GREENPEACE

UNPREDICTABLE; IRREVERSABLE; UNNATURAL

The story of Genetically Engineered Foods

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Genetic engineering (GE) refers to a set of technologies that are being used to change the genetic makeup of cells of plants and animals to bring about a desired commercial function e.g. insect resistant plants, herbicide tolerant plants, increased protein content in vegetables etc. For the first time humans have decided to alter the natural evolutionary process and create new plants and animals through techniques that involve highly complicated manipulations of genetic material and other biologically important chemicals.

UNPREDICTABLE
Genetic engineering can have unpredictable effects because the process is imprecise and random. Inserted genes may disrupt natural genes, be unstable in their new environment, or function differently than expected. There are two ways in which genetic engineering may affect food safety: Gene disruption or instability may lead to new toxins being produced; and the new protein produced by the foreign gene may cause allergies or toxicity.

IRREVERSABLE
Releasing GE organisms into the environment poses special threats to the environment and the food chain. GE crops are living and have the ability to reproduce and multiply. Through crosspollination, the foreign genes they contain can be transferred to other crops and wild species. Genetic contamination can, therefore, magnify over time. GE seeds can also be spilt, mixed with non-GE seed and grown illegally, compounding the problems.

UNNATURAL
Cow genes in Wheat[1] and Spider genes in potato[2] are just some examples of genetically engineered organisms that are being created by scientists in laboratories. Transferring genes across the species barrier doesn't occur in nature. Through genetic engineering scientists have embarked on a journey to alter the evolutionary process. The impacts of this are unknown.

This document takes you through some of the incidents that have been described as accidents and the impact to our food and health in the dangerous world where food is genetically engineered.

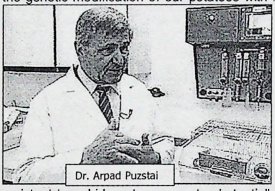
Critical health impacts caused by GMOs

There have been several cases of GM crop disasters in the past. This section takes us through the few cases that have battled corporate efforts to suppress facts and survived the day to reach the concerned citizen. In some of these cases, scientists owned up to the monumental disaster and eventually were ostracized by the proponents of the Genetic Engineering technology. In other cases, data was deliberately suppressed and the risks of the technology had to be forced open by environmental groups

[1] Scientists at the University of Nebraska (Lincoln, USA) have used cow genes in wheat to give wheat fungal (fusarium resistance).
[2] Ref: Scheller J, Henggeler D, Viviani A, Conrad U. 2004. Purification of spider silk-elastin from transgenic plants and application for human chondrocyte proliferation, Transgenic Research 13: 51-57.

Rats that suffered after feeding on GE potato

In 1995 Dr. Arpad Puzstai started a publicly funded major scientific investigation (by the then Scottish Office Agriculture, Environment and Fisheries Department, SOAEFD) into the possible environmental and health hazards of GM potatoes. British GE scientists were using a gene taken from snowdrop bulbs had transformed the potatoes. The gene of this sugar-recognizing protein (GNA) has been known to give natural protection against insect pests. It had also shown in extensive and appropriate nutritional studies carried out by our research group at the Rowett Research Institute in Aberdeen before the genetic modification of our potatoes with the GNA gene that animals ingesting this protein as part of their diet even at an 800-fold excess of that present in GM potatoes, suffered no significant harmful consequences. Therefore it was expected for it to be safe for animal and, later after appropriate testing, possibly for human consumers.[3]


Dr. Arpad Puzstai

Unfortunately, the studies revealed that the two lines of field-grown GM potatoes, which originated from the same transformation and were both resistant to aphid pests were not substantially equivalent in composition to parent line potatoes, nor to each other. Even more importantly, we showed from the results of four rat feeding studies of different designs and durations (10 to 110 days) that diets containing GM potatoes in comparison with iso-proteinic and iso-energetic non-GM parent potato diets had in some instances interfered with the growth of young rapidly growing rats, the normal development of some of their vital organs, induced changes gut structure and function and reduced their immune responsiveness to injurious antigens. In contrast, the animals fed on diets containing the parent, non-GM-potatoes or these potatoes supplemented with the gene product had no such effects.[4]

The controversy began in August 1998 when Dr Arpad Pusztai, 68, made a public statement about his fears, about the £1.6m study he conducted at the Rowett Research Institute (RRI).

Though the establishment ganged up against him, Dr. Pusztai's findings have never been disproved. This work has in fact clearly demonstrated that, in addition to possible toxicological studies, the safety of GM – food must be established in both short-term and long-term feeding, metabolic and immune-response studies with young animals as these should be the most appropriate to respond to and show up any nutritional and metabolic stresses affecting the normal development of young animals into healthy adults.

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[3] Source: Dr Arpad Pusztai; Submission of Health Impacts of GM Crops: Evidence to the Clerk to the Health and Community Care Committee of The Scottish Parliament)

[4] A Pusztai et al. (1999) Expression of the insecticidal bean alpha-amylase inhibitor transgene has minimal detrimental effect on the nutritional value of peas fed to rats at 30% of the diet. The Journal of Nutrition, 129, 1597-1603.
SWB Bwen an A Pusztai (1999) Effects of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. The Lancet, 354, 1353-1354.
A Pusztai (2002) Can science give us the tools for recognizing possible health risks of GM food? Nutrition and Health (2002) 16, 73-84
7. A Pusztai (2002) GM food safety: Scientific and institutional issues. Science as Culture, 11, 70-92.

Within 48 hours after his public statement he was suspended in disgrace and later forced to retire. The RRI said he had misinterpreted his results.

When Dr. Pusztai initially voiced his concerns about the health implications of genetically modified foods on ITV's *World In Action* on August 12th 1998, the biotech company, Monsanto, was quick to react in the press on 13th August 1998, asserting in The Times that "...these revelations are absolute dynamite", adding that "We have...food scares and doom-laden utterances without anyone looking at the facts."[5] The lobby group, Foodfuture, added that the scandal was due to "sloppy science and over-blown reporting..."[6]

Some opinions of other independent scientists on Dr. Puzstai's study:

A group of scientists, drawn from 13 different countries, had re-examined his work and signed a joint memorandum[7] saying his conclusions were justified (1999). The group included toxicologists, genetic engineers and medical experts. "We found that his data is sound", said their spokesman, Dr Vyvyan Howard, a toxipathologist at Liverpool University.

Dr. Putzai's revelations have been backed by an independent analysis by consultant pathologist Dr Stanley Ewen, of Aberdeen University, who examined the preserved rats' organs. But a leading expert said: 'These were measurable changes in the rats fed modified potato - and we feel there's been a cover-up. There should be more openness in the whole business about public money and how it being used in this field."[8]

Mice that suffered from inflammation of the lungs after feeding on GE peas[9]

After a decade of research, a field trial of genetically engineered (GE) peas was stopped in Australia because a study[10] found serious health impacts in mice that were given the GE peas to eat. The GE peas contained a gene from a bean to make the peas resistant to damage by the pea weevil.

The gene inserted into the GE peas was designed to produce an alpha-amylase inhibitor, a protein that prevents the digestion enzymes of insects from working. This causes the plant to be toxic to them when eaten.

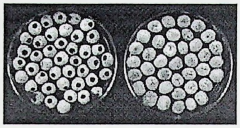
Small changes in protein structure can cause big changes in allergenicity.

Although the chemistry of the protein produced in the GE pea was almost exactly the same as that produced naturally in the bean, the structure of the protein was

[5] The Scotsman, 13th August 1998.
[6] The Guardian, 13th August 1998.
[7] Fears erupt over Genetic food, 12th February 1999, BBC.
[8] The UK Mail, dated 31 Jan 1999.

[9] CSIRO Plant Industry; 2005; Effective risk assessment of GM field peas
[10] Vanessa E. Prescott, Peter M. Campbell, Andrew Moore, Joerg Mattes, Marc E. Rothenberg, Paul S. Foster, T. J. V. Higgins, and Simon P. Hogan JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY Volume 53, Issue 23 (November 16, 2005) pages 9023 - 9030

unexpectedly changed in the GE plant. Small changes in the 3D protein structure can affect their potential to cause allergies. In this case, the researchers found that the GE peas caused allergenic reactions in mice.



The CSIRO-developed GM field peas (right)

When they inhaled the GE pea protein it caused inflammation of the lungs and when they ate the GE peas they became more sensitive to other food allergies. These effects were not observed with beans that naturally produce this protein.

In the case of this study, the toxic effects were seen within the four weeks of the experiment. Had the toxic effects developed over a long-term period, they may not have been detected by the study. This demonstrates why it is so important that GE crops are properly tested and are not released into the environment.

Rats that suffered after being fed GE corn

On 23 April 2004, *Le Monde* reported that the French expert body in charge of GMO evaluation (CGB, Commission du Génie Biomoléculaire) had expressed doubts about the safety of GM maize MON863. Results of a rat feeding study that Monsanto delivered to EU authorities showed significant variations between rats fed conventional maize and those fed with MON863. The variations included an increased number of white blood cells in the males, reduced immature red blood cells in females, a significant increase in blood sugar in the females and a higher frequency of physical irregularities in the kidneys of the males, such as reduced weight and inflammation.

Greenpeace protest in Europe against GE corn, 2003.

Monsanto requested that documents concerning the risk assessment, like rat feeding trial results, should be classified as "confidential business information". According to European law, the public has a right to full access to information concerning the risk assessment of GMOs. In particular Article 25 of Directive 2001/18/EC indicates that "in no case" should the information related to "environmental risk assessment" (defined as "the evaluation of risks to human health and the environment, whether direct or indirect") be kept confidential.

The Directive also indicates that the risk assessment should "be carried out in a scientifically sound and transparent manner based on available scientific and technical data".

Greenpeace had been pursuing this since April 2004, and it took us more than a year to see the interests of society at large would prevail to have access to "confidential business information" over Monsanto's economic interests and its policy of opacity and secrecy.

