to comprehend the short-term and long-term impacts GM crops on health and the environment.
- It fails to see the need for transparency when it comes to GM crops.

#### State Governments - Clueless

Although agriculture is regulated at the state level, states have been left with no decision-making power as far as field trials of untested and potentially hazardous GM crops are concerned. States are merely left with a monitoring role, which is also questionable given the complete absence of knowledge about when field trials are initiated, and communication in this regard. Though the formation of the SBCC and DLC have been mandated for approvals of field trials, it is seldom followed.



#### Case in point

Take for instance the field trials of Bt rice and Bt okra that were conducted in the states of Chattisgarh and Bihar in 2006 and 2007 respectively, although neither of the two states fell under the list of SBCCs provided by the GEAC.<sup>35</sup> Kerala was another state where Bt rice field trials were permitted in 2007 although the SBCC was not formed at the time.

Even in states where SBCCs have been constituted, the state governments were not informed about trials taking place in the state. West Bengal is one such clear example. Citing reports by the monitoring authority, Bidhan Chandra Krishi Viswavidyalaya, Prof. T.K. Bose, a member of the State Agriculture Commission, alleges that Maharashtra Hybrid Seeds Company (Mahyco) conducted illegal field trials on Bt brinjal, Bt tomato without following biosafety and monitoring measures as suggested by the DBT although they were permitted to conduct trials on Bt rice and Bt okra. He demanded legal action against the company. Even after a year, the GEAC has not accepted failure on its part.

Kerala is the only state, which has been capable of thwarting the GEAC's attempts to conduct field trials in the state. Although the state was identified as a site for Bt rice by Mahyco in 2006, civil society, the State Biodiversity Board and the state government stood in the way while highlighting biodiversity, health and socio-economic concerns.

#### **Legalising Contamination**

The existing regulatory mechanism in India is incapable of preventing the uncontrolled illegal spread of untested GMOs into the food chain. In India, Bt cotton leads the way.

By 2005, illegal Bt cotton was all over the country. The Central Institute of Cotton Research in its investigations in Gujarat found the traces of Cry 1Ac gene in at least 12 varieties of cotton, which were not approved. As a matter of fact, there is more land under illegal cultivation than under legal cultivation. When the matter of illegal seeds in Gujarat was brought to the notice of the GEAC, they ordered that the Bt cotton fields be burnt. As the state government failed to implement the order or reprimand Navbharat Seeds as it would have cost them their votes from the powerful farming community; the stand emboldened seed producers to covertly multiply production and sell these seeds, further contaminating the cottonseed market.

In 2005, 21 civil society organisations across six Indian states organised themselves to form the Monitoring and Evaluation Committee (MEC) since the Government set up MEC was not doing its job. The newly-formed MEC presented a report to the government titled Field Trials of GM Crops in India: Illegal and Unscientific. The report documented 19 cases of field trial violations where farmers mixed the field trial - I) gene Bt cotton called bollgard II) produce with non-GM cotton and sold it into the market across the country.38 The GEAC called a special meeting in January 2006, where the seed companies, the state governments and representatives of the MEC were invited to discuss the findings of the report. No action was taken and the following year, these varieties were commercially approved!

In December 2005, a team from the Centre for Sustainable Agriculture (Gangadhar Vagmare, Ramprasad and Kavitha Kuruganti) uncovered a Bt okra field trial being conducted in Guntur District of Andhra Pradesh. Sowing of the plot took place on the August 7, 2005, overlooked by a representative of Monsanto-Mahyco to oversee the trial in Brahma Raju's plot/farmland. The investigating team documented several violations and issues of concern with the trial. Firstly, the farmer was not informed that this was a transgenic crop trial or that it was planted in his field. The farmer and his family consumed the untested Bt okra from the trial plot at least twice.39 These discrepancies and gaps in information within the governmental bodies have left regulation a nightmare in India. The latest example was with the rice field trials in 2006. The Punjab Agricultural University in response to a Right to Information Act application filed on rice field trial locations accepted that their scientists visited a field trial in Bhatinda District of Punjab whereas the regulatory body had given permission for Ludhiana.40

#### Bio safety studies – When the fox guards the chicken coop

One of the most glaring regulatory gaps is the system in which biosafety of GM crops is given the least importance.

The current system is silent on whether GMOs could be released into the environment before they are found safe. The safety tests are conducted in conjunction with the field trials. This creates a situation where the GMO would have contaminated the surrounding crops by the time it's found to be safe or otherwise.

The Bt cotton spread and contamination between 1996 and 2001 during its field trials stage stands as a stark example.

The startling fact is that even after two years of field trials, none of the regulatory bodies have any conclusive evidence on the biosafety of GM rice, okra and mustard. In its response to an RTI application filed by Divya Raghunandan, Greenpeace India, the DBT responded by saying that, "As regards the allergenicity and toxicity data on transgenic rice, mustard and okra, the case is under consideration of RCGM". 41 The only crop that the regulatory bodies claim to have data on is Bt brinjal. But both GEAC and RCGM have thwarted every attempt by the public to scrutinise this data.

The fight for the information on biosafety data on Bt brinjal stands as one of the longest RTI battles in the country. Raghunandan filed an RTI application on February 23, 2006 for information on the biosafety study data of approved Bt brinjal varieties before large-scale trials of Bt brinjal could be started in the country. Though Mahyco's Bt brinjal was permitted to undergo large-scale trials in the *kharif* of 2007, the safety test reports produced by the company were never divulged even four years

after the first release into the environment in the form of field trials in fields across the country. Only in August 2008, more than 30 months after the RTI application was filed, were reports on Bt brinjal made public.

Another peculiarity of the existing regulations for GM crops in the country is that the GM crop developers themselves have been given the task of ensuring safety. This, along with the lack of availability of biosafety data for independent analysis, the most important information regarding GMOs, alienates its stakeholders – the public and agriculturalists.

In an interesting episode, the Supreme Court appointed member of GEAC, Dr. Pushpa Mittra Bhargava pointed out the discrepancies in the biosafety report summary presented by Mahyco to the GEAC. It was noted that the presence of Cry1Ac protein was noticed in both Bt and the non-Bt brinjal samples tested.<sup>42</sup>

"An extremely important point is that whatever tests have been conducted (e.g. toxicity or allergenicity tests) before confined field trials, have been done either by the applicant himself or by an outside party (such as Intox, Rallis, or Shriram Institute) to which samples were supplied by the applicant. There has been absolutely no proof that the tests were actually conducted by the applicant or that appropriate samples were supplied for the tests conducted by an outside party. Thus, it is perfectly possible (given the track record of the companies concerned and the fact that no independent and reliable validation procedure exists in the country), even probable that, for toxicity tests, animal tests and allergenicity tests, the samples that were given or used were of normal, non-genetically engineered material. In such a case, any adverse effect of the GMO would never come to light," Dr P.M. Bhargava summarised.43

"The World Trade Organisation describes national laws banning GMOs as an "unfair trade practice" simply because it places "profits before people". We want a blanket moratorium on all GM foods in India until 2018. The government should conduct careful, comprehensive and transparent testing in the public domain with reputed, independent, scientists who will record the safety features in the short and long term and determine the effects of GM plants on neighbouring conventional and organic plants."

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#### The case of porous borders

The Indian borders so far, have been porous to the entry of any GM food. This has been taking place since the existence of the 1989 rules under the Environmental Protection Act refurbished by the 2006 DGFT notification under the Foreign Trade Act of 1992. Both the rules categorically state that no GM food feed or any raw material should be imported into India without permission of the GEAC.

Back in 2001, Greenpeace exposed the lack of monitoring at the borders when it tested products from the retail shop shelves in Delhi, which were found to contain GM ingredients. The situation has not changed in 2008. In May 2008, a recheck of imported products by Greenpeace proved the presence of GM corn chips, this time 'Doritos' from Pepsico from the U.S.A. being sold in the supermarkets in India. Though GEAC discussed this issue at length in its 85th meeting dated June 28, 2008, no action was taken even after the submission of samples by Greenpeace.

The corn chips tested is just the tip of the iceberg as India imported a total of 2,776.58 tonnes of corn in the year 2006-2007 of which 1,813.96 tonnes came from Argentina and 201.76 from the US, two countries known to grow genetically engineered corn, and where there are no laws of segregation between GM and non-GM corn.<sup>46</sup>

# National Biotechnology Regulatory Authority (NBRA)

The NBRA is said to be an outcome of the national task force on Agricultural Biotechnology led by Dr. M.S. Swaminathan. The task force in its report submitted in May 2004 recommended the need for a single window clearance system for GM crops in India. This was seen necessary to speed up the approval process in the country so that industry could bring its products to the market at the earliest, reducing the gestation period and thereby improving commercial gains.

