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Indian Medical Parliamentarians' Forum

IMPF Policy Brief for Parliamentarians

Genetically Modified (GM) Food - A threat to food safety and security in India

Introduction

Genetic engineering (GE) is simply the artificial transfer of genes from one species to another species, 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, which disrupts the organism's natural function and renders it unstable in character and function.

Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species. Such methods are used to create GM plants - which are then used to grow GM food crops. (WHO, 2008)[1]

It is this crude, imprecise operation and the paucity of information, a direct result of the meager scientific information the issue has been accorded, which has resulted in genetic engineering of crops, food and even trees to be mired in controversy across the world. The primary purpose of this policy brief is to highlight this argument to parliamentarians who must consider it before the Genetic Engineering Approval Committee (GEAC) goes ahead with the approval for the commercialisation of the first food crop in India, Bt brinjal. Parliamentarians have the power to take a stand and prevent this flawed and detrimental technology, which has proven public health risks, being rolled out across the country.

GM food: safety concerns

The Food and Agriculture Organisation (FAO) of United Nations Organisation has defined food security as physical, social and economical accessibility to safe, sufficient and nutritious food. One factor that has made GM food unacceptable is their history of health hazards, which is backed up by a multitude of scientific studies, some of which are highlighted below:

GM crops could lead to infertility: According to the latest study published by the Austrian Ministry of Health, Family and Youth, mice fed with GM corn having Mon810 and NK603 genes were found to have

a smaller litter in the long term.[2] This was derived from the outcomes of a multi-generation reproduction study done over a period of 20 weeks. Interestingly, this was the first time a study of such a nature was conducted anywhere in the world.

What is worrying is that around the same time the Genetic Engineering Approval Committee (GEAC), the nodal agency for any release of GM crops in India, gave Monsanto Inc permission to conduct open air trials of GM corn with similar gene constructs implicated in the Austrian study. This clearly shows the callousness with which the GM regulators operate in India.

Impacts on internal organs and immune system: Dr. Arpad Pusztai (1998)[3] 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 subjected to transgenic (a gene which has been transferred from a different species) potatoes were observed to have had adverse effects in their vital organs including the kidney, thymus, and gastrocnemius muscle.

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 Mon863, a genetically engineered maize type by Monsanto.[4] There were also stark and observable weight gain differences between rats fed with Mon863 and non-GE maize. There was a 3.3% decrease in weight in males and 3.7% increase in 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 by a protein known for its allergenic properties introduced into a transgenic plant as in the case of Brazil nut proteins in GM soya bean.[5] What is more worrisome is the allergenecity produced due to unknown changes in a normal protein when expressed in a new environment of the transgenic plant.

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 alpha-amylase 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 found to have developed lung inflammation.[6] Interestingly, these effects were not observed with beans that naturally produce this protein.

Threat to infants and invalids: A report by the Royal Society recognised that food allergies are far more common in children than in 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.[7]

Horizontal gene transfer (HGT) and antibiotic resistance to microbes: Scientific studies in the past have given clear indications that the bacterial genes used in genetic modification could get transferred to the bacteria in the gut leading to untoward effects Mercer *et al.* reported that such transfer could start in the mouth itself. [8] Furthermore, plasmid DNA and GM-DNA were found in micro-organisms that naturally live in the human intestines and saliva. 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.[9]

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.[10]

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.[11] 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 cross-pollinated 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. Some contain viral sequences such as the 'spike' protein gene, the pig corona virus, in the same family as the SARS virus.[12,] If the tradition of contamination caused by genetically engineered crops is followed, there is a high likelihood vaccines and pharmaceuticals will mix with normal food crops.

Mutations: Multiple effects may occur when new genes are inserted into plants to give them 'desirable' traits. The impacts are unknown and tricky to trace. Mutations could lead to deletions and rearrangements of host DNA and the introduction of superfluous DNA. Secondary procedures associated with plant transformation, including tissue culture and infection with *tumefaciens*, can also result in mutations.[13]

Contamination is inevitable

Any GM organism is a living organism that is capable of reproducing, multiplying and spreading. One of the greatest concerns about GM crops is their un-traceability and uncontrollability once released into the environment. This makes any release of GMOs into the environment irreversible. Unlike pesticides or other agrochemicals, which could be stopped and removed from the environment if they are found to be toxic, GMOs be it plants, animals or micro-organisms leave no scope for tracing or and removing them from the environment. This potential threat to human life needs to be dealt with immediately before irreversible damage is committed.