The chronology of the campaign is as follows:

· On 5 May 2004, Greenpeace wrote to the German agriculture ministry, which was in charge of the initial risk assessment report, to request access to the full documents concerning Mon 863.

· On 4 August 2004, the German agriculture ministry replied that the applicant, Monsanto, had refused to agree to publish the initial rat study MSL-18175, which had been classified as "confidential business information". · On 21 March 2005, the German authority decided to give access to the full document, because Monsanto could not show that its request for confidentiality was backed by EU or national law.

· On 27 April 2005, Monsanto filed an appeal against the decision of German government and, in addition, took out an injunction to stop the authorities publishing the data.

· On 9 June 2005, the German court decided to reject Monsanto's request; the data could not be seen as confidential, the right of society to transparency had to be given more weight than Monsanto's economic interests. The company appealed the decision.

· On 20 June 2005, the court rejected the appeal, and ruled that the documents be made public.

GE Corn (Starlink) – a potential allergen to humans enters the food chain

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 was a type of insect resistant GE corn grown in the USA from 1998, which produced the *Bt* protein, Cry9C. It was only approved for animal feed and industrial purposes, as there were concerns that the Cry9C protein could cause allergies because it shares characteristics of other allergens.

However, in September 2000, StarLink was found in corn taco shells and other foods, and over 300 corn products had to be withdrawn from the market. Traces of StarLink corn were also found in corn-based foods in Japan and Korea. It is not known how StarLink came to be in the human food chain - it may have been inadvertently mixed with other corn at a mill, a conventional crop may have cross-pollinated with a StarLink crop, or a farmer may have sold StarLink corn for human food to get a higher price.

While StarLink is not being grown anywhere in the world at the moment, it may have contaminated other corn seed and remain in the food chain. The episode raises questions about the ability of regulatory authorities to control GE crops.

Industry observers estimate that the entire cost of the scandal has exceeded US $1 billion. Neil E. Harl, a professor of economics at Iowa State University, estimates that the company has already paid out more than $500 million to farmers, food processors and grain handlers[11]. At least 300 food products in the US had to be recalled, at an undisclosed cost to the food manufacturers. There were also recalls in Canada and Japan. US corn farmers lost huge markets all around the world. US government officials estimated that it might take four years to get StarLink out of the US food and seed supply. Now, three years after the scandal, approximately 1% of samples sent to USDA testing labs are still found to contain StarLink[12].

Some of the costs of the contamination scandal can be detailed:

- Aventis paid at least $100 million to buy back the 2000 crop.[13]
- The United States Department of Agriculture spent $20 million to buy seeds from small companies whose seed stock was contaminated.[14]
- Kraft lost an estimated $10 million in lost sales from its taco shells alone.[15] Taco Bell franchises were awarded $60 million by all the taco shell manufacturers: Kraft, Azteca Foods and Mission Foods.[16]
- Aventis, Garst and four food companies (Kraft, Kellogg, Azteca Foods and Mission Foods) settled a class action consumer lawsuit for $9 million to customers who said they suffered allergic reactions[17].
- Aventis and Garst settled a class action lawsuit by farmers seeking compensation for lost markets. The lawsuit sought damages as well as a requirement for Aventis to decontaminate all soil, farming equipment, etc. to prevent further contamination. The firms will pay $110 million; farmers are likely to receive only US$1 per acre.[18]

Unintended effects of Genetically Modified Organisms (GMOs):

There are numerous cases of documented unexplainable effects of GMOs. Here are a few examples:

- Researchers at Monsanto who were trying to increase the content of carotenoids (a chemical which is used to form vitamin A) in oilseed rape (canola) found that vitamin E and chlorophyll levels in the seeds were dramatically and inexplicably reduced[19].

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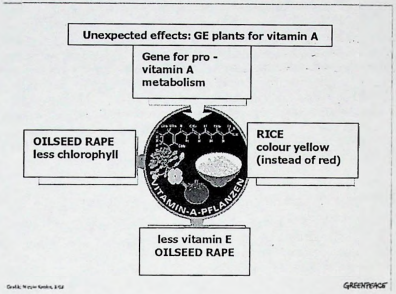
[11] Jacobs, P. 2003. Traces of contaminated grain still showing up in corn supply. 30 November. San Jose Mercury News.
[12] Ibid
[13] Reuters. 2000. Aventis sale of bio-crop unit could hurt farmers. 27 November
[14] Schuff, S. 2001. Major seed companies say they have StarLink isolated. 12 March. Feedstuffs.
[15] Madigan, K. 2003. Risky business. Los Angeles, CA: State Public Interest Research Groups, As You Sow Foundation
[16] Cohen, D. 2001. Taco Bell franchisees to get $60 million. 8 June. Reuters.
[17] Carroll, J. 2002. Judge will approve a settlement on use of StarLink corn products. 7 March. Wall Street Journal (New York)
[18] No author. 2003. Aventis settles StarLink lawsuit. 12 February. Chemical Week.

[19] Shewmaker, C.K., Sheehy, J.A., Daley, M., Colburn, S. & Yang Ke, D. (1999) Seed-specific over expression of phytoene synthase: increase in carteroids and other metabolic effects. The Plant Journal, 20, 401-412.

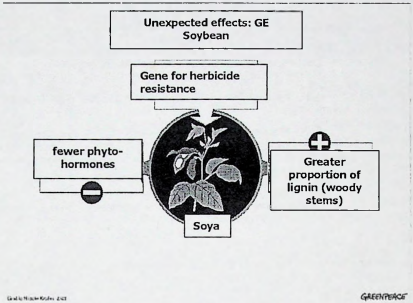


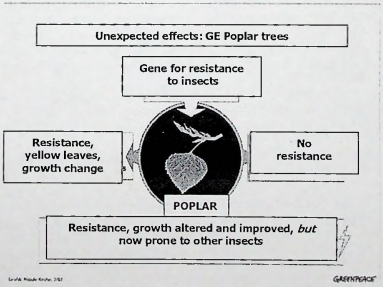
- The colour of the infamous "Golden" rice is an unexpected effect of GE. The GE construct originally contained three genes. The first two genes produce lycopene (red pigment in tomatoes) while the final gene transforms the lycopene to beta-carotene (yellow pro-vitamin A).

  Rice kernels from plants with only the first two genes were expected to turn out red because of the lycopene, but they were yellow. The reason behind the colour of rice turning out yellow and not red with just the first two genes is not understood. Scientists involved in the study have been unable to explain how the rice turns yellow with only two genes.[20]

- Monsanto's GE Roundup Ready soybeans have suffered unexpected crop losses in hot, dry weather due to stem splitting caused, most probably, by increased lignin[21]. The soybeans' phytoestrogen levels are also 12-14 % less than in conventional soybeans, which may mean that soy-based products derived from Roundup Ready soybeans would be less useful as sources of phytoestrogens.

[20] Beyer P. et al. 2002, Golden rice: introducing the B-carotene biosynthesis pathway into rice endosperm by genetic engineering to defeat vitamin A deficiency. American Society for Nutritional Sciences, 132: 506S-510S.
[21] Coghlan, A. (1999) Splitting headache – Monsanto's modified soybeans are cracking up in the heat. New Scientist, 20th November, p.25.





- Disconcerting effects have been observed with poplar trees: a field test which was started in 1996 produced female blossoms on a plant after only three years, whereas normally poplars start blossoming only at the age of eight years. This early

blossoming could increase the rate of unintended spread of the GE trait into the population.[22]

- In China, poplar trees were engineered for insect resistance. The trees did express the desired effects towards the pest insects in field trials. However, just two years later, new and unexpected sensitivities towards other insects occurred.[23]

How 'risk assessment' fails to measure human health impacts

Risk assessment is often portrayed as a relatively straightforward process – simply identify all possible hazards, calculate the probability that they may arise, work out what the risk is, decide if it is acceptable and how to manage it. It sounds very scientific and impartial, but it is not. This protocol was initially conceived to deal with failures in machinery, when it is applied to GMOs it struggles with the complexity of the natural environment. Because it is this system that underlies the regulation of GMOs worldwide, protection of the environment and human health is being compromised.

The **'Precautionary Principle'** builds on a series of straightforward and well-established ideas that[24]

- Prevention is better than cure;
- The polluter should pay.
- We should look for 'no regrets' options.
- We should recognise the intrinsic value of non-human – as well as human – life.
- The complexity and variability of the real world limits the ability of scientific knowledge to predict.
- We must recognise the vulnerability of the natural environment.
- The rights of those who stand to be affected by an activity must be prioritized rather than those who stand to benefit from it.
- There must be scrutiny of all available alternatives and an examination of justifications and benefits as well as risks and costs.
- Long-term, holistic and inclusive perspectives are needed in environmental protection.
- Policy analysts have concluded that the Precautionary Principle is more scientific than conventional risk assessment.[25]

Therefore, a precautionary approach introduces a more scientifically rigorous analysis, with a broader scope and wider range of experts. Precaution is involved at all steps in decision making, in areas where action may lead to seriously harmful effects, from the practice of science and the research agenda, to regulation and governance. Because the threats of GE are so broad, and it's harmful impacts could be severe and irreversible, the precautionary principle must be strictly applied.

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[22] Fladung, M.; Nowitzki, O., Ebbinghaus, D., Schellhorn, A.; Bentien, G., Ahuja, M.R. & Muhs, H.J. 1999, Field release of ROLC-transgenic Aspen-Populus. Online: http://users.ox.ac.uk/~dops0022/conference/forest_biotech99_home.html, Poster 46, 3.12.1999.

[23] Ewald, D. & Han, Y. 1999, Freisetzungsversuche mit transgenen Pappeln in China. UBA-Fachgespräch „Freisetzung transgener Gehölze – Stand, Probleme, Perspektiven" 20. & 21. Sept., Humboldt-Universität zu Berlin.