The task force recommended that a national "autonomous statutory National Biotechnology Regulatory Authority (NBRA) be in the place of the existing GEAC." <sup>47</sup> The DBT was quick in getting hold of this recommendation and came up with the proposal for an autonomous technocrat-run body with no interference from the government.

The national biotechnology development strategy was approved by the Government on November 17, 2007. In a quick move supported and pushed by the biotech industry, the department announced a public consultation processes. In the name of consultation, the draft of the National Biotechnology Regulatory Authority Bill was made available on the DBT website on May 27 and different 'stakeholders' were asked to take part in a consultation process starting on June 6. The last date for comments was 16 days later, June 22! The consultation was a clear case of asymmetry in information where the DBT had discussions with the biotech industry even before the draft was put in the public domain for comments, at a session in an industry event called Bio 2008 held in Bangalore on April 26, 2008.48 This led to massive protests, to the extent that the consultation process in Bangalore had to be called off due to farmers and civil groups protesting against the lop-sided manner in which the entire consultation was conducted. 49 The public protests forced DBT to extend the deadline to the end of July.

The NBRA though has the potential to become a comprehensive step to protect the biosafety of the country. Unfortunately, the priorities of the DBT lie elsewhere. There are major concerns with the existing NBRA proposal:

- The act is named as a Biotechnology Regulatory Act while the entire rules and regulations are focussed only on Genetic Engineering and its products.
- The centralised decision making lies in the hands of a few technocrats.
- There is a clear conflict of interests as the department formed to promote biotechnology is trying to regulate the process.
- Other ministries are completely kept out of decision making, making participation farcical.
- The state governments do not have any decision making powers.
- Liability issues are completely avoided; there have been no discussions or measures taken to compensate farmers in case of contamination.
- There are no measures to penalise promoters in case of contamination.



#### OF MICE AND MEN

BY ANKITA ANAND AND SHEKHAR SINGH

The secrecy surrounding science has often been expected to be forgiven and forgotten. It is often assumed that the relevant observations and inferences derived would be too much for an untrained mind to handle. But as we developed a broader understanding of our problems, we came to realize that even 'technical' issues greatly impact the most basic of people's concerns

With people finding themselves the biggest stakeholders in the Government's decision making, the layman decided to lay down the rules this time. The Right to Information Act, proudly and endearingly addressed as the 'People's Act', came into being. The demand that followed, that of having a say in the decision making process, was here to stay.

On more than one occasion, the Indian government has earned approving nods from giant corporations in its 'no nonsense' approach when it comes to talking business. Environment waivers have been awarded to several such groups with the benign generosity of a faithful parent. Regulations, laws, rules, guidelines, strictures, all are dismissed with the wave of a hand. And if we cannot bend, we shall amend.

Relatively, when it comes to giving information to its own people, we see the same government practicing remarkable parsimony. When GM foods came to be known as bad news, Monsanto-Mahyco's anxiety over their consumers getting 'out of the market' was only expected. But what to make of the RCGM's (Review Committee for Genetic Manipulation) petulant guarding of its meeting minutes close to its chest? Those who were supposed to be our knowledge providers found it difficult to transcend their sympathy for (the imagined) "competitive position of the third party".

It is precisely because such disclosures were not initiated, that a need for participatory consumerism was felt by many civil society organisations and one of the longest RTI battles to be began in 2006. Random, unofficial and at times, irrelevant, information was fed to the people in crumbs and the farce is being played out till date. For instance, in response to an RTI application filed by Greenpeace activist Divya Raghunandan, the DBT put forth the argument that the requested data on toxicity and allergenicity on mustard, okra and rice cannot be provided as it is under generation and has not been submitted to the RCGM. Contrarily, the DBT Appellate authority went on to put on record that the same data is under RCGM'S consideration.

In an ideal situation, all such knowledge should have been accessible in the public domain, as it is one of the many "obligations of public authorities" under Section 4 of the RTI Act. The failure is all the more flagrant when seen in the light of Section 4(c), under which a public authority is required to "publish all relevant facts while formulating important policies or announcing the decisions which affect public;". Again, in Section 4 (3) it is made clear that "...every information shall be disseminated widely and in such form and manner which is easily accessible to the public."

While all these provisions have been passed over, there is Mahyco on the other hand that presented a harried application to the CIC complaining that Section 2(n) of the Act has been violated because Mahyco's submissions as the "third party" were never invited. The company never chose to enlighten anyone on how information about whether they were manufacturing something toxic and allergenic would ruin their "competitive advantage." Even if reason is thrown to the winds and it is assumed for a moment that such a thing were to happen, this case should be treated as the quintessential representative of the spirit of the Act, which mandates that "larger public interest warrants the disclosure of such information." In the same application, Mahyco pleads that its arguments be considered in favour of "the principles of natural justice." It is most intriguing to discover that those who do not flinch from putting the lives of millions at stake subscribe to such humanitarian philosophies.

The Department of Biotechnology insists on becoming the sentinel to Monsanto-Mahyco's commercial interests instead of the health and survival issues of the citizens of India. Activists accused of keeping their fingers glued to the panic button have been facing the exasperation that comes from stating the obvious over and over again. The fact that field trials of GM crops are still on is a distinct indicator of the seriousness, or the lack thereof, with which public health is treated in this country.

Groups like ToxicsLink have already used the RTI to uncover alarming data on biomedical waste and import waste. The GM foods debate is yet another case where the direct co-relation between the right to know and the right to live rings true. It is precisely to uncover such vital information that the Act was designed. By turning its back to people's Right to Information, the Government is only lending certitude to the suspicion that it has something to hide. It is perplexing to witness the G overnment's camouflage tactics in relation to its professed commitment to transparency. In a country where mice and men are made equally vulnerable subjects of experiment and people's representatives turn into indifferent kings, the fates of its people can easily be shoved into dark grottos by alien pied pipers.

In fact, this case highlights what might well become one of the main challenges to the transparency regime in the years to come. The world is becoming more and more specialised and information is being expressed increasingly in a language that the lay person cannot understand. Therefore, even if people can exercise their right to information, it is not much use unless they can comprehend the information they get, and that too, in the correct context.

In such a scenario, it is incumbent on governments to take an initiative in demystifying all these "technologies" which critically affect the lives of people. It is a concurrent responsibility of people's groups to develop information clearing houses where such mystified information can be accessed from governments and other "technical" institutions and made available to the people in simple terms and in a relevant context. It is admirable that Greenpeace has started doing this about many of the issues they work on, including the whole area of GMOs.

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# THE END OF CHOICE FOR CONSUMERS AND FARMERS

Choice is a fundamental right. And when it comes to GM food, it is perhaps the only option a consumer is left with in order to protect himself from a food technology so mired in controversy.

In this light, it becomes imperative for the consumer to demand the right to know and the right to choose, primarily because of:

- Concerns pertaining to effects (such as toxicity and allergenicity) that GM foods could have on health.
- Ethical and cultural concerns with respect to the possible use of animal genes in plant products.
- Environmental concerns that are a direct result of this form of intensive agriculture.

#### Not a matter of choice

It is essential to understand that the word "choice" in this case has significant and varied implications. Let's take a look at it from the following scenarios:

The fact that GM crops cannot easily be distinguished from non-GM crops, makes labelling imperative. This is essential since segregation of genetically engineered agricultural produce such as grains and vegetables is a humungous, virtually impossible task once such produce has reached the open markets. Successful labelling is contingent on a number of factors – distinguishing production

region-wise, separate mechanisms for procurement, segregation, processing and packaging. The existence of GM and GM-free regions and the monitoring that goes into keeping them isolated is widely questioned even in developed countries. Contamination on the ground, by seed and pollen, during storage and transportation has been widely reported. But the Genetic Engineering Approval Committee (GEAC) of India terms the approval of a transgenic crop as "deliberate release", which leaves no space for distinguishing a GM from a non-GM variety.

If Bt brinjal does indeed get commercialised, the scope and scale of contamination will be huge. Take the example of Bt cotton for instance. Not only has the Bt cotton seed market been monopolised, but pollination has rendered non-GM species subject to contamination, which makes availability of non-GM seeds practically impossible. Given the fact that laws in India do not deal with issues relating to genetic pollution and contamination, both farmer and consumer are left with no choice and no legal recourse either. This means in the future, after commercialising certain varieties of crops, if we choose to change our stance for the same reasons - health, safety and environment, there will be no going back. In other words, GM contamination is permanent and irreversible. Once this monster is out, there is no getting it back.