Contamination could occur at any of the four stages:

In the last 10 years of GM crop history, there have been 216 cases of contamination. In 2007 alone, there were 39 new instances of GM crops contaminating regular crops in 23 countries.[14] Several of these were the result of open air field trials. In India, the contamination of regular hybrids by Bt cotton have been documented and acknowledged by GEAC itself.[15]

Current Situation in India

Bt cotton is the sole GM crop commercially cultivated in India. Despite it resulting in socio-economic chaos and heightened environmental problems, there has been a quantum jump in investment in GM research over the last few years, especially in the last three years.

Today, around 238 verities of 56 GM crops are at different stages of trials in India at various private and public institutes. This also includes 169 varieties of 41 food crops. (See Table 1)

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.

Table 1: A compilation of Crops being genetically modified in India,

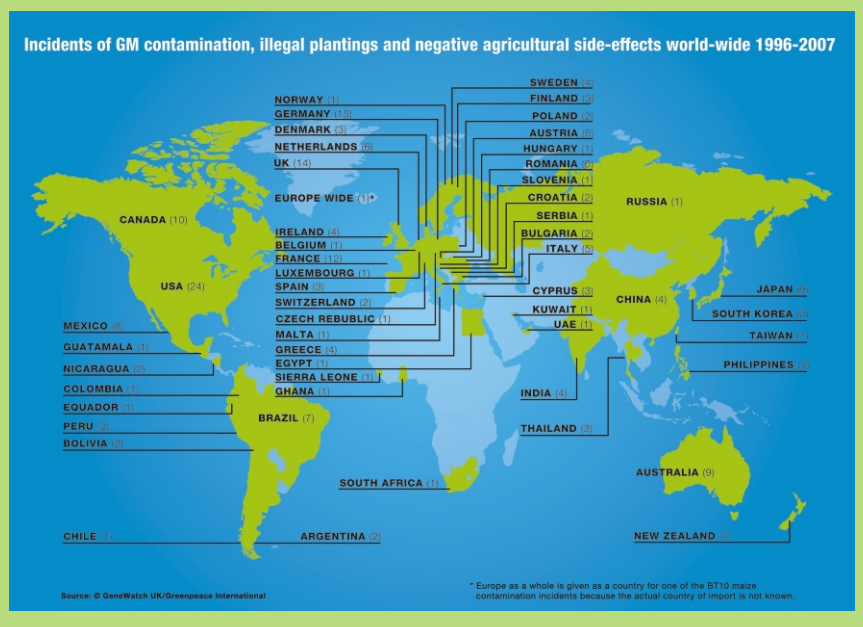
Cereals	Pulses	Vegetables	Fruits	Spices	Oil seeds	Medicinal herbs	Cash Crops
Rice	Black gram	Brinjal	Acid lime	Black Pepper	Mustard	Brahmi	Cotton
Wheat	Chick pea	Okra	Apple	Cardamom	Ground nut	Ashwagandha	Jute
Maize	Cow Pea	Tomato	Banana	Chilli	Sunflower	Creat	Coffee
Ragi	Pigeon Pea	Cauliflower	Papaya	Ginger	Saw flower	Jivanthi	Tea
Pearl millet	Soya Bean	Cabbage	Pomegranate		Castor		Tobacco
		Onion	Musk melon				Sugarcane
		Potato	Water melon				Carnation
		Yam					Rubber
		Cassava					

Source: www.igmoris.nic.in

Box 1

The Global GM Scenario

GM organisms are being projected as the panacea to the world's food crisis a vision of sustainable agriculture with increased productivity achieved through improved crop varieties as well as decreased input costs and declining environmental problems.[16] Yet, countries across the world are banning GM foods in any form import of packaged foods and any form of trials laboratory or field.



It is estimated, 91% of the GM crops are grown in just three countries of the world the USA, Brazil and Argentina. And while Monsanto continues to spread across the world, several countries are banning GM foods altogether. Several European nations have recently joined the league to completely ban GM crops at a policy level. France, Hungary, Italy, Greece, Austria and Poland have already banned Mon810, the only commercially cultivated variety of corn in Europe. As recently as May 2008, the French parliament rejected a bill that sought to allow genetically engineered crops, in line with a 2001 European Union Law.

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. The Western Australian Government has extended its moratorium on genetically engineered crops (food and fibre especially canola and cotton) by another four years starting from 2008.