[24] Stirling, A (1999) Science and precaution in the management of technological risk. Report for the European Commission – JRC Institute of Prospective Technological Studies, Seville. http://www.jrc.es/pub/EURdoc/eur19056len.pdf

[25] European Commission (2000), Communication on the Precautionary Principle, COM (2000)1, Brussels: European Commission

Genetically Engineered Brinjal
Safe for the country? Safe for you?

Genetically Engineered (GE) food for Indians: Are we being experimented upon?

Most genetic engineering (GE) crops are processed into food for humans and animals - but are they safe to eat? GE can have unexpected and unintended effects because the process is imprecise and random. Inserted genes may disrupt natural genes, be unstable in their new environment, or function differently than expected. This echoes a scientist's comments in the scientific journal, *Nature*, about the long-term effects of GE food that: "*Under current monitoring conditions, any unanticipated health impact of such foods would need to be a 'monumental disaster' to be detectable*".[1]

This concern for food safety of GE food has been debated and discussed in the west for over a decade. Today public pressure from European consumers has ensured that most major food companies and retailers do not stock GE foods on their shelves.

Wal-Mart Germany:
The world's leading retailer, Wal-Mart, does not have a clearly defined GM policy: "As a matter of principle, Wal-Mart Germany is anxious to exclusively offer food which is free of genetically modified food ingredients and which does not contain any additives or flavourings derived from genetically modified organisms (...). We continue to work to exclude genetically modified ingredients in the future within the means available to us."
(From a letter to Greenpeace Germany, September 2003)

Kellogg
Kellogg has given a non-GM commitment for its products sold in Europe: "This commitment towards consumers is applied to the use of cereals was well as to other ingredients in Europe. Kellogg is aware of the European consumers' opinion and therefore does not use genetically modified maize or soya ingredients respectively the derivatives thereof in breakfast cereals sold in Europe. Concerning the maize used by Kellogg in Europe for breakfast cereals, a variety grown in Argentina is used. We will continue to assure that it is of non-GM origin. All products sold by Kellogg in Europe do not contain any ingredients of genetically modified raw materials."
(From a letter to Greenpeace Feb 2004)

Coop Switzerland
(Coop guidelines: Genetic Engineering in Food and Feed – May 2003)
Coop declared on the issue of genetically modified rice:
"If Thailand would plant genetically modified rice on a large scale in the future, we would have to rethink the procurement of rice from this region. Because consumers in Switzerland, and in Europe in general, are so skeptical, the commercialization of genetically engineered rice is not realistic in the near future."
(From a letter to Greenpeace Switzerland in August 2004)

Marks and Spencer, UK
"In 1999, responding to consumer concerns, Marks & Spencer announced that it would cease selling products containing GM ingredients and derivatives. As a 100% 'own brand' company this policy covers all food and drink purchased at Marks & Spencer. This policy remains in place and confirms that Marks & Spencer will not be selling any GM labelled foodstuffs in 2004."
(Letter to Greenpeace UK, February 2004)

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[1] Butler, D. & Relchhardt, A. (1999) Long-term effect of GM crops serves up food for thought. Nature, 398, 651-653

Europe's rejection of GE food has cost the GE seed industry dearly, which is why they are strategically forcing open the Asian market. India has responded to this in a confused manner. On one hand our scientists and policy makers cannot resist a foreign investment especially when it is packaged as a "cutting edge technology" but on the other hand they are more than sure that the real solutions for the agriculture crisis lie elsewhere. *"We can't close our eyes to biotechnology for agriculture. At the same time we cannot deviate from the goal of sustainable development in terms of environment and the basic interest of the farmer and consumer safety. So our approach is a case by case basis"*, Kapil Sibal, Minister for Science and Technology *(GM crops, drugs critical for India's development: April 10, 2006; Agence France Presse)*

Engineering for Convenience: GM Brinjal

Underlying the biotech industry's claim that GE foods are needed to feed the world lies a fundamentally flawed analysis. The United Nations' World Food Programme ensures us that more than enough food is already being produced to provide the world with a nutritious and adequate diet - one-and-a-half times the amount required. Much genetic engineering research in food has been directed at meeting the commercial needs of seed and pesticide producers, food processors and others who benefit from the sale of this technology.

Genetically Engineered Brinjal (eggplant/aubergine) could well become India's first Genetically Engineered [Genetically Modified] food crop. Brinjal is the second most-cultivated vegetable crop in India. It is cultivated over 5 lakh hectares with an annual yield of around 8 lakh tones.[1] Brinjal is indeed a strategic choice for a seed company to break in and take control of the seed market in the country.

What are they doing to brinjal?

A genetically modified brinjal has a foreign gene from the bacteria *Bacillus thuringenesis* which is injected into the plant so that the plant can produce pesticides and protect itself from the Brinjal Fruit and Shoot Borer. The process used for this is complicated, and it is both time consuming and resource intensive. The company responsible for this technology claims that farmers will benefit from it, as they will not have to spend on pesticides as each cell and each plant has been converted into a pesticide factory to destroy insects.

However the precise impact on consumers has never been estimated. If approved, this will be the first time a brinjal will be genetically engineered and Indians will be the first in the world to be exposed to it. Since all changes in a GE brinjal are internal one can never really spot the difference between a GE and a non- GE brinjal.

Why we should be worried about eating GM Brinjal

1. Antibiotic resistance
Two Antibiotic resistant markers are part of the gene package that is inserted in the GM brinjal- one for neomycin resistance and one for streptomycin resistance. This raises serious issues of infectious microbes becoming resistant to antibiotics that are used in the treatment of human ailments.

[1] Indian Horticultural Database, 2004, National Horticulture Board

2. Toxicity of proteins released by the bacterial genes
Crystal [Cry] proteins used in this GM Brinjal have time and again been proved to be dangerous to human health. Crystal proteins are found to elicit immune responses when injected or ingested.[2]

3. Current safety testing does not include testing for allergic reactions
The company evades a discussion of the potential toxicity of the Bt brinjal by saying that the proteins, alkaloids, carbohydrates etc in GM brinjal are no different from non-GM brinjal. This testing principle called substantial equivalence is fundamentally flawed. Substantial equivalence means that molecules are chemically similar. It does not examine the structural variances in proteins, which causes serious rejections and allergies.

4. No long term safety testing conducted
All clinical tests to assess the health impacts of Bt brinjal have been short term ones, just like drug trials. But brinjal is a food crop, and therefore is regularly eaten, unlike drugs. Therefore the fact that the long-term implications of GM brinjal have not been assessed is a cause for grave concern.

5. Babies are at a higher risk
Infants are always considered as a high-risk group and the effects of such novel food items like Bt brinjal needs to be checked for their effects on infants. No such study was done in the case of Bt brinjal. The Royal Society of London has in the past expressed concern in this regard[3].

6. Ecological Imbalance
Bt brinjal, like any other GE crop, may impact ecological systems by the creation of invasive species, the loss of diversity, or through toxic effects on non-target species. Toxins from *Bacillus thuringenesis (Bt)* have shown to kill butterflies, moths, and beetles and suffer negative effects, as in the case of the Monarch butterfly in the United States.[4]

7. Loss of consumer choice
The advent of GM Brinjal will also be the end of consumer choice in the country as the consumers will never be able to recognize GM Brinjal from a Non- GM Brinjal in the market.

8. Farmer's seed sovereignty under threat
India is the center of diversity for brinjal and farmers from last 4000 years have developed hundreds of varieties that they used, saved, and exchanged according to their choice and the need of the hour. Bt brinjal like any other GM crop comes with a list of Dos and Don'ts specified by the patent regime. On one side with their aggressive marketing techniques, multi national seed giants and their subsidiaries will lure the farmers into their seed trap, and on the other the farmer will be denied the system of saving and exchanging as this goes against the profit motives of the company. All this will finally lead the Indian farmer to depend on multinational seed companies for the most important input in agriculture – the seed.

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[2] Intragastric and intraperitoneal administration of Cry1Ac protoxin from *Bacillus thuringiensis* induces systemic and mucosal antibody responses in mice. Life Sciences 64(21): 1897-1912

[3] Royal Society (2002) Genetically modified plants for food use and human health – an update. Policy document 4/02. February 2002. http://www.royalsoc.ac.uk.

[4] Losley, J.E., *et al.* 1999. Transgenic pollen harms monarch larvae. *Nature* 399: 214

9. Irreversible genetic contamination
Brinjal is a highly cross-pollinated crop. This is something that even the company agrees to[5] This will lead to contamination of all the non GM Brinjal crops cultivated near by and will thus eliminate the numerous verities that the farmers of the country have developed through ages.

10. Organic farmers at risk:
Organic farmers groups are at highest risk, as any adventitious presence of GM material in organic food materials will disqualify them from calling their products organic, even after painstakingly following all the stringent rules set by certifying agencies for years to achieve organic certification.

11. Increase in the cost of brinjal
The entry of GM food will increase food prices as GM foods have to be tested, packed and labeled as per the upcoming Food Safety and Security Bill. The Indian market (where packed food items form a minority) will have to change drastically and the cost of this change will fall on the consumer. Prices of organic produce also might increase, as more tests may be needed to assure consumers that any GM material has not contaminated their food.

12. Regulatory problems
As has been proven time and again Indian GMO regulatory system is not yet ready with a foolproof mechanism to implement the rules that they have laid down. The Bt cotton and the Bollgard II episodes where the regulatory bodies failed miserably even to monitor limited field trials stand as proof of this inadequacy[6].

The Country at a Crossroads

India is at a crossroad. Never before in the history of independent India has the country been put in a situation where it is faced with such significant ecological and socioeconomic threats from a single technology. Never before has the entire population been turned into a laboratory for the testing of a novel food item. The precautionary principle which modern science advocates, promotes the rights of those who stand affected by the activity which must be prioritized rather than those who stand to benefit from it[7]. We cannot leave it up to our elected representatives to make this crucial decision for us; the brinjal is our wakeup call. Let our voices be heard.