"As I understand it, crops grown from GM foods leave the soil barren and unfit for the growth of crops in the future. Also, the long-term effects of consuming such foods are not known. I am convinced that GM field trials should not be conducted in the first place. However, given that they are, I am appalled that consumers are given no indication. Even if a consumer wants to make an informed decision, how is he or she to tell GM from non-GM foods? There is a definite need for stringent labelling laws in India."

DR. UMA MEHTA MEDICAL OFFICER, CGHS, MUMBAI



#### CONTAMINATION OF ORGANIC PRODUCE

According to the International Federation of Organic Agriculture Movements (IFOAM)

"Organic agriculture is a production system that sustains the health of soils, ecosystems and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects. Organic agriculture combines tradition, innovation and science to benefit the shared environment and promote fair relationships and a good quality of life for all involved."

Organic agriculture processes necessitate that agrochemicals and GMOs should not be used in the farming process. Organic cotton in India is widely gaining recognition for its export markets but contamination from GM cotton is a looming threat

Vivek Cariappa, a certified organic farmer and President of the Organic Farmers Association, in Mysore District of Karnataka manages a 30-acre organic cotton farm together with his family. They have been exporting cotton from the Association (covering about 200 acres), and making fabric and clothes from the cotton grown on their own farms for the last 24 years. In 2006-07, they found many farmers in the area switching to Bt cotton. Cotton farmers in India have extremely small landholdings,

averaging 1.5 acres. Thus, the refugia regulation, stipulated by the GEAC as "five border rows of non-Bt cotton on all sides of the field." never gets actually implemented. With this situation, it was only a matter of time before the organic cotton cultivated by the Organic Farmers Association got contaminated. As expected, in 2007, when they tested the cotton for renewal of the certification, the cotton was found to be contaminated. This is despite repeated tests, the costs of which were borne by the farmers. The farmers were forced to sell the cotton at a low price. Since India has no laws on liability due to contamination, farmers are not even eligible to seek compensation. What is really scary is that contamination is not only restricted to crops of the same species – in this case ladies finger or okra belonging to the same family as Bt cotton can also be contaminated.

Since then, Vivek and Juli Cariappa, members of the Organic Farming Commission of Kamataka, have been pushing for a ban on new GM commercialisation in the State – so far in vain.

Despite choosing not to get on the GM bandwagon, Vivek and the other organic farmers of Mysore have had their choice disregarded, and effectively forced to become GM cotton farmers. This same process will make all Indians GM consumers, once food crops are released.

There is no doubt that what happened to Bt cotton will happen to brinjal as well as rice, mustard, ladies finger and all the 56 crops (both food and non-food) when they are commercially released.

#### Case in point

Europe has the most stringent labelling laws in the world. Since 2004, the European Union's new (second phase) labelling and traceability legislation for genetically engineered food, feed and ingredients have been enforced. These new rules, which are amongst the strictest worldwide and apply to one of the world's largest food markets in terms of value, will have major repercussions on the markets but will never be completely effective in checking contamination and illegal entry of GM food products.

Over time, there have been numerous instances when products in the market were found to be genetically engineered without the approval or knowledge of the authorities. For instance, in 2006 despite labelling measures, U.S. rice was found to be contaminated with LL601 variety of genetically engineered rice, unapproved for consumption even in the US. Even though the exact details of how the contamination took place remains a mystery, we can safely draw the following conclusions:

Firstly, since the rice was never approved for commercial planting, the contamination could have only taken place at the field trial stage. Secondly, there have been only a few field trials, and all of them are less than one acre – a size considered 'tiny' by the regulators. <sup>50</sup> Thirdly, the Louisiana State University, which conducted the field trials, reported contamination in their foundation seeds – seeds, which form the stock from which the commercial varieties are replicated. Moreover, Bayer, the company which owns the LL601 variety, in an effort to limit its liability referred to the contamination as "an act of God". <sup>51</sup>

contamination remained unnoticed until Greenpeace exposed it in 2006. Since then, the contamination has now been independently confirmed in over 17 countries in the EU and a total of 24 countries worldwide.

The LL601 fiasco triggered a huge marketing and financial disaster for US rice and also proved how despite stringent labelling and monitoring systems, the EU failed to detect contamination.

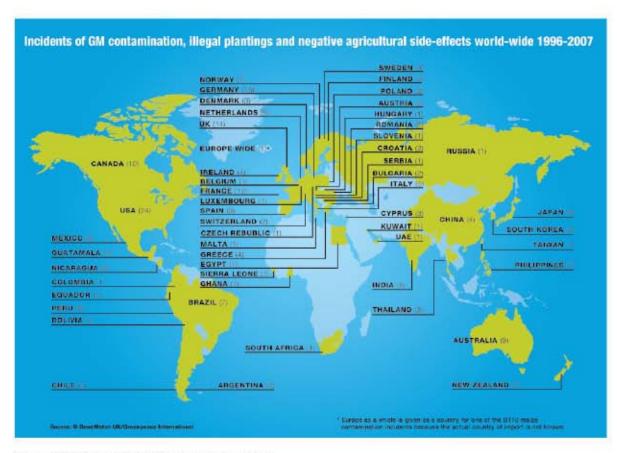
More recently, in India, Doritos corn chips, a brand of Frito Lays – part of the PepsiCo group, was found to contain MON863 and NK603 varieties of GM corn in the markets of New Delhi. Though, the contamination was reported to the authorities in May 2008, no action had yet been taken at the time of the publishing this report.

The GEAC, which agreed that this is a matter of grave concern, and decided to independently carry out testing<sup>52</sup> from a nationwide sampling, changed its stance later and refused to take action. They advised Greenpeace, which reported the contamination, to approach the Directorate General of

Foreign Trade (DGFT), which has specified in one of its notifications in 2006<sup>53</sup> that, any imported GM food should have the permission of the GEAC and else is liable for penal action under the Foreign Trade (Development and Regulation) Act, 1992.

Thus, with the GEAC refusing to regulate GM processed foods in India, the only law that regulates such contamination is the notification laid down by the DGFT. Unfortunately, this again is not independent of the GEAC, which makes it a vicious cycle. A cycle that in effect leaves the consumer completely vulnerable to unregulated and unpermitted GM foods.

The GM Contamination Register, a database of all contamination managed by Greenpeace International and GeneWatch UK, recorded 216 contamination events in 57 countries over the last 10 years on an annual basis.<sup>54</sup> The 2007 incidents of contamination and illegal release involved cotton (one), fish (four), maize (nine), oilseed rape (two), papaya (one), rice (twenty) and soybean (two). These alone account for 25 per cent of the total number of contamination cases that have been recorded in the last decade.



Source @ 2007 GeneWatch UK/Greenpeace International

#### The GM divide

There is a wide difference between the perception of GM food in Europe and in the rest of the world. The same applies to retailers' positions globally. Twenty-seven of the 30 top retailers have a non-GM policy throughout the EU.

After years of public debate and massive rejection by consumers, the industry in Europe has been forced to take a strong stand. A number of retailers had already anticipated the latest EU labelling legislation and implemented non-GM policies prior to the introduction of the new labelling laws in April 2004. Indeed, many companies have clearly had non-GM policies in place covering all GM ingredients including vegetable oils and maize starch etc. since 1999/2000 and in some cases even earlier – e.g. Carrefour, Auchan, Lidl, Sainsbury's, Big Food Group, Coop Italia, Marks & Spencer.

In contrast, the Indian retailers' positions reflect the uncertainties and discrepancies in the Indian regulatory system. Besides, with consumer awareness growing slowly, there has been no consumer rejection so far, which would compel retailers to take a cautious stand.

#### Here are the positions of some retailers, from their communications to Greenpeace India PepsiCo, India

"Approval of genetically-modified foods differs from country to country regarding both use and labelling. For this reason, PepsiCo adheres to all relevant regulatory requirements regarding the use of genetically-modified food crops and food ingredients within the countries it operates." (2008)

#### Nestle India Limited

"The Quality and Safety of our products and the integrity of the ingredients from which they are manufactured are paramount for Nestle. All raw materials used by Nestle comply with strict regulatory and safety evaluations. Currently Nestle India does not use any GM ingredients." (2007)

#### MTR Foods Limited.

"We have policy to use 100% natural and hence GE items are unacceptable." (2007)

#### The way forward: Stop unsafe GE crops from getting into your food:

We need stringent labelling laws to be enforced, farmers need to be given the right to choose (and keep) a GE free crop, and there must be provisions to penalise offenders and affix liability for contamination, if we are to ensure consumers and farmers have a free choice.