It's not just the developed countries who have taken precautionary steps, because of massive public concern. Both Thailand and Vietnam, two of the largest rice growing countries in the world, have banned any open air release of genetically modified rice.

In 2006, rice exporters in India, following unregulated rice field trials and fear of revenue losses, demanded a ban on GE rice field trials in six key rice producing (and exporting) states. The ban was granted in 2007[17], facilitated by a growing farmer resentment manifested by destruction of field trials in Karnal in Haryana and Coimbatore in Tamilnadu.

Despite this, 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 contains a toxic gene from the bacterium *Bacillus thuringenesis* (Bt), which is artificially induced 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 bio-toxin.

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.

Genetic Engineering threatening Indian traditional medicines

It's not just food that is under threat from genetic modification, so are India's traditional systems of medicine. According to the information provided in government websites, the Kerala Agricultural University is in the process of R&D on *Jivanti* and *Ashwagandha* while the Rajiv Gandhi Centre for Biotechnology is conducting studies on *Brahmi* and *Creat*.[18]

The above mentioned research institutions are trying to induce alien genes into the herbs so as to increase a particular chemical component in the plant. According to the Ayurveda and Siddha practitioners, this goes against the basic philosophy of these systems. The Indian medicine systems depend on the synergistic nature of traditional herbs. Moreover many of the food articles that people use are also used as medicines. Thus, genetic modification of food and medicinal herbs will wipe out the essence of an age-old practice of traditional medicine in India.

The GE regulatory system in India

There are five 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), Recombinant DNA Advisory Committee (RDAC), which are involved in the approval and monitoring of GM research in the country. Apart from all these Committees there is also the Recombinant DNA Advisory Committee (RDAC), which advises on general research orientations.

Of these the GEAC, an autonomous 32-member body comprising ex-officio members and experts, is the nodal agency for the open air release of any GM organisms in India.

Although agriculture and food are regulated at the state level, states have been left with no decision-making powers 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.

The existing regulatory mechanism in India is

incapable of preventing the uncontrolled illegal spread of untested GMOs into the food chain. This has been proven by the Bt cotton experience. Apart from the fact that existing studies mandated can hardly ascertain the long-term safety of GMOs to the human health and environment, the manner in which approvals are given is a matter of grave concern. Dr. Pushpa Bhargava, the Supreme Court nominee to GEAC in an affidavit to the court had categorically said that unless there is an overhauling of the regulatory testing and unless there is a comprehensive review of Bt cotton in the past seven years in the country, no further approvals, for even field trials, should be undertaken.

The regulatory system is inherently flawed given that it permits the release of GMOs, which endanger the health of humans, animals, plants 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 of GM crops on health and the environment.

It fails to see the need for transparency when it comes to GM crops.

Absence of information on the biosafety of GM food crops

It is horrifying to note that even after four years of open field trials; there is not a single biosafety study available for crops such as Bt rice, Bt okra, Bt tomato and GM mustard.

It took a 30-month RTI battle by Greenpeace, along with a PIL in the Supreme Court by Aruna Rodrigues et al, to get the biosafety studies of Bt brinjal available for public scrutiny. The regulatory bodies, be it GEAC or RCGM, had taken the side of the seed company,Mahyco, in fighting the common man's right to know what is in their food. The Central Information Commission had to finally remind them twice, vide their orders in April 2007 and November 2007, that when it comes to matters of public health, Public interest is more important than commercial interest.

It is shocking that this un-scrutinised, non-peer reviewed, unpublished information produced by the company, who has a business interest, is the only information based on which the GEAC is going ahead with the approval of Bt brinjal.

What the experts say

The UN Agriculture Assessment (also known as IAASTD International Assessment of Agricultural Science and Technology for Development) aims to provide information for decision makers on how to structure agricultural research and development to cope with current and future challenges. The IAASTD is a scientific assessment, very similar to the Intergovernmental Panel on Climate Change (IPCC). At its heart is the work of over 400 scientists from all around the world who took stock of the current situation in global agriculture and identified some key challenges and options for action for the future of farming. The following quotes were taken from the Global Summary and the Executive Summary of the Synthesis Report of the IAASTD meeting in April 2008, They have been included because they highlight the UN view that GM crops can decrease and increase yields, and that there are many benefits to sustainable agricultural practices:

"The application of modern biotechnology outside containment, such as the use of GM crops is much more contentious. For example, data based on some years and some GM crops indicate highly variable 10-33% yield gains in some places and yield declines in others. (IAASTD, Synthesis Report Summary)

"The impacts of transgenic plants, animals and microorganisms are currently less understood. This situation calls for broad stakeholder participation in decision making as well as more public domain research on potential risks." (Global Summary, p. 20).