For further information: www.greenpeaceindia.org

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To:

June 14, 2006

Dr Anbumani Ramadoss
Hon'ble Minister for Health & Family Welfare
Government of India.

Respected Sir

Sub: **Bt BRINJAL – HUMAN HEALTH HAZARDS AND BEYOND**

We are a group of concerned civil society organizations, representing lakhs of Indians, approaching you to intervene into the matter of Bt Brinjal, which is on the verge of obtaining permission for large scale trials and seed production in this country. This would be the first time that a GM food crop could be allowed to be released into the open environment for this stage of research. This is the first time in the world that a GM crop would be grown as a vegetable with the Bt toxin incorporated into it and consumed with very little processing. It is not out of place to remind here that it was during large scale trials that Bt Cotton's illegal proliferation began in this country and the regulators only watched with helplessness. Things have not improved an iota since 2001 when such contamination began with Bt Cotton in this country.

There are grave concerns with regard to these various developments and since the Health Ministy's mandate is to protect the health of all Indians and since the Ministry constitutes one of the important regulators of GM in agriculture in India [by virtue of the presence of the Ministry's representatives in the GEAC, expected to play a very important role in decision-making related to GMOs] we approach you to seek your positive intervention in the issue.

We would like to begin by stating that while we welcome the fact that GEAC has offered, for the first time more than a decade after GM crop research began in India, to put up data related to findings from biosafety tests on Bt Brinjal, the entire process run was completely unacceptable. The data that was put up, as presentations by M/S Mahyco to the GEAC, is completely inadequate for any intelligent and scientific feedback to be provided. This also showed the world how GEAC, in which the Health Ministry representatives are expected to play a pro-active role to protect the health interests of Indians, takes its decisions. It is clear that a body that should ask basic, scientific questions related to health and environmental implications in addition to socio-economic implications for our farmers, has decided to function as a mere 'bureaucratic approval' body and runs its processes only on such company-produced meaningless presentations.

We provide our feedback on Bt Brinjal hereunder. Below, we bring up biosafety issues as well as more fundamental issues beyond biosafety. Much of this feedback should also serve as a feedback on the serious shortcomings of our biosafety regime in general and why there is a need to invoke the precautionary principle on GM crops.

Numerous studies worldwide have raised serious questions about potential health impacts of delta-endotoxins. Key assumptions used as the basis for safety claims have been overturned and several adverse findings suggest that GM foods are unsafe. GM-fed animals had problems with their growth, organ development and immune responsiveness, blood and liver cell formation as well as damaged organs [bleeding stomachs, excessive cell growth, inflammation in lung tissue], sterility problems and increased death rates including among the offspring. Risks are increased by the fact that the genes inserted into GM food not only survive digestion, but transfer into body organs and circulation. Transgenes or their fragments have been found in the blood, liver, spleen and kidneys.

1. **The Bt gene is a known toxin that impacts human health and livestock health adversely**: Introduction or creation of a new or known allergen or toxin is a potential consequence of genetic manipulation, as experience worldwide shows.

   - When Bt Cotton was introduced in India, the same set of tests that are now being applied for Bt Brinjal have apparently been run by the company involved and everything was proclaimed to be safe. However, the human health effects of Bt Cotton in India are being reported from all cotton-growing states now. Most farmers and farm workers are experiencing allergies of different kinds. Further, a recent scientific investigation made a clear correlation between the exposure to Bt Cotton and these adverse health effects [copy of the report attached – Annexure 1].

   - Similarly there were also reports on mortality of sheep after grazing on Bt Cotton recently [copy of the Fact Finding Team's preliminary investigation report attached – Annexure 2]. While there have been no systematic investigations done in other places, there are informal reports however that livestock is being adversely impacted upon grazing on Bt Cotton fields from other places too.

   - While this is the case with cotton, the consequences with a food crop, that too a vegetable crop which will be consumed quite directly, are unimaginable. Never before in the world has the Bt toxin been introduced into a vegetable crop, where the toxin would be consumed in large quantities and without much processing. We are annexing several scientific papers which point out that Cry1Ac gene – Annexure 3, the Bt gene being used in Bt Brinjal, has many established adverse health impacts. These published, peer reviewed papers by scientists demonstrate that recombinant Cry1Ac protoxin is a powerful immunogen (able to produce an immune response), and when fed to mice, induced antibody responses similar to those obtained with the cholera toxin. Research shows that Cry1Ac actively binds to the inner surface of the mouse small intestine. This contests the often-heard argument that Cry proteins don't affect mammals since they supposedly do not have receptors that bind the truncated toxin in the gut!

     The entire infamous episode of Starlink contamination [where Cry9C toxin was used] raises the question of whether other Bt toxins that were supposedly screened might nevertheless be allergens. Scientists accept that without a better understanding of food allergenicity, this question cannot be adequately answered. There are serious limitations to current allergy testing procedures for GMO proteins. For example, recent results in Australia revealed that a protein previously consumed safely in beans had become immunogenic (similar to allergic reaction) when engineered into GMO peas. The immunogenicity of the GMO peas would not have been detected by currently used tests. Therefore, new allergy tests, and careful, long-term tests, are needed to assure the safety of Bt brinjal. Other possible risk issues, such as possible unintended harmful changes in the Bt brinjal plants, can also only be addressed by careful long-term and other testing. We cannot afford to make the mistake committed by Australian regulators who discovered the GM peas case only after almost irreversible field trials. We are annexing to this letter four such infamous accidents which proved to be disastrous for human health and environment – Annexure 4.

   - There are some nutritional and toxicological studies carried out on ingested plant GM DNA which provide information on the potential nature of the hazards of GM foods/feeds. These include: wasteful growth of gut tissues and bacterial proliferation, development of intestinal tumours, depression of the body's immune system, interference with the normal development of vital organs of the body (liver, kidneys, sexual organs, etc.) and

reproduction. The seriousness of these effects cannot be overemphasized because the harm will be the most pronounced in the young, the old and in people with intestinal disorders.

- The human clinical study carried out and published till date provides strong evidence of Horizontal Gene Transfer from food to humans. These studies showed that fragments of GM DNA were incorporated into the bacteria resident in the gut of human volunteers. Significant amounts of transgenic DNA is found to survive most commercial processing or in the gut of mammals, as per studies in various places.

2. The other genes introduced are toxic too:

Antibiotic resistance: In creating Bt Brinjal, NptII gene has been used as a selectable marker. NptII codes for *kanamycin resistance* and globally, there are serious concerns with antibiotic resistance marker genes for obvious reasons – when there is horizontal gene transfer to gut or soil bacteria, this could spread antibiotic resistance widely. Gene flow, especially to pathogenic organisms, related to antibiotic resistance has been established in past studies. This will imply that disease treatment would be more and more difficult.

The Bt Brinjal also has an aad marker gene. *Streptomycin resistant marker* according to EFSA this is a potentially dangerous marker to animals and human beings and should not be used in the case of GM plants used as food.

Transcriptional activity in human cells with CaMV 35 S: Similarly, use of the CaMV 35 S [cauliflower mosaic virus] promoter, used in creating Bt Brinjal is a matter of concern. Published research shows that the 35S promoter can initiate transcriptional activity in human cells, despite the promoter being a plant-specific one. A scientific paper attached throws further light on this – Annexure 5.

The cauliflower mosaic virus (CaMV), the viral promoter used in Bt Brinjal has similarities with the human hepatitis B virus. As all genomes of living species contain dormant viruses, there is a potential for the CaMV promoter to reactivate them raising concerns related to cancers.

One of the major omissions in present day GM risk analysis is that no attempt has so far been made to investigate the obvious link between GM food and intestinal tumour development. As Dr Arpad Puzstai points out, "full reproductive experiments are required in which the reproductive performance of both male and female rats fed on GM- versus non-GM diets should be monitored for several generations because any problems with reproduction could have disastrous consequences for the environment".

The problems encountered in the study of 'growth factor-like' effects on young rats, was attributed most likely, to the CaMv (cauliflower mosaic virus) viral promoter, a promoter put into Bt Brinjal too. Evidence suggests that the CaMv 35S promoter might be especially unstable and prone to horizontal gene transfer and recombination with all the attendant hazards: gene mutation, cancer, re-activation of dormant viruses and generation of new viruses.

Hazards from GM crops released into the environment may spread more readily through Horizontal Gene Transfer because GM constructs are specifically designed to cross the interspecies barrier.

3. Past history with corporate research shows suppression of important information: Monsanto, which is supplying the technology to Mahyco and others in the case of Bt Brinjal,

is known from past experience to suppress facts that are unfavourable to the company and its potential markets. A secret study on Bt Maize showed significant harm caused to rats fed on the variety called MON 863. The study shows kidney abnormalities and unusually high levels of white blood cells. What is shocking was that the company then went ahead to conclude that these findings were irrelevant and should not be attributed to Bt Maize even though the rats fed on non-Bt Maize showed no such signs! Given such dubious history, how are the regulators relying on data produced only by the company?

The agronomic data unreliable and manipulated: Going through the Annual Report of the All India Coordinated Research Project – Vegetable Cultivation on ICAR-supervised Bt Brinjal multi-locational trials in 2005-06, it is clear that the data presented is manipulated and unreliable. It is not clear why at least 3 out of the 11 Centres for trials did not report back. The data was not statistically analysed and wrong conclusions were drawn based on skewed averages. It is not clear how some centres could obtain such unbelievably high yields while most of the centres were below average. Is this going to be the situation in real life too for farmers? There is no data at all on pesticide use obtained through the trials though Bt Brinjal is developed ostensibly to reduce the use of pesticides. It is also clear that there were no trials taken up to compare with safer, cheaper, farmer-controlled alternatives like organic brinjal cultivation or NPM or IPM approaches. There was not even a comparison against IPM experience from all over the ICAR establishment from more than 10 years' of work.