In a scenario where food crops are approved for GE, we may have to fall back on crops untouched by the Green and Gene Revolutions – small millets. Although these hidden cereals have a high cultural and anthropological value, they have been systematically phased out by the Green Revolution since they have a low market value and are of little or no interest to either agri-biotech companies or an entrepreneurial society of genetic engineers.

With increasing investment in GE research and amendments in the regulatory system (essentially ensuring quick approvals), we will be left with little or no choice if we fail to assert our right to choose. There is only one definite outcome of the genetic engineering of food – the end of choice.

"We constantly discuss with our students the inherent dangers of GM foods, more in terms of what is done rather than why it should not be done, which is really limited. I definitely feel that there are not enough studies, which are conducted to conclusively prove GM foods as safe. Even at the field trial stage, there are ecological concerns. As far as these are not completely ruled out, no food crop should be commercialised. Additionally, foods need to be labelled as GM or non-GM, I have the right to choose what I want consume, I have the right to make an informed choice."

GEETA NARAYAN
READER, MICROBIOLOGY,
MICHIBALOOLUGGE, MICHIBALO



# GENETICALLY MODIFIED FOOD - AS SEEN BY CONSUMERS AROUND THE WORLD, ESPECIALLY IN DEVELOPING COUNTRIES

BY BEJON MISRA EXECUTIVE DIRECTOR, CONSUMER VOICE NEW DELHI

Genetically engineered foods have been viewed as unsafe by most consumers around the world, and consumers demand comprehensive mandatory labelling on all foods derived from GMOs (Genetically Modified Organisms). This was revealed by ABCNEWS.com on June 20, 2001 through a poll administered on American citizens (see box)

Despite the fact that 90% of Canadians support the labelling of GMOs, government regulators, pressured by the US and the biotech lobby have thus far ruled out mandatory labelling. Even in India, the consumer's health and safety have been compromised by the Indian Government.

In a recent letter to the Honourable Prime
Minister, consumer organisations have drawn
attention to the Government's recent action
related to the import of GE foods, which
could damage public health and for which
the Government would be made liable.

#### ABCNEWS.com FINDINGS

- 52% believe such foods are unsafe, and an additional
- 13% are unsure about them
- 93% say the federal government should label foods stating whether or not it has been genetically modified
- 57% also say they'd be less likely to buy foods labelled as genetically modified

The Ministry of Environments and Forests had issued a notification on August 23, 2007 withdrawing existing regulatory regulations pertaining to the import of GE foods. So far, in view of the known health risks associated with engineered foods, the government's guidelines suggested that import of GE foods cannot take place without the express permission of the GEAC, the apex regulatory body in India, and should be kept away from the consumers till these have gone through complete field trials and are found safe for human consumption. India, at various international consultations, has always taken a strong position on comprehensive mandatory labelling of foods containing GMOs in order to provide the consumer the choice to make an informed decision. This was appropriate since it permitted India to monitor the entry of food products produced by a new technology that is known to produce toxic and allergic compounds. The Indian regulations ensured that India maintained a vigil, also guaranteed that food rejected by other countries – Europe, Africa and Middle East – was not forced down our throats.

The arbitrary withdrawal of the regulatory guidelines without any scientific reason or consultation with the stakeholders engaged in GE technology and policies associated with it, is preposterous. At a time when there is growing scientific evidence suggesting the adverse impacts GE foods can have on health, it is incomprehensible that instead of upgrading our food testing systems and strengthening our systems, the government has chosen to be lax. This decision can have serious repercussions on the health of consumers and perhaps undermine the consumers' ethical and religious sentiments.

Labelling of foods and food ingredients produced using GMOs can also be considered under the Codex Alimentarius Commission. Codex texts clearly state that these other legitimate factors (OLFs) can be used during risk management phase and that labelling is a valid use for such factors. The Codex Alimentarius Commission states: "When elaborating and deciding upon food standards Codex Alimentarious will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade. In this regard, it is noted that food labelling plays an important role in furthering both of these objectives".

Furthermore, the objectives of the Codex Intergovernmental Task Force on Foods Derived from Biotechnology includes consideration of such OLFs: "To develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices".

Obvious OLFs are religious or cultural concerns. For example, if a gene from an animal was inserted into plants (such as the gene of an arctic flounder were to be inserted into tomatoes, or that from a scorpion were to be inserted into corn); vegetarians would want to know, so as to avoid such foods. If a gene from pigs was engineered into plants, kosher Jews and halal Muslims would want to be made aware of that. Labelling just seems like an appropriate and logical method and helps further "promotion of fair trade practices."

In sum, the Codex texts associated with foods derived from GE/GM as well as the Codex Commission's Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors Are Taken into Account clearly supports the labelling of foods or food ingredients derived from GE/GM.

The new notification in India on GM food will, in effect, provide unrestricted entry to untested foods of dubious origins, especially since the imported GM foods do not have to be labelled. This denies consumers the right to exercise their choice concerning the food they wish to consume. This move violates the Consumer Protection Act, 1986, which grants consumers the right to make an informed choice. It also goes against India's long standing commitment to mandatory labelling of GE foods, a position the Indian delegation has consistently maintained at international negotiations, particularly at the WHO-FAO led Codex Alimentarious Commission on Codex Committee on Food Labelling.

Three nations continue to produce almost 99% of all GE crops - the US (74%), Argentina (15%), and Canada (10%) though the export markets for crops in these countries are perceptibly growing smaller, not larger.

Consumer health and safety is paramount and should always prevail over trade and commercial interest. It is high time the Indian Government demonstrate its commitment towards the consumer and his rights. The draft notification on mandatory labelling of all foods derived from GMOs is collecting dust and must get implemented and enforced before consumers are placed in harm's way.

"Genetically Engineered foods are infamous for the degradation of soil on which the crops are grown, pests are known to get immune after a while, which makes the purpose of these seeds redundant. I suppose there are negative and positive aspects to genetically engineered foods as with anything new, but a lot of research needs to be done. It has not been conclusively proved that GE foods are positive. As far as commercialisation is concerned, at what cost is it being done? Is it at the cost of the environment, and health of people? At the moment there are too many negatives. Only if it can be proved that there will be no ill effects upon consumption, should they be commercialised."

VERNON COELHO HOD, FOOD AND PRODUCTION, IHM, MUMBAL





# THE GM FOOD EXPLOSION

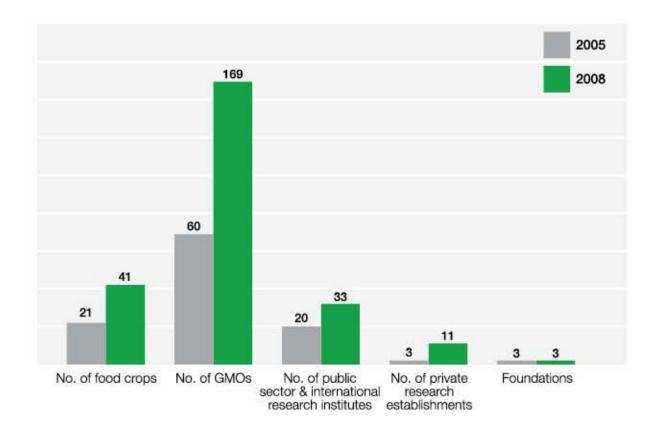
Despite the fact that Bt cotton, the only non-food crop commercially cultivated in India, resulted in socio-economic chaos, heightened environmental problems and seems to have a played a indubitable role in the of deaths of sheep and cattle, there has been a quantum jump in investment in GM research, especially in the last three years.

In 2005, when the first compilation of research on genetically engineered crops was done, there was hardly any information available in the public domain. Information was obtained with the help of the *Right to Information Act*, which was enforced only by a few states until 2005 when it was passed by the Central Government. The only source of information for anyone concerned was personal communication, personal visits to sites and offices, desktop research and some anecdotal notes.