"Policies that promote sustainable agricultural practices (...) stimulate more technology innovation, such as agroecological approaches and organic farming alleviate poverty and improve food security." (IAASTD, Global Summary, Options for Action)

Will GM crops be the end of consumer choice?

The right to make an informed choice is the fundamental right of any consumer. In the case of GM foods, countries have come up with strict labelling laws for segregating GM food from non-GM, regular food. This is the only saving grace for a citizen to ensure that he or she is not subject to potentially dangerous GM food. The European Union has taken the lead in the labelling of GM foods. It has been joined by Asian countries Japan, China, South Korea and the Gulf Countries Council (GCC), which includes all the seven Arabian states. Although 93% of the Americans support labelling (going by in a poll conducted by Fox News), the US continues to remain a dark horse in this matter.

Although the number of countries banning GM foods, and ensuring the labelling of foods is growing, India, in contrast does not even have a labelling law in place, thereby revoking the people's right to make an informed choice. In a country like India, it is also a question of ethics, where a large population is vegetarian due to cultural reasons. The use of animal genes in plants could seriously hurt the cultural sentiments of this section of the population.

Along with the GM threat from within the country, there is also the threat from imported food items. In 2003, the first instance of such import to India was thwarted by civil society groups when USAID wanted to import Starlink corn, which was mired in controversies in USA because of its allerginicity, to India as part of the CARE food AID programme.[20] 5 years on, India's borders still remain porous to GM food being dumped on the country. In May 2008, Greenpeace India found out that PepsiCo's Doritos, imported from USA, contain GM ingredients.[21] Although a complaint was launched with GEAC, no action has been taken so far.

Stringent labelling laws need to be enforced and there must be provisions to penalise offenders and affix liability for contamination, to ensure that people have the right to choose.

Policy recommendations

In the light of this evidence, and the likelihood of commercialising GM brinjal, Parliamentarians should protect the Indian population by demanding the Government to:

Stop the commercial release of Bt brinjal until an independent analysis proving the safety to human beings and environment in the long term has been conducted, and is made available for public scrutiny.

Enforce a moratorium on all open air field trials of GM crops until an independent analysis proving the safety to human beings and environment in the long term has been conducted, and is made available for public scrutiny.

Ban research on genetic modification of medicinal herbs and trees, which threaten traditional Indian medical practices

Set up a parliamentary committee to review not only the socio-economic, environmental and health impacts of Bt cotton from 2002 up till 2008 (on humans and animals), but also the regulatory system, which has been doling out approvals in a haphazard manner.

Take immediate action against illegal GM foods imported into India and put in place a mechanism at ports, to screen imported food for GM ingredients.

Ensure that labelling, traceability and liability laws are made operational before approving field trials of any GM food crops.

Allocate ample resources in terms of personnel, money and infrastructural support for low external input, non-chemical, non-GM farmer friendly sustainable agriculture.

EXCERPTS FROM: 'URGENT INTERIM APPLICATION' FILED BY PETITIONERS IN SUPREME COURT AS PART OF THE PIL FILED BY MS Aruna Rodriguez *et al.* AUG '08
BIO-SAFETY CRITIQUE & GUIDELINES RECOMMENDED BY DR P BHARGAVA

Six outstanding issues sum up just how faulty and perfunctory the Regulator's approach to bio-safety has been. Even the current inadequate norms for safety testing have NOT been applied to GM food crops like Bt okra and Bt brinjal before they were field tested.

A. In No case has there been an appropriate and comprehensive risk assessment.

B. Tests have been carried out by the Applicant (crop developer), or by an outside agency (for example Rallis), to whom samples were provided by the applicant.

C. All tests have used a surrogate protein not the actual protein derived from the GM plant. Assuming identicality of the two is scientifically untenable.

D. No chronic toxicity tests have been done. It is amazing that it is not recognised that in many cases the effects may be only long-term effects. Examples would be aflatoxin and many agents that cause cancer.

E. EVENT-BASED approval, to which GEAC has been resorting till now, without further experimentation, may not be justified on account of differences in the case of different hybrids, in the nature and the extent of glycosylation of proteins.

F. CBI (Confidential Business Information) is a *lame excuse for not giving the detailed primary data, which, if given, may go against the Applicant as has happened in the past.*

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