There is a serious and objectionable conflict of interest in the fact that majority of the tests were undertaken by the company promoting Bt Brinjal [pollen flow studies, Cry1Ac protein expression, baseline susceptibility, protein estimation in cooked fruits, soil analysis, substantial equivalence studies etc. etc.]. Out of the various tests conducted, only four were conducted by public sector institutions, that too funded by the company. Where are independent studies to verify the claims of the company? **Where are studies especially from the Health Ministry to confirm the safety of the product?**

4. **The science of GM is imprecise:** It is well known that GE is based on imprecise science and is an unpredictable technology as there is little control on where the new genetic construct will lodge within one or more of the target cell chromosomes. It is also well known that tests are not conducted to assess the results from the variety of genes that are inserted along with the desired gene [the markers, promoters, terminators, metabolites etc. etc.]. Scientists do not understand the mechanisms of GE-induced changes in gene expression in sufficient detail. They do not know what to look for and these things are termed 'unintended effects'. It is for this reason that on a whole range of issues, a great deal of research is required before any outcomes can be predicted in a reasonably assured manner.

   Unlike in other countries, in a country like India where a majority of our livelihoods depend on agriculture, any irrevocable or irreversible change to our agriculture needs to be reasonably sure that the benefits being projected are drawn from sound, long term scientific testing and that risk assessment parameters are broad-based. Elsewhere, risk assessment of GMOs also asks a very pertinent question – "is it [introduction of a GMO] socially and ethically justifiable?". We are annexing a paper on such risk assessment – Annexure 6 so that the regulators might at least now pick up the appropriate framework for risk assessment given that millions of farmers in this country would be affected by your decisions. This kind of assessment is very important since there is very little awareness related to GM technology in farmers and consumers. This requires that informed public debate takes place before any decisions taken.

5. **The tests done here are not adequate – Are we even asking the right questions?** A Public Interest Litigation [PIL] on the lack of rigorous biosafety testing for GMOs in India

points out that the current biosafety regime is woefully inadequate in India. A copy of the PIL petition is attached in the form of a booklet – Annexure 7 for ready reference. Often, we do not even have the right questions to ask when testing for safety of GMOs. As pointed out earlier, elsewhere, biosafety regime is inclusive of such pertinent questions as "is this socially and ethically justifiable?". This requires the testing to be done against other known safer alternatives including ecological/sustainable agriculture practices. However, this was not done in the case of Bt Brinjal. Another paper – Annexure 8 by Dr Pushpa Bhargava way back in 2002 outlines what the biosafety regime should constitute. Going by the set of studies that the company has been asked to do by the regulators, it is obvious that feedback has not been picked up and lessons not learnt. An annexure provides specific feedback on the biosafety claims on Bt Brinjal – Annexure 9.

6. **There is no justifiable reason whatsoever for experimenting on and introducing Bt Brinjal [and GM crops in general]:** The GEAC or the DBT [Department of Biotechnology] has no good reason and justification to promote a GM Brinjal in this country. Pest management on Brinjal is being successfully practiced by numerous IPM, NPM and organic farmers with non-chemical, non-GE approaches with very satisfactory results all over the country. Within the ICAR establishment, numerous research projects, including on farmers' fields, show that there are very good, inexpensive and absolutely safe results following non-chemical IPM methods in particular and IPM methods in general. Given such vast experience, why is there no political will to put the control over the technology in farmers' hands? We are attaching to this letter a collection of such experiences – Annexure 10 which should provide a way forward for our thinking. We are once again reiterating that for the pest management paradigm to shift in this country, what is needed is political will and not GE-like solutions. We all know that pesticide use in fact has very little to do with pest/disease incidence any more and it has suited the pesticide industry and the regulators/agriculture scientists very well to encourage such a situation so far. To get out of this, we don't need a technology-fix but an alternative paradigm of pest management which empowers the farmers to understand their farm ecology and depend on local resources and sustainable practices for pest management.

   More importantly, there is no crisis with Brinjal production. In fact, due to overproduction, farmers do not get adequate market price.

7. **Potential environmental hazards with Bt Brinjal:**

Existing evidence on environmental hazards with GM crops is enough for a precautionary principle to be invoked regarding their regulation. For instance, it was found in studies that GM crops grown in the UK were not only harmful to beneficial insects like ladybirds but could also indirectly harm other and higher life forms, including mammals, domesticated or wild animals/birds and ultimately man, both in the short- and long-term.

India is a Center of Origin and diversity for Brinjal: Our pool of genetic reserves would inevitably be contaminated and this is extremely dangerous given that we are a Centre of Origin and diversity for Brinjal. We have grown Brinjal for the past 4000 years in this country and it is an extremely popular and widely consumed vegetable. Needless to say, horizontal gene transfer from Bt Brinjal into wild, related species of brinjal has serious implications for the very future of Brinjal research and cultivation in the country. The genetic diversity is important because some of the strains will be naturally resistant to lethal pathogens and pests that may destroy the crops in the future. Once lost, this lack of diversity can lead to the complete loss of the crop. Several published experiments with Bt in rapeseed and sunflower have provided preliminary data that Bt genes can indeed give some wild plants a competitive advantage. If the gene spreads in wild relatives of brinjal, its escape into the environment will be permanent. The toxin produced by the gene may then kill insects that feed on the wild plants. India is a haven of butterflies and the

Cry1 Ac gene targets lepidopterans including these butterflies and moths. These insects, in turn provide food for other organisms such as birds and mammals, which may then suffer harm. For these reasons, it is important to determine the possible harmful effects of the Cry1Ac gene in sexually compatible wild relatives and their ecosystems.

The Cartagena Protocol on Biosafety, the only international law to specifically regulate genetic engineering and GMOs (largely focused on transboundary movement, but whose scope also applies to the use of all GMOs), recognises the importance of centres of origin and diversity, and requires this to be taken into account during the risk assessment. How has this principle been applied in the case of Bt Brinjal in India?

In the case of pollen flow, it is well known that there is ample opportunity for cross pollination in the case of Brinjal. It has been reported that the extent of natural outcrossing is from 2 to 48% in the case of India. Further, it is not clear whether there is enough data on the wild and weedy plants that are either close relatives or have some degree of cross-compatibility with these brinjal varieties. No tests have been done to check for cross-pollination with such relatives.

Further, farmers from various parts of the country are reporting a decline in their soil productivity after growing Bt Cotton. While the regulatory tests related to Bt toxin presence and persistence in the case of Bt Cotton showed that the half-life of Cry1Ac protein in plant tissue was calculated at 41 days [which could then persist in the soil as other studies from elsewhere show], it is not clear how in the case of Bt Brinjal it is non-detectable in soil samples tested. Worldwide, it is generally accepted that Bt toxin does alter the soil micro-biology and that more studies are needed to understand the impact of Bt toxin on soil ecology.

It is not clear if the regulators studied the impact of Bt Brinjal on ecologically sensitive areas like the Eastern and Western Ghats and considered how they would prevent the entry of Bt Brinjal into such ecologically sensitive areas.

We should also consider a scenario where our predominant pest management strategy relies more and more on one gene -- the Bt toxin gene, across crops for a range of pests. Such a monoculture of the gene across crops and varieties is bound to spell doom sooner or later.

Resistance is already predicted in the target pest and resistance management strategy suggested is a 5% refuge. However, Bt Cotton experience shows that farmers do not follow these resistance management strategies. How will this be done in the case of Bt Brinjal? If there are several GM crops grown together, the resistance build up will be faster.

8. **Consumer choices and rights:** Transgenic contamination (contamination of the natural environment by GMOs) by more than one method, including wind blown and by cross-pollination is an established fact, beyond dispute and there can be no co-existence between GM and non-GM crops. Segregation even at the physical level is impossible in India. What happens to consumer choices and rights in such a case? Where would be the consumer's right to choose in the case of vegetables, even if we assume that segregation upto an extent is possible and labelling could be made mandatory? Indian vegetable purchases from supermarket shelves are minuscule and obviously, labelling is not going to be an answer here. How do we then provide non-GM brinjal to Indian consumers?

In conclusion, drawing from the experience with another hazardous technology like pesticides, it is obvious that biosafety and impact assessments are not carried out before irreversible release of the technology into the environment. Very often, experimentation is done at the expense of poor Indians including Indian children as scapegoats. Can India afford to make similar mistakes again?

Given all the above, we demand that:

1. Since the effects of this technology/modified organism are unknown and since these are potentially hazardous, the use of this technology and release of those organisms must wait until the hazards are properly understood and the effects known. **This requires the precautionary approach to be followed.**
2. **Biosafety testing should include testing for medium and long term effects** on the environment and human/animal health, in addition to asking questions on the justification of releasing the GMO into the open environment on social and ethical grounds. For this, the regulators as a beginning, should put together all the available data on safer alternatives, as any environment assessment should, like IPM, NPM, organic etc., and compare Bt Brinjal with such alternatives.
3. Proper biosafety tests should be taken up by **independent and scientifically competent bodies in a transparent manner**. Such tests should be allowed to take appropriate time needed to understand the medium and long term effects instead of being hastened in the pursuit of 'fast-track approvals'.
4. The results of such tests **should be made public** and data published in a manner that it can be closely examined by the scientific community. It shall also be **presented to all primary stakeholders [farmers and consumers]** in a manner that meaningful debates are possible, through for instance, mandatory public notice and public hearings etc.
5. Such reviews and debates should also look at issues beyond biosafety and delve into socio-cultural and political aspects related to GM agriculture, given that millions of our lives and livelihoods depend on agriculture here in India.
6. The GEAC, especially representatives from the Health Ministry, Environment Ministry and the Agriculture Ministry on the Committee, should take on board current scientific data [health and environmental] from elsewhere to understand the potential impact of GMOs and to ask the relevant questions in the Indian context. Based on such available data, they should lucidly justify why a precautionary principle cannot be invoked straightaway, instead of falling into the trap of the Department of Biotechnology which apparently has only one mandate of promoting GMOs.