YEAR 2005	
No. of food crops (food crops)	21
No. of GMOs (food crops)	68
No. public research institutes/ International research institutes working on food crops	20
No. of private companies working on food crops	3
Foundations working on food crops	3

Today, most of the information is obtained from the Government-established Indian GMO Research Information System's (IGMORIS) official website, www.igmoris.nic.in

No. of crops (all)	56
No. of food crops	41
No. of GMOs (all)	236
No. of GMOs (food crops)	169
No. public research institutes/ International research institutes working on all crops	43
No. public research institutes/ International research institutes working on food crops	33
No. of privatel research institutes working on all crops	31
No. of private research institutes working on food crops	11
Foundations working on food crops	3



Going by the latest figures, cotton leads the list with about 36 events (laboratory or field trials) of which 29 have been conducted by the private sector. With their aggressive marketing strategies, as well as the monopolised the Bt cotton market, most companies have sublicensed Monsanto-Mahyco's technology.

Rice leads the food crops with 24 events, most of which are conducted by public sector Institutions, Foundations and two private companies leading the research. Tomato is the second most

experimented food crop with 23 events, by many public research institutes and four private companies. The other crops are sorghum and tobacco closely followed by brinjal, groundnut, pigeon pea, potato, mustard, sugarcane, cowpea and soy.

Apart from the food crops, there are a number of non-food species like commercially grown trees and medicinal herbs, which are being genetically engineered.

"Synergy is the key in any traditional herbal medicine. The holistic pharmacokinetics of herbal ingredients is widely accepted genetic. Engineering crops entails attempts to improve a particular active molecule by altering the plant's taste, action, active principle, therapeutic efficacy, nutritional benefits, pro-biotic activity and a lot more. Traditional Indian systems of medicine is not based on rational phyto molecules, it has its own scientific theory based on Pancha Boothic Pancheekaranam. The six tastes are fundamental for any therapeutic recipe. Altering the components will ruin both transgenic plants' efficacy as well as through out-crossing and gene transfer, the plants' unique and innumerable curative abilities."

DR.G. SIVARAMAN



Number of GM food crops in research - classified by cereals, oil seeds, cash crops, vegetables, fruits pulses and spices

Cash crops	NO OF GMOS	36	-	*	2	9	m	<del>,</del> .	10		
Cash	CROP	Cotton	Jute	Coffee	Carnation	Sugarcane	Rubber	Tea	Tobacco		
spə	NO OF GMOS	9	4	က	-	7					
Oil seeds	CHOP	Mustard	Castor	Safflower	Sunflower	Groundnut					
Spices	NO. OF GMOS	3	2	4	-						
Spi	CROP	Black pepper	Cardamom	Chilli	Ginger						
its	NO. OF GMOS	•	-	<del></del>	33	÷	+	2			
Fruits	CROP	Acid lime	Apple	Banana	Papaya	Pomegranate	Muskmelon	Watermelon			
ses	NO OF GMOS	က	4	ro	7	m	10	2	ro.		
Ā	CROP	Black gram	Chickpea	Cowpea	Pigeon pea	Ragi	Sorghum	Pearl millet	Soyabean		
ables	NO OF GMOS	80	2	2	က	က	-	7	23	-	
Vegetables	CROP	Brinjal	Cabbage	Cassava	Cauliflower	Okra	Onion	Potato	Tomato	Yam	
Cereals	NO. OF GMOS	က	25	-							
	сног	Maize	Rice	Wheat							

#### GM research: trends

#### 1. Increasing private share in GM research

Though cotton has the most number of private sector players, the investment in private sector research is fast catching up. There are about 31 private entities involved in GM research, 11 of which are on food crops.

#### Increasing collaborative research between private and public sector institutes.

There are 16 universities and private companies that are doing collaborative research with public sector institutes. Apart from direct investment, there are a number of collaborations, joint ventures and research given out on a contract basis. Over 20 events in black pepper, corn, soya bean, potato, rice, rubber, sorghum, sugarcane, tea and tomato were either collaborated or funded by the private sector and other research institutions outside the country. India also receives significant funds from foreign foundations.

#### 2a. External funding

There is also a significant presence of external funding agencies in GM research over food crops. Rockefeller Foundation and the USAID programmes are notable among them.

#### Rockefeller Foundation

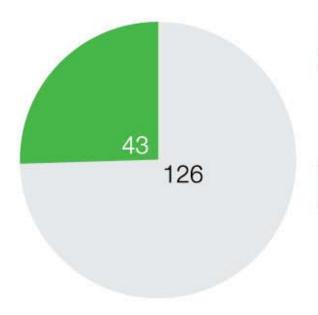
The Rockefeller Foundation funds research on a number of transgenic food crops in India. Eight events, six of them in rice and one in sorghum and sugarcane each, are being funded by the Foundation. Most of them also involve collaboration with international institutions. The various research themes and traits that are being developed are: nutritional enhancement, pest resistance and abiotic stress resistance. The institutions involved are the Tamil Nadu Agricultural University, Central Rice Research Institute, Cuttack, University of Delhi and Punjab Agricultural University. The Rockefeller Foundation has a history of bringing "Green Revolution" to India. The Foundation funded programmes as early as 1956 even before the Ford Foundation, USAID or the World Bank funded research initiatives for Higher Yielding Varieties and hybrids. With "Green Revolution's" true cost becoming increasingly visible in the form of steadily falling soil fertility and increasing farming costs, and the adverse effects pesticides have on human health, the genesis of the gene revolution by the same players would be tantamount to replicating mistakes of the "Green Revolution."

#### Agricultural Biotechnology Support Project II

The Agricultural Biotechnology Support Project II (ABSP II) is a US Agency for International Development (USAID) programme to promote the spread of genetically engineered crops in developing countries of Asia and Africa. ABSP II is led by the College of Agriculture at Cornell University, Ithaca, New York. It involves a consortium of private, public and governmental partners. ABSP II operates in India with Sathguru Management Consultants, a private firm based in Hyderabad. Mahyco, which is a part of the consortium, has so far signed three contracts for Bt brinjal with public sector research institutions -Tamil Nadu Agricultural University, University of Agricultural Sciences, Dharwad and Indian Institute of Vegetable Research, Varanasi. It has also facilitated research contracts with public research institutes in Bangladesh and Philippines. The ABSP I as the name indicates is the phase I of ABSP which focused on introducing agribiotech solutions in Kenya, Egypt and Indonesia. The objective is to engineer 'non-competitive' crops along with the commercially successful GM crops soya, cotton, maize or canola. The crops researched during the ABSP I and II projects are like a Trojan Horse, which aided in "easing" regulations and opening the door for successful commercial food crops.

#### 2b. Public-private partnerships

Formal partnership research between public sector institutes and private companies have increased due to projects like ABSP II. The nature of these agreements is kept under cover and information related to these is not available in official reports. The important issue as far as these partnerships are concerned is Intellectual Property Rights. A transgenic crop, at any point during the development process, like methods of transformation, processes, apart from the gene constructs, can be patented, making the issue of patent infringement a major threat. India is witnessing a surge in patent applications since the Patents Act was amended in 2005. This has increased the possibility of illegal infringement, which will result in withdrawing from a transgenic research project after having spent large amounts of taxpayers' money.



Public Sector
Private Sector

No. of GMOs (All crops)		No, of GMC (Food crop	
Public sector research (41 institutes)	162	Public sector research (41 institutes)	126
Private sector research (34 institutes)	74	Private sector research (34 institutes)	43

## 2c. Contract research becomes a reality

While there are only a few cases of contract research, this is clearly a dangerous trend. Unlike collaborative research, where there is a hope for an appropriate sharing of the results of the commercial release of the crop, contract research means the public sector institute would have no rights over the crop they are developing. This is a particularly terrifying trend, which would ensure the knowledge of the public sector institutes effectively sold to the private sector institutes without it benefitting the public.

The National Biotechnology Development's Strategy of 2006, which is the precursor to the Draft National Biotechnology Regulatory Authority Bill, has a stated intention of fostering public-private partnerships and ensuring that at least 30% of all agriculture research in the public sector has a partner from the private sector.

Considering what has been stated in the 2006 strategy, the increase in collaborative research comes as no surprise.

"Genetic Engineering in agriculture cannot be contained because of cross pollination. The latent characteristics by gene manipulations will never be fully understood, its ill-effects cannot be accounted for, or controlled. These endanger the health and environment. There is no doubt that such technology, which overlooks existing and natural based methods in agriculture is unsound."