In summary, we demand that the Health Ministry as one of the most important stakeholder-regulators of GMOs in this country play its rightful and expected role in protecting the health interests of Indians, to take a precautionary approach and reject the proposal to permit Bt Brinjal large scale trials in the country.

Sincerely,

Sd/- Members of Coalition for GM-Free India

Annexure 9:

Specific feedback to the company's claims on its findings through Bt Brinjal tests and trials:

It is utterly meaningless to comment on the company's claims that Bt Brinjal is safe and profitable apparently based on their studies and trials with Bt Brinjal. This is because no protocols are described for the tests nor any numbers or tables presented. However, from whatever's put up on the MoEF's website,:

1 The tests related to allergenecity and toxicity prescribed as part of biosafety testing are obviously inadequate as the experience with Bt Cotton in India shows. Despite being cleared as safe, Bt Cotton is reported to be causing widespread allergies in cotton growing belts of the country. Therefore, the protocols for such tests need to be re-looked at to capture the real adverse potential and such revised and better protocols applied for Bt Brinjal testing, especially given that it is a food crop with the toxin consumed in large quantities with no or very little processing.

2 Feeding tests done on goats do not capture the potential hazards as goats are known to be hardy animals, compared to sheep for instance. The protocol used in the case of Bt Cotton was to feed goats with cotton seed and the results apparently showed that there is no difference between feeding the goats with Bt Cotton seed and non-Bt Cotton seed. There were no multi-generational feeding tests done. What was not clear however was what the exact research protocol was - how old was the cotton seed, for instance? It is now clear that the tests did not capture the reality of farmers grazing their animals on Bt Cotton plants and not seeds. They also do not in any way predict what could happen with sheep. In the case of Bt Brinjal, there was no change in the testing regime from the Bt Cotton testing regime, despite such valuable lessons emerging from the field and despite this being a vegetable!

3 It is not enough to understand the effect of the Bt gene alone while understanding the impacts on human health and environment. It is important to capture the effects of the other genes transferred too. For this, a set of tests have to be evolved and undertaken.

4 It is surprising that the company says that the Bt toxin rapidly degrades in the soil. Published literature shows that this is not the case. There are many studies that show that Bt toxin can persist in the soil and retain its insecticidal activity. It is in any case known that the half life period of Cry1Ac toxin in plant tissue in the case of Bt Cotton is around 41 days. In such a case, why are the studies done by the company showing that the protein presence was non-detectable? At what stage of the crop was the test done?

5 What is the implication of growing Bt Brinjal in terms of the next crop, given the potential impacts on soil?

6 It is also surprising that pollen flow studies were done for just one year in two locations. Other information from India on pollen flow in Brinjal has results that should make any regulator sit up and take a cautious approach. The protocols used for devising Minimum Standards for Seed Production and Certification should be used here, since they have the worst case scenario built into the framework.

7 Such pollen flow studies should begin by listing out the wild species and related [compatible] species available in India in various regions of brinjal cultivation and check the effect of Bt Brinjal growth on such species, in a controlled environment [and not in farmers' fields]. Where is the data on associated biodiversity [like insects, birds, animals, microbes etc.] which depend on brinjal and its related crops [both wild, related and cultivated] and where are the impact studies on such associated biodiversity?

8 No detailed molecular characterization has been provided by the company. This is important, since we now know that developers cannot control where the transgene insert lands and that DNA rearrangements occur, with the potential to affect the spatial and temporal expression patterns of nearby genes.

9 Bt protoxins differ immunologically from the truncated proteins used for testing purposes. There is evidence that the toxic portion of Cry1A proteins can have a different 3-D conformation depending on whether it is part of the protoxin or in its free state. DNA structurally associated with the protoxin is released during the proteolysis process that generates the toxic fragment from the protoxin. If safety testing was performed on truncated versions of bacterial surrogate proteins rather than the full-length plant-produced Bt proteins that people are actually exposed to, such testing is absolutely inadequate. It has been found often that biosafety testing does not take into account such a difference and it is not clear how the tests were conducted here.

10 It is obvious that investigations have not been carried out to check whether the bacteria in the GM agro-ecosystems have 'picked up' DNA sequence fractions of kanamycin resistance reporter genes or streptomycin-resistance reporter genes.

11 What do the "isolated instances of necropsy" findings in all treatments indicate and what is the company's explanation, in the case of Sub-Chronic Oral Toxicity studies in rats? How many such instances in Bt-treated rats and how many in non-Bt treated?

12 Where is the data on how the Bt Brinjal affects children?

13 Where is the data on the cultural diversity that exists with regard to the cooking of brinjal in this country? Brinjal is also used for medicinal purposes in India. What impact would Bt Brinjal have on such use? Where is data related to socio-cultural importance of Brinjal in different communities in India and the possible impact of Bt Brinjal on the same?

14 Where is data on quantified protein expression related to pest incidence in the complete growing season of the crop? Given that the expression of the toxin is highest in the fruit, the consumed part, what implications does this have for human health for particular hybrids?

15 Deeper investigations into what the farmers have observed during field trials of Bt Brinjal – of color change in the fruits as the day passes – have to be taken up.

16 There is no data that shows that pesticide use does come down with Bt Brinjal – by how much? How does it compare with NPM and organic practices?

FINALLY, WHERE ARE INDEPENDENT RESEARCH PROJECTS BY THE REGULATORS THEMSELVES TO OBJECTIVELY TEST FOR RESULTS ON EACH OF THE ABOVE ISSUES?

GREENPEACE

To
Shri, Sharad Pawar,
Minister of Agriculture,
Krishi Bhawan
New Delhi

June 13, 2006

Greenpeace has been researching and documenting the potential hazards associated with Genetic Engineering (GE) of our crops for over a decade now. Internationally there is a raging controversy as to whether GE crops are viable, sustainable and more importantly safe for the environment, the health of animals and humans.

Our current concern stems from the fact that GE alters the natural evolutionary process and creates new plants and animals through techniques that involve highly complicated manipulations of genetic material and other biologically important chemicals. Genetic engineering gives rise to unexpected and unpredictable effects rendering any risk assessment unsound and irrelevant. GE is a crude and un-precise method that can create unexpected effects regardless on the source of gene introduced or type of gene that is introduced.

GE cotton has been in our fields for the last 4 years; it was approved after the company and the government claimed that all safety tests had been done. Two months ago a report by the Centre for Sustainable Agriculture (CSA) documented a grave incident where around 1600 sheep had died after grazing on GE cotton fields in Warangal district of Andhra Pradesh. The NGO makes a strong case for GE cotton being the cause of death.

We draw your attention to the FAO/WHO codex guidelines on the assessment of the GE food safety, which advises a need to consider unpredicted changes as result of genetic engineering (FAO/WHO, 2003)[1]. It is for the government to investigate the matter and arrest all further genetic crop experiments both in the lab and in open fields.

While cause for sheep dying remain unresolved, we believe that GM crops must be viewed with caution and the health of the nation must be put before corporate profit. In the 67th meeting of the Genetic Engineering Approval Committee (GEAC) held on 22nd May 2006, which has representation from your Ministry, the committee had heard a presentation by M/s Mahyco on the results of the biosafety studies conducted in respect of Bt Brinjal Cry 1 Ac.

From the minutes of the GEAC's meetings, we come to know that brinjal with the same Bt gene whose safety is presently under question, is now being considered for large scale field trials by the GEAC, paving the way for India's first food crop that could be eaten by millions across the country.

[1] FAO/WHO 2003. Codex Alimentarius Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants CAC/GL 45-2003 ftp://ftp.fao.org/es/esn/food/gurde_plants_en.pdfFAO/WHO 2002.

It is a known fact that large-scale field trials practically lead to uncontrolled release of GMOs in the environment. We must also keep in mind the consistent regulatory failure in the past and India's dubious record in handling Bt cotton where it was impossible to control the flow of unauthorized seeds. You will agree that given the ground realities in our country any approval of a large-scale field trial is a potentially dangerous act because it acts as a tacit approval equivalent to a commercial approval and therefore must not be allowed.

We have also learnt that the GEAC, in response to the complaints by the CSA on the 1st of June 2006, rather than commissioning a study with experts on bio safety studies, preferred to rely on the study done by the state agricultural department, which lacks the expertise to study a biosafety disaster of this scale.

We are very concerned by the casual attitude of the approval committee and the various ministries to this GE time bomb at a time when a decision to approve large scale field trials of Bt brinjal is scheduled. The decisions taken now will impact the health and lives of every citizen of the country, our cattle and the environment that nurtures us and therefore we urge you to proceed with caution.

It is in this context that we demand the agricultural ministry:

(1) Commission an investigation on the sheep mortality in Warangal, Andhra Pradesh and make public the terms of reference of the investigation.
(2) Assess the health impacts of GE crops by conducting an exhaustive long term health impact study on the various crops for both food and feed.
(3) In the interim stop all field trial permissions for all new genetically modified organisms (GMOs) – starting with Bt brinjal.
(4) Withdraw permissions for commercial releases of all existing GE crops.

We sincerely hope that you would ensure justice to the cattle and people of India.

Yours sincerely,

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UNPREDICTABLE; IRREVERSABLE; UNNATURAL

The story of Genetically Engineered Foods

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Genetic engineering (GE) refers to a set of technologies that are being used to change the genetic makeup of cells of plants and animals to bring about a desired commercial function e.g. insect resistant plants, herbicide tolerant plants, increased protein content in vegetables etc. For the first time humans have decided to alter the natural evolutionary process and create new plants and animals through techniques that involve highly complicated manipulations of genetic material and other biologically important chemicals.