DR. DHARINI KRISHNAN

NUTHITION EXPERT AND SECRETARY

ENVIRONMENTAL RESEARCH FOLINDATION







#### STRANGE GM CROPS

Frankentrees: Engineering Apocalypse for India's Forests By Philip Carter

The problems related to genetically engineered crops have already been well-established. The escape of genetically engineered seeds into the wild has become such a quandary with crops that obtaining uncontaminated seeds is becoming virtually impossible. On the other hand, reports of debilitating sheep before their eventual death as a result of feeding on remnants in fields of Andhra Pradesh where Bt cotton was harvested are extremely disturbing.

Frankentrees, popularly referred to as GE trees multiply this type of danger many times over. Given that tress are perennial, and a central element of the terrestrial ecosystem the adverse environmental effects threats they pose are magnified and multiplied several times over.

The main objective of engineering trees is to use Bt genes in order to develop insect resistance. It is also the most wordsome trend in GE tree development. Several countries are involved in research and/or commercialisation of GE trees on a large scale. According to the German Government-supported group 'GMO Safety", the Chinese Government has allowed large-scale plantations of Bt poplar trees in the northern parts of the country in an effort to combat desertification due to excessive logging since 2002. The Institute for Science in Society (ISIS), suggests that over a million transgenic trees had been planted by 2005 as a part of the "Green Wall of China" project, which aims at planting a 4,500-km.-long "protective belt" of trees along the edge of the Gobi Desert.

Although in some cases, GE trees are engineered to be sterile, it is has been acknowledged that this isn't completely effective, and inevitably, some trees produce seeds and pollen that spread. As Bt poplar are indistinguishable from ordinary trees, there is no way to remove this contamination from wild forests. With a large-scale project like the 'Great Wall of China' the magnitude of contamination can never be really understood, let alone be controlled. NGOs in the west, including ISIS,

report the resultant genetic contamination of nearby native poplar trees; this has been confirmed by the Nanjing Institute of Environmental Science. Once a genetic trait has escaped from a plantation, wild trees can, through prodigious amounts of pollen, contaminate wild species over great distances and over prolonged periods of time. Since wild trees like pine can transport their pollen over 600 km, and pollen contamination from GM pine could travel as far as a non-GM pine, if GM trees were genetically engineered, worst fears of contamination can become a reality.

If Bt tree plantations of various species become widespread, the long-term effects on forest ecosystems are likely to be devastating. There are also questions over the long-term effectiveness of this approach, as the target insects can develop resistance. This has already been observed in the case of Bt cotton. The Central Institute of Cotton Research in Nagpur reported one in every 400 bollworms, a pest against which the plant was engineered, to have developed a resistance to the bacteria in some areas where it was grown.

Although no GE tree field trials are known to have occurred in India till date, research is being carried out at a number of institutions like the research to enhance the rubber-producing ability in rubber trees or enhancing the cellulose production in eucalyptus. Internationally, a major area of interest for multinational companies is engineering trees with reduced lignin content, which makes them cheaper to process into paper, although such trees tend to be weak and susceptible to diseases.

However, the most dangerous development for the forests of India and neighboring countries is present efforts funded by the Indian government, to genetically modify bamboo. This research, at the Institute of Himalayan Bioresource Technology, is backed by the Department of Biotechnology and aims at standardising methods for growing GE bamboo of various kinds.

Bamboo, indigenous throughout South, Southeast and East Asia, China, and Japan, is an important building material as well as the main source of food for umbrella species ranging from elephants in India to the iconic "zhu xiong" or giant pandas in China. If Bt is successfully engineered into bamboo, it will only be a matter of time before entire plantations are sterilised, gene escape into native plantations a certainty, and biodiversity skewed and jeopardised.

Such a scenario will have apocalyptic effects for the Indian environment, potentially undoing years of work to maintain the rich biodiversity to sustain the diversity of species, restoration of forest comidors for the revival of species such as the elephant and the forest produce on which millions of Indians depend. The threat of poisoning will not only place species such as Elephas maximus in harm's way, but it will also poison the soil via a dense underground mat of rhizomes and roots, which spread horizontally from which new shoots emerge. Pests will eventually develop resistance as is already evident in the case of Bt cotton. The terrestrial ecosystem on the other hand will be destroyed, forever.

More recently, in May 2008, the United Nations' Convention on Biological Diversity met in Bonn, Germany, to discuss the banning of GE trees against a backdrop of pressure from biotechnology firms such as ArborGen, the world's largest company developing GE trees keen to capitalise from the patented varieties. Concerns raised by the African delegation, strongly in favour of a moratorium, were shot down. It is however left to the discretion of individual countries to enforce a ban at a national level. In this light, it is of paramount importance that the indian Government pulls the plug on the deadly misuse of science for the sake of the forest biodiversity and the people who depend on it.

Philip Carter is a Canadian environmental journalist, presently living in Japan. In addition to GM trees, he has written about wildlife corridor conservation in Jharkhand State, India, and the logging of the ancient coastal rainforest in British Columbia, Canada. His articles have been published in India, Canada, England and Japan. www.goldeneagleviews.com



### MEDICINAL HERBS

Jivanti Holostemma adakodien is known by various names such as rasayana – rejuvenative, vayahsthapana - anti aging, svasahara - anti asthmatic and snehopaga - oleating (oiling) adjunctive emphasising the herb's many healing properties. This twining shrub with large flowers is grown all over the Indian subcontinent, especially in Punjab, Gujarat and Kondan.

Every part of the jivanti plant is used for its medicinal properties - root, leaves and bark. The herb is used in various concoctions and used externally (for various skin disorders) and skin inflammation as well as consumed internally for a number of ailments ranging from respiratory diseases to common cold, as a cure for colitis, dysuria to name just a few.

The Kerala Agricultural University is in the process of R&D "Genetic transformation and hairy root culture in Ada-Kodien (Holostemma adakidien K. Schum)" on jivanti – where the hairy roots are induced in the seedling hypocotyls of Holostemma with A. rhizogenes strain PcA4.

Brahmi Bacopa monniera belongs to the Family Scrophulariaceae and has been used in Ayurveda. for centuries. The species is known to thrive along ditches and in low-lying wet areas in India and Southeast Asia.

Whole plant, roots, leaves, stalks - practically every part of the plant is known for its medicinal properties. Brahmi is known to be a purgative. known to cure several neurological, cardiac. cognitive and respiratory disorders. It is also conditions among other things.

The Rajiv Gandhi Centre for Biotechnology is conducting a study "Metabolic engineering of Brahmi for enhanced bacoside content" to

achieve enhanced bacoside content. Thus far, tested in transgenic green house and will be tested under field conditions after obtaining the permission from the RCGM.

Ashwagandha Withania somnifera is a shrub with bright yellow flowers and red fruit, which belongs to the Solanaceae family. Ashwagandha grows in dry subtropical regions of Rajasthan, Punjab, Haryana, Uttar Pradesh, Gujarat, Maharashtra and Madhya Pradesh where it is commercially

The scientific name somnifera suggests similarity to ginseng, which is used in traditional Chinese medicine. It is also known for its rejuvenating, anti-inflammatory, and boosting properties. The herb is used as a cure for diabetes, known to increase the white blood cell count, and is a curative for coronary and respiratory diseases.

The Kerala Agricultural University is conducting induction and enhancement of secondary metabolites in Aswagandha [Withania somnifera (L.) Dunal]"

Creat, karlyat or Indian chinacea Andrographis paniculata as it is known, is widely distributed throughout India from Uttar Pradesh, Assam, Madhya Pradesh, Tamil Nadu and Kerala, It is an herb popularly used in Ayurveda. The herb is known for its cooling, laxative, vulnerary, antipyretic, antiperiodic, anti-inflammatory, expectorant, depurative, soporific, anthelmintic, and digestive properties.

The Rajiv Gandhi Centre for Biotechnology is conducting research on Creat to engineer the metabolism of andrographolides accumulation in Andrographis paniculata Nees.

## GM Crops in field trials

Field trials are open-air experiments of GE crops conducted in fields. They pose a risk to the environment and health because these untested GM seeds could cross pollinate and therefore contaminate neighbouring crops. Since a GM crop cannot be differentiated from a regular food crop, there is a high risk of untested GM seeds or crops getting mixed up with other seeds and grains and entering the food chain.

Compared to 2005, the numbers of food crops undergoing field trials have risen from six to 11 – okra, pigeon pea, cauliflower, cabbage and corn are the ones that have been added to the list. The figures do not represent field trials that are currently being conducted, but are indicative of a transgenic crop that has been tested in the field at some location in the country now or over the last few years. Information on field trials is confidential although government authorities never officially accept this.

Crops in field trials	Stages of regulation
Brinjal	Final season of field trial, commercialisation expected in 6 months
Mustard	Second year of limited-scale field trials
Rice	Second year of limited-scale field trials - Expected to go into large-scale trials soon
Potato	Strip trials
Groundnut	Strip trials
Cabbage	Limited-scale field trial
Pigeon pea	Limited-scale field trial
Okra	Limited-scale field trial
Tomato	Second year of limited-scale field trial
Cauliflower	First year of limited-sclae field trial
Corn	Not available

Brinjal is the only food crop that has passed the large scale field trial stage and thereby has risked large-scale contamination in the 12 different locations it was tested in 2007 and 2008. Though, the biosafety of the crop has not been independently verified, the government hopes to go ahead with the commercialisation of Bt brinjal.

# RESEARCH INSTITUTES

#### Public research institutes involved in GM food research:

- 1 Central Agricultural Research Institute, Port Blair, Andaman and Nicobar Islands
- Central Food Technological Research Institute, Mysore, Karnataka 2.
- 3. Central Potato Research Institute, Shimla, Himachal Pradesh
- Central Research Institute of Dryland Agriculture, Hyderabad, Andhra Pradesh 4.
- 5. Central Rice Research Institute, Cuttack, Orissa
- 6. Central Tuber Crops Research Institute, Thiruvananthapuram, Kerala
- 7. Centre for Plant Molecular Biology, Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu
- 8. Directorate of Oil Seeds Research, Hyderabad, Andhra Pradesh
- 9. Directorate of Rice Research, Hyderabad, Andhra Pradesh
- 10. Dr. Y.S. Parmar University of Horticulture and Forestry, Solan, Himachal Pradesh
- 11. G.B. Pant University of Agriculture and Technology, Pantnagar, Uttarkhand.
- 12. ICAR Research Complex for NEH Region, Umaim, Meghalaya
- 13. Indian Agricultural Research Institute, New Delhi
- 14. Indian Institute of Spices Research, Kozhikode, Kerala
- Indian Institute of Technology, Guwahati, Assam 15.
- 16. Indian Institute of Vegetable Research, Varanasi, Uttar Pradesh
- 17. Indian Institute of Horticultural Research, Bangalore, Karnataka
- 18. Indira Gandhi Agricultural University, Raipur, Chattisgarh
- 19. Industrial Toxicology Research Centre, Lucknow, Uttarpradesh.
- Institute of Genomics and Integrative Biology, New Delhi 20.
- 21. Institute of Himalayan Bio-resource Technology, Palampur, Himachal Pradesh
- 22. Kerala Agricultural University, Thirussur, Kerala
- 23. M.S. University of Baroda, Vadodara, Gujarat
- 24. Madurai Kamraj University, Madurai, Tamil Nadu
- 25. National Botanical Research Institute, Lucknow, Uttar Pradesh
- 26. National Research Centre for Sorghum, Hyderabad, Andhra Pradesh
- 27. National Research Centre on Plant Biotechnology, IARI, New Delhi
- National Research Centre on Rapeseed-Mustard, Jabalpur, Madhya Pradesh 28.
- 29. Punjab Agricultural University, Ludhiana, Punjab
- 30. Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram, Kerala
- 31. Sugarcane Breeding Institute, Coimbatore, Tamil Nadu
- 32. University of Agricultural Sciences, Bangalore and Dharwad, Karnataka
- University of Delhi, New Delhi

#### Private institutions involved in GM food research:

- Avesthagen Private Ltd., Bangalore, Karnataka. 1.
- 2. Bejo Sheetal Seeds Pvt. Ltd., Jalna, Maharashtra
- 3. Entomology Research Institute, Loyola College, Chennai, Tamil Nadu
- 4. Indo-American Hybrid Seeds (India) Pvt. Ltd., Bangalore, Karnataka
- 5. Maharashtra Hybrid Seeds Company Ltd., Jalna, Maharashtra
- 6. Metahelix Life Sciences Pvt. Ltd., Bangalore, Karnataka.
- Monsanto Research Centre, Mumbai, Maharashtra 7.
- 8. Nirmal Seeds Pvt. Ltd., Jalgaon, Maharashtra
- 9. Nunhems Seeds Pvt. Ltd., Bangalore, Karnataka
- 10. Sungro Seeds Research Limited, New Delhi
- Vasantdada Sugar Institute, Pune, Maharashtra

### Entities involved in collaborative research with public sector research institutes:

- CAMBIA, Australia 1.
- 2. Cornell University, USA
- 3. CSIRO, Australia
- 4. International Rice Research Institute, Philippines

- John Innes Centre, UK
- Kansas State University, USA
- Mahyco, Maharastra, India
- 8. Spic science foundation, Tamil Nadu, India
- Swarna bharati Bio-tech Private Limited, Andhra Pradesh, India
- The Energy and Resources Institute, New Delhi
- Tuskegee University, USA
- 12. University of California, Davis, USA
- 13. University of Freiburg, Germany
- 14. University of Ottawa, Canada
- 15. University of Zurich, Switzerland
- Wagenigen University, The Netherlands

## Various crops that are genetically engineered in India and their status

	Cereals	Status		Pulses	Status
1	Maize	Lab trials	16	Black gram	Lab trials
2	Rice	Field trials	17	Chickpea	Lab trials
3	Basmati Rice	Lab trials	18	Cowpea	Lab trials
4	Ragi	Lab trials	19	Pigeon pea	Lab trials
5	Sorghum	Greenhouse	20	Soyabean	Lab trials
6	Pearl millet	Lab trials		Spices	Status
7	Wheat	Lab trials	21	Black pepper	Lab trials
	Cash crops	Status	22	Cardamom	Lab trials
8	Cotton	Commercially released	23	Chilli	Lab trials
9	Jute	Lab trials	24	Ginger	Lab trials
10	Coffee	Lab trials		Oil Seeds	Status
11	Carnation	Lab trials	25	Mustard	Field trials
12	Sugarcane	Lab trials	26	Castor	Lab trials
13	Rubber	Lab trials	27	Safflower	Lab trials
14	Tea	Lab trials	28	Sunflower	Lab trials
15	Tobacco	Lab trials	29	Groundnut	Field trials

	Vegetables	Status
30	Brinjal	Field trials
31	Cabbage	Field trials
32	Cassava	Lab trials
33	Cauliflower	Lab trials
34	Okra	Lab trials
35	Onion	Lab trials
36	Potato	Lab trials
37	Tomato	Lab trials
38	Yam	Lab trials
	Trees	Status
39	Bamboo	Lab trials
40	Casuarina	Lab trials
41	Poplars	Lab trials
42	Eucalyptus	Lab trials

	Fruits	Status
43	Acid lime	Lab trials
44	Apple	Lab trials
45	Banana	Lab trials
46	Papaya	Lab trials
47	Pomegranate	Lab trials
48	Muskmelon	Lab trials
49	Watermelon	Lab trials
	Other crops	Status
50	Arabidopsis	Lab trials
51	Aswagandha	Lab trials
52	Brahmi	Lab trials
53	Creat	Lab trials
54	Jivanti	Lab trials
55	Mouseear cress	Lab trials

# REGULATORY BODIES

## The regulatory procedures for the development and commercialisation of transgenic crops in India

**GEAC** – The Genetic Engineering Approval Committee is an inter-ministerial committee under the Ministry of Environmental and Forests, which is the final nodal agency for the approval of any import, export, transport, manufacture, process, use or sale of any genetically engineered organisms/substances or cells.

RCGM – The Review Committee on Genetic Manipulation functions from the Department of Biotechnology (DBT), under the Ministry of Science and Technology. The Committee's mandate is to come up with guidelines for regulatory processes with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety. It also reviews high-risk categories and controlled field experiments to ensure precautions and containment conditions are followed as per the guidelines.

IBSC – The Institutional Bio-safety Committee comprises scientists engaged in DNA analyses, a medical expert and a nominee of the DBT who is mandated to make an emergency plan according to the manuals/guidelines of the RCGM and make available copies to the DLC /SBCC and the GEAC.

SBCC - The State Biotechnology Coordination Committee is a state level body formed to inspect, investigate and take punitive action against violators of statutory provisions through the Nodal Department and the State Pollution Control Board/ Directorate of Health/ Medical Services. The Committee has the mandate to review periodically the safety and control measures in the various industries/institutions handling genetically engineered organisms/hazardous micro-organisms.