UNPREDICTABLE
Genetic engineering can have unpredictable effects because the process is imprecise and random. Inserted genes may disrupt natural genes, be unstable in their new environment, or function differently than expected. There are two ways in which genetic engineering may affect food safety: Gene disruption or instability may lead to new toxins being produced; and the new protein produced by the foreign gene may cause allergies or toxicity.

IRREVERSABLE
Releasing GE organisms into the environment poses special threats to the environment and the food chain. GE crops are living and have the ability to reproduce and multiply. Through crosspollination, the foreign genes they contain can be transferred to other crops and wild species. Genetic contamination can, therefore, magnify over time. GE seeds can also be spilt, mixed with non-GE seed and grown illegally, compounding the problems.

UNNATURAL
Cow genes in Wheat[1] and Spider genes in potato[2] are just some examples of genetically engineered organisms that are being created by scientists in laboratories. Transferring genes across the species barrier doesn't occur in nature. Through genetic engineering scientists have embarked on a journey to alter the evolutionary process. The impacts of this are unknown.

This document takes you through some of the incidents that have been described as accidents and the impact to our food and health in the dangerous world where food is genetically engineered.

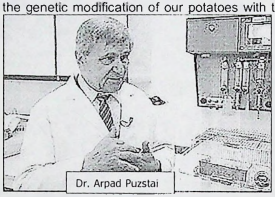
Critical health impacts caused by GMOs

There have been several cases of GM crop disasters in the past. This section takes us through the few cases that have battled corporate efforts to suppress facts and survived the day to reach the concerned citizen. In some of these cases, scientists owned up to the monumental disaster and eventually were ostracized by the proponents of the Genetic Engineering technology. In other cases, data was deliberately suppressed and the risks of the technology had to be forced open by environmental groups

[1] Scientists at the University of Nebraska (Lincoln, USA) have used cow genes in wheat to give wheat fungal (fusarium resistance).
[2] Ref: Scheller J, Henggeler D, Viviani A, Conrad U. 2004. Purification of spider silk-elastin from transgenic plants and application for human chondrocyte proliferation, Transgenic Research 13: 51-57.

Rats that suffered after feeding on GE potato

In 1995 Dr. Arpad Puzstai started a publicly funded major scientific investigation (by the then Scottish Office Agriculture, Environment and Fisheries Department, SOAEFD) into the possible environmental and health hazards of GM potatoes. British GE scientists were using a gene taken from snowdrop bulbs had transformed the potatoes. The gene of this sugar-recognizing protein (GNA) has been known to give natural protection against insect pests. It had also shown in extensive and appropriate nutritional studies carried out by our research group at the Rowett Research Institute in Aberdeen before the genetic modification of our potatoes with the GNA gene that animals ingesting this protein as part of their diet even at an 800-fold excess of that present in GM potatoes, suffered no significant harmful consequences. Therefore it was expected for it to be safe for animal and, later after appropriate testing, possibly for human consumers.[3]


Dr. Arpad Puzstai

Unfortunately, the studies revealed that the two lines of field-grown GM potatoes, which originated from the same transformation and were both resistant to aphid pests were not substantially equivalent in composition to parent line potatoes, nor to each other. Even more importantly, we showed from the results of four rat feeding studies of different designs and durations (10 to 110 days) that diets containing GM potatoes in comparison with iso-proteinic and iso-energetic non-GM parent potato diets had in some instances interfered with the growth of young rapidly growing rats, the normal development of some of their vital organs, induced changes gut structure and function and reduced their immune responsiveness to injurious antigens. In contrast, the animals fed on diets containing the parent, non-GM-potatoes or these potatoes supplemented with the gene product had no such effects.[4]

The controversy began in August 1998 when Dr Arpad Pusztai, 68, made a public statement about his fears, about the £1.6m study he conducted at the Rowett Research Institute (RRI).

Though the establishment ganged up against him, Dr. Pusztai's findings have never been disproved. This work has in fact clearly demonstrated that, in addition to possible toxicological studies, the safety of GM – food must be established in both short-term and long-term feeding, metabolic and immune-response studies with young animals as these should be the most appropriate to respond to and show up any nutritional and metabolic stresses affecting the normal development of young animals into healthy adults.

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[3] Source: Dr Arpad Pusztai; Submission of Health Impacts of GM Crops: Evidence to the Clerk to the Health and Community Care Committee of The Scottish Parliament)

[4] A Pusztai et al. (1999) Expression of the insecticidal bean alpha-amylase inhibitor transgene has minimal detrimental effect on the nutritional value of peas fed to rats at 30% of the diet. The Journal of Nutrition, 129, 1597-1603.
SWB Ewen an A Pusztai (1999) Effects of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. The Lancet, 354, 1353-1354.
A Pusztai (2002) Can science give us the tools for recognizing possible health risks of GM food? Nutrition and Health (2002) 16, 73-84
7. A Pusztai (2002) GM food safety: Scientific and institutional issues. Science as Culture, 11, 70-92.

Within 48 hours after his public statement he was suspended in disgrace and later forced to retire. The RRI said he had misinterpreted his results.

When Dr. Pusztai initially voiced his concerns about the health implications of genetically modified foods on ITV's *World In Action* on August 12th 1998, the biotech company, Monsanto, was quick to react in the press on 13th August 1998, asserting in The Times that "...these revelations are absolute dynamite", adding that "We have...food scares and doom-laden utterances without anyone looking at the facts."[5] The lobby group, Foodfuture, added that the scandal was due to "sloppy science and over-blown reporting..."[6]

Some opinions of other independent scientists on Dr Puzstai's study:

A group of scientists, drawn from 13 different countries, had re-examined his work and signed a joint memorandum[7] saying his conclusions were justified (1999). The group included toxicologists, genetic engineers and medical experts. "We found that his data is sound", said their spokesman, Dr Vyvyan Howard, a toxipathologist at Liverpool University,

Dr. Putzai's revelations have been backed by an independent analysis by consultant pathologist Dr Stanley Ewen, of Aberdeen University, who examined the preserved rats' organs. But a leading expert said: 'These were measurable changes in the rats fed modified potato - and we feel there's been a cover-up. There should be more openness in the whole business about public money and how it being used in this field.'[8]

Mice that suffered from inflammation of the lungs after feeding on GE peas[9]

After a decade of research, a field trial of genetically engineered (GE) peas was stopped in Australia because a study[10] found serious health impacts in mice that were given the GE peas to eat. The GE peas contained a gene from a bean to make the peas resistant to damage by the pea weevil.

The gene inserted into the GE peas was designed to produce an alpha-amylase inhibitor, a protein that prevents the digestion enzymes of insects from working. This causes the plant to be toxic to them when eaten.

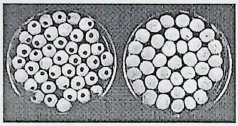
Small changes in protein structure can cause big changes in allergenicity.

Although the chemistry of the protein produced in the GE pea was almost exactly the same as that produced naturally in the bean, the structure of the protein was

[5] The Scotsman, 13th August 1998.
[6] The Guardian, 13th August 1998.
[7] Fears erupt over Genetic food, 12th February 1999, BBC.
[8] The UK Mail, dated 31 Jan 1999.

[9] CSIRO Plant Industry, 2005; Effective risk assessment of GM field peas
[10] Vanessa E. Prescott, Peter M. Campbell, Andrew Moore, Joerg Mattes, Marc E. Rothenberg, Paul S. Foster, T. J. V. Higgins, and Simon P. Hogan JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY Volume 53, Issue 23 (November 16, 2005) pages 9023 - 9030

unexpectedly changed in the GE plant. Small changes in the 3D protein structure can affect their potential to cause allergies. In this case, the researchers found that the GE peas caused allergenic reactions in mice.



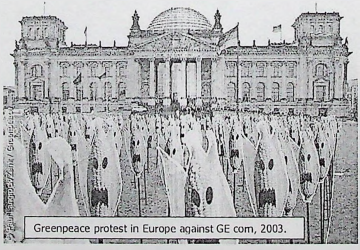
The CSIRO-developed GM field peas (right)

When they inhaled the GE pea protein it caused inflammation of the lungs and when they ate the GE peas they became more sensitive to other food allergies. These effects were not observed with beans that naturally produce this protein.

In the case of this study, the toxic effects were seen within the four weeks of the experiment. Had the toxic effects developed over a long-term period, they may not have been detected by the study. This demonstrates why it is so important that GE crops are properly tested and are not released into the environment.

Rats that suffered after being fed GE corn

On 23 April 2004, *Le Monde* reported that the French expert body in charge of GMO evaluation (CGB, Commission du Génie Biomoléculaire) had expressed doubts about the safety of GM maize MON863. Results of a rat feeding study that Monsanto delivered to EU authorities showed significant variations between rats fed conventional maize and those fed with MON863. The variations included an increased number of white blood cells in the males, reduced immature red blood cells in females, a significant increase in blood sugar in the females and a higher frequency of physical irregularities in the kidneys of the males, such as reduced weight and inflammation.



Greenpeace protest in Europe against GE corn, 2003.

Monsanto requested that documents concerning the risk assessment, like rat feeding trial results, should be classified as "confidential business information".

According to European law, the public has a right to full access to information concerning the risk assessment of GMOs. In particular Article 25 of Directive 2001/18/EC indicates that "in no case" should the information related to "environmental risk assessment" (defined as "the evaluation of risks to human health and the environment, whether direct or indirect") be kept confidential.

The Directive also indicates that the risk assessment should "be carried out in a scientifically sound and transparent manner based on available scientific and technical data".

Greenpeace had been pursuing this since April 2004, and it took us more than a year to see the interests of society at large would prevail to have access to "confidential business information" over Monsanto's economic interests and its policy of opacity and secrecy.

The chronology of the campaign is as follows:

· On 5 May 2004, Greenpeace wrote to the German agriculture ministry, which was in charge of the initial risk assessment report, to request access to the full documents concerning Mon 863.