DLC – The District Level Biotechnology Committee functions under the District Collectors wherever deemed necessary. The DLCs have been constituted to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications to the environment.

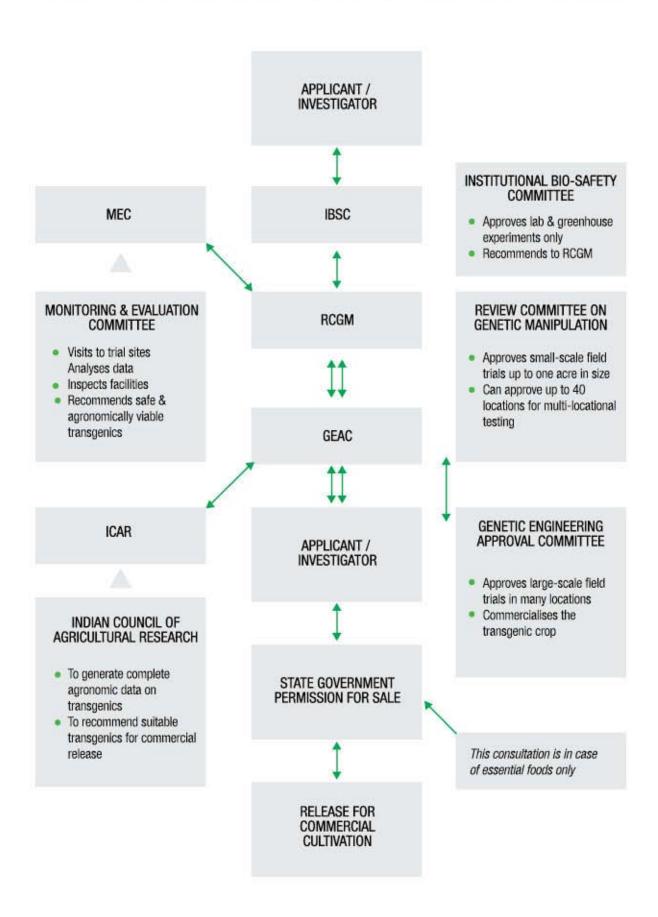
RDAC - The Recombinant DNA Advisory Committee reviews developments in biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time.

## The regulation for GM foods is generally in two categories

For planting of GM crops – that is genetically engineered organisms that are being sought approval for being grown for agricultural purpose in India.

For the sale of GM foods – foods that are be derived from a produce of a GM crop, which is not previously permitted for agriculture in India. The regulation permits or denies approval for the sale of GM food which has been imported from outside of India.

## Flowchart for approval of planting of GE crops in India: present structure under the EPA 1986.



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## **GLOSSARY**

Abiotic – not biological; especially: not involving or produced by organisms; the abiological synthesis of amino acids.

Agrochemical – an agricultural chemical (as an herbicide or an insecticide).

Allergen – a substance such as a protein that induces an allergic reaction.

Anthrax – an infectious disease that occurs in of warm-blooded animals (as cattle and sheep) caused by a spore-forming bacterium – Bacillus anthracis, transmissible to humans especially by the handling of infected products (as wool), and characterised by cutaneous ulcerating nodules or by often fatal lesions in the lungs; Also, the bacterium causing anthrax

Antibiotic - tending to prevent, inhibit, or destroy life

Antigen – any substance (as an immunogen or a hapten) foreign to the body that evokes an immune response.

**Bacillus thuringiensis (Bt)** – a naturally occurring soil bacterium, occurring across the world. Several strains can infect and kill insects, which is why it is developed for insect control.

Biotoxin - a toxic substance of biological origin.

Bollworm - corn earworm; or any of several other moths that feed on cotton bolls as larvae.

Cholera toxin – (CTX, Ctx, or CT) – a protein complex secreted by the bacterium Vibrio cholerae. CTX is responsible for the harmful effects of cholera infection.

Chromosomal DNA – A collection of DNA sequences that code for genes. The sequences are generated in the laboratory from mRNA sequences.

Cry proteins or crystal proteins – these have so far been grouped into 16 distinct groups, which either code for a 130 kD a or a 70 kD a protein.

Cry I proteins are insecticidal to Lepidopteron insects; all the proteins, even the Cry IA subfamily, have a distinctive insectidal spectrum.

CryllA proteins are active against both Lepidoptera and Diptera, while Cry IIB is specific to Diptera.

Cry III proteins are active against Coleoptera species, while CrylV proteins are specific to Diptera. But the CytA protein does not show any insecticidal activity, is cytolytic for a variety of vertebrate and invertebrate cells, and exhibits no homology with other Cry proteins.

Cry1Ac protoxin is a potent immunogen able to induce a specific immune response in the mucosal tissue, which has not been observed in response to most other proteins.

Cytokines – any of a class of immunoregulatory proteins (as interleukin or interferon) that are secreted by cells especially of the immune system.

**DNA** (deoxyribonucleic acid) – the molecule that encodes genetic information. DNA is a double-stranded molecule held together by weak bonds between base pairs of nucleotides.

DNA sequencing – Determination of nucleotide or base sequence of a DNA molecule/fragment is known as DNA sequencing.

**Delta endotoxins** – insecticidal toxins produced by Bacillus, a species of bacteria.

Endotoxins – a toxic heat-stable lipopolysaccharide substance present in the outer membrane of gramnegative bacteria that is released from the cell upon lysis.

Enhancer – nucleotide sequence that increases the rate of genetic transcription by preferentially increasing the activity of the nearest promoter on the same DNA molecule.

**Gene** – the fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product (i.e., a protein or RNA molecule).

**Genetic engineering** – the manipulation of an organism's genetic endowment by introducing or eliminating specific genes through modern molecular biology techniques.

**Genome** – all the genetic material in the chromosomes of a particular organism; its size is generally given as its total number of base pairs.

**Glycoprotein** – a conjugated protein in which the non protein group is a carbohydrate. GRAS: Generally Recognised As Safe – substances intentionally added to food that do not require a formal pre market review by the FDA to assure their safety, because their safety has been established by a long history of use in food.

HGT: Horizontal Gene Transfer – also Lateral Gene Transfer (LGT), any process in which an organism incorporates genetic material from another organism without being the offspring of that organism. By contrast, vertical transfer occurs when an organism receives genetic material from its ancestor, e.g. its parent or a species from which it evolved. Artificial horizontal gene transfer is a form of genetic engineering.

Interferon alpha – an interferon produced by white blood cells that inhibits viral replication, suppresses cell proliferation, and regulates immune response and that is used in a form obtained from rDNA to treat various diseases.

Lepidopteran – any of a large order (Lepidoptera) of insects comprising the butterflies, moths, and skippers that as adults have four broad or lanceolate wings usually covered with minute overlapping and often brightly colored scales and that as larvae are caterpillars

Leukocytes – any of the blood cells that are colourless, lack haemoglobin, also called leukocyte white blood corpuscle.

Microbes – an organism (as a bacterium or protozoan) of microscopic or ultramicroscopic size.

Monocultures – the cultivation or growth of a single crop or organism especially on agricultural or forest land.

Mutation – a relatively permanent change in hereditary material involving either a physical change in chromosome relations or a biochemical change in the codons that make up genes. Organophosphates – an organophosphorus compound (as a pesticide) of, relating to, or being a phosphorus-containing organic compound and especially a pesticide (as malathion) that acts by inhibiting cholinesterase.

Phytoremediation – the process of using plants for pollution clean-up of contaminated soils or water

Plasmids – an extrachromosomal ring of DNA especially of bacteria that replicates autonomously.

Promoter – a binding site in a DNA chain at which RNA polymerase binds to initiate transcription of messenger RNA by one or more nearby structural gene.

rBGH – recombinant Bovine Growth Hormone – a synthetic form of growth hormone Injected into cows to increase growth rates and milk production.

rDNA – Recombinant DNA – a form of artificial DNA that is engineered through the combination or insertion of one or more DNA strands, thereby combining DNA sequences that would not normally occur together.

SARS – Severe acute respiratory syndrome – a severe respiratory illness that is caused by a coronavirus, is transmitted especially by contact with infectious material (as respiratory droplets or body fluids), and is characterised by fever, headache, body aches, a dry cough, hypoxia, and usually pneumonia.

**Tissue culture** – the process or technique of making body tissue grow in a culture medium outside the organism; a culture of tissue (as epithelium)

**Transgenic** – An experimentally produced organism in which DNA has been artificially introduced and incorporated into the organism's germ line.