· On 4 August 2004, the German agriculture ministry replied that the applicant, Monsanto, had refused to agree to publish the initial rat study MSL-18175, which had been classified as "confidential business information". · On 21 March 2005, the German authority decided to give access to the full document, because Monsanto could not show that its request for confidentiality was backed by EU or national law.

· On 27 April 2005, Monsanto filed an appeal against the decision of German government and, in addition, took out an injunction to stop the authorities publishing the data.

· On 9 June 2005, the German court decided to reject Monsanto's request; the data could not be seen as confidential, the right of society to transparency had to be given more weight than Monsanto's economic interests. The company appealed the decision.

· On 20 June 2005, the court rejected the appeal, and ruled that the documents be made public.

GE Corn (Starlink) – a potential allergen to humans enters the food chain

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 was a type of insect resistant GE corn grown in the USA from 1998, which produced the *Bt* protein, Cry9C. It was only approved for animal feed and industrial purposes, as there were concerns that the Cry9C protein could cause allergies because it shares characteristics of other allergens.

However, in September 2000, StarLink was found in corn taco shells and other foods, and over 300 corn products had to be withdrawn from the market. Traces of StarLink corn were also found in corn-based foods in Japan and Korea. It is not known how StarLink came to be in the human food chain - it may have been inadvertently mixed with other corn at a mill, a conventional crop may have cross-pollinated with a StarLink crop, or a farmer may have sold StarLink corn for human food to get a higher price.

While StarLink is not being grown anywhere in the world at the moment, it may have contaminated other corn seed and remain in the food chain. The episode raises questions about the ability of regulatory authorities to control GE crops.

Industry observers estimate that the entire cost of the scandal has exceeded US $1 billion. Neil E. Harl, a professor of economics at Iowa State University, estimates that the company has already paid out more than $500 million to farmers, food processors and grain handlers[11]. At least 300 food products in the US had to be recalled, at an undisclosed cost to the food manufacturers. There were also recalls in Canada and Japan. US corn farmers lost huge markets all around the world. US government officials estimated that it might take four years to get StarLink out of the US food and seed supply. Now, three years after the scandal, approximately 1% of samples sent to USDA testing labs are still found to contain StarLink[12].

Some of the costs of the contamination scandal can be detailed:

- Aventis paid at least $100 million to buy back the 2000 crop.[13]
- The United States Department of Agriculture spent $20 million to buy seeds from small companies whose seed stock was contaminated.[14]
- Kraft lost an estimated $10 million in lost sales from its taco shells alone.[15] Taco Bell franchises were awarded $60 million by all the taco shell manufacturers: Kraft, Azteca Foods and Mission Foods.[16]
- Aventis, Garst and four food companies (Kraft, Kellogg, Azteca Foods and Mission Foods) settled a class action consumer lawsuit for $9 million to customers who said they suffered allergic reactions[17].
- Aventis and Garst settled a class action lawsuit by farmers seeking compensation for lost markets. The lawsuit sought damages as well as a requirement for Aventis to decontaminate all soil, farming equipment, etc. to prevent further contamination. The firms will pay $110 million; farmers are likely to receive only US$1 per acre.[18]

Unintended effects of Genetically Modified Organisms (GMOs):

There are numerous cases of documented unexplainable effects of GMOs. Here are a few examples:

- Researchers at Monsanto who were trying to increase the content of carotenoids (a chemical which is used to form vitamin A) in oilseed rape (canola) found that vitamin E and chlorophyll levels in the seeds were dramatically and inexplicably reduced[19].

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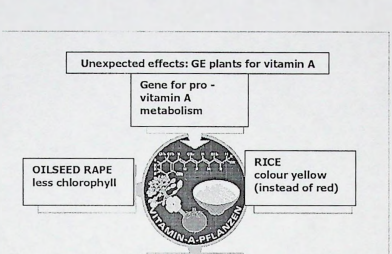
[11] Jacobs, P. 2003. Traces of contaminated grain still showing up in corn supply. 30 November. San Jose Mercury News.
[12] Ibid
[13] Reuters. 2000. Aventis sale of bio-crop unit could hurt farmers. 27 November
[14] Schuff, S. 2001. Major seed companies say they have StarLink isolated. 12 March. Feedstuffs.
[15] Madigan, K. 2003. Risky business. Los Angeles, CA: State Public Interest Research Groups, As You Sow Foundation
[16] Cohen, D. 2001. Taco Bell franchisees to get $60 million. 8 June. Reuters.
[17] Carroll, J. 2002. Judge will approve a settlement on use of StarLink corn products. 7 March. Wall Street Journal (New York)
[18] No author. 2003. Aventis settles StarLink lawsuit. 12 February. Chemical Week.

[19] Shewmaker, C.K., Sheehy, J.A., Daley, M., Colburn, S. & Yang Ke, D. (1999) Seed-specific over expression of phytoene synthase: increase in cartenoids and other metabolic effects. The Plant Journal, 20, 401-412.



- The colour of the infamous "Golden" rice is an unexpected effect of GE. The GE construct originally contained three genes. The first two genes produce lycopene (red pigment in tomatoes) while the final gene transforms the lycopene to beta-carotene (yellow pro-vitamin A).

  Rice kernels from plants with only the first two genes were expected to turn out red because of the lycopene, but they were yellow. The reason behind the colour of rice turning out yellow and not red with just the first two genes is not understood. Scientists involved in the study have been unable to explain how the rice turns yellow with only two genes.[20]

- Monsanto's GE Roundup Ready soybeans have suffered unexpected crop losses in hot, dry weather due to stem splitting caused, most probably, by increased lignin[21]. The soybeans' phytoestrogen levels are also 12-14 % less than in conventional soybeans, which may mean that soy-based products derived from Roundup Ready soybeans would be less useful as sources of phytoestrogens.

[20] Beyer P. et al. 2002, Golden rice: introducing the B-carotene biosynthesis pathway into rice endosperm by genetic engineering to defeat vitamin A deficiency. American Society for Nutritional Sciences, 132: 506S-510S.
[21] Coghlan, A. (1999) Splitting headache – Monsanto's modified soybeans are cracking up in the heat. New Scientist, 20th November, p.25.

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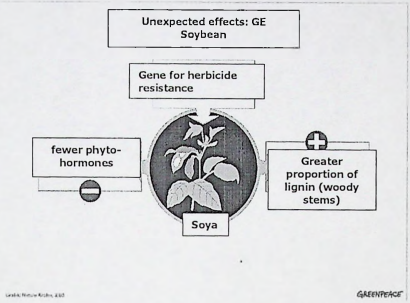

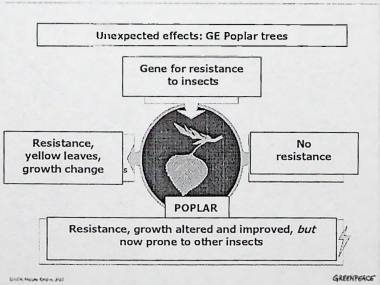

- Disconcerting effects have been observed with poplar trees: a field test which was started in 1996 produced female blossoms on a plant after only three years, whereas normally poplars start blossoming only at the age of eight years. This early

blossoming could increase the rate of unintended spread of the GE trait into the population.[22]

- In China, poplar trees were engineered for insect resistance. The trees did express the desired effects towards the pest insects in field trials. However, just two years later, new and unexpected sensitivities towards other insects occurred.[23]

How 'risk assessment' fails to measure human health impacts

Risk assessment is often portrayed as a relatively straightforward process – simply identify all possible hazards, calculate the probability that they may arise, work out what the risk is, decide if it is acceptable and how to manage it. It sounds very scientific and impartial, but it is not. This protocol was initially conceived to deal with failures in machinery, when it is applied to GMOs it struggles with the complexity of the natural environment. Because it is this system that underlies the regulation of GMOs worldwide, protection of the environment and human health is being compromised.

The **'Precautionary Principle'** builds on a series of straightforward and well-established ideas that[24]

- Prevention is better than cure;
- The polluter should pay.
- We should look for 'no regrets' options.
- We should recognise the intrinsic value of non-human – as well as human – life.
- The complexity and variability of the real world limits the ability of scientific knowledge to predict.
- We must recognise the vulnerability of the natural environment.
- The rights of those who stand to be affected by an activity must be prioritized rather than those who stand to benefit from it.
- There must be scrutiny of all available alternatives and an examination of justifications and benefits as well as risks and costs.
- Long-term, holistic and inclusive perspectives are needed in environmental protection.
- Policy analysts have concluded that the Precautionary Principle is more scientific than conventional risk assessment.[25]

Therefore, a precautionary approach introduces a more scientifically rigorous analysis, with a broader scope and wider range of experts. Precaution is involved at all steps in decision making, in areas where action may lead to seriously harmful effects, from the practice of science and the research agenda, to regulation and governance. Because the threats of GE are so broad, and it's harmful impacts could be severe and irreversible, the precautionary principle must be strictly applied.

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[22] Fladung, M.; Nowitzki, O., Ebbinghaus, D., Schellhorn, A.; Bentien, G., Ahuja, M.R. & Muhs, H.J. 1999, Field release of ROLC-transgenic Aspen-Populus. Online: http://users.ox.ac.uk/~dops0022/conference/forest_biotech99_home.html, Poster 46, 3.12.1999.

[23] Ewald, D. & Han, Y. 1999, Freisetzungsversuche mit transgenen Pappeln in China. UBA-Fachgespräch „Freisetzung transgener Gehölze – Stand, Probleme, Perspektiven" 20. & 21. Sept., Humboldt-Universität zu Berlin.

[24] Stirling, A (1999) Science and precaution in the management of technological risk. Report for the European Commission – JRC Institute of Prospective Technological Studies, Seville. http://www.jrc.es/pub/EURdoc/eur19056len.pdf

[25] European Commission (2000), Communication on the Precautionary Principle, COM (2000)1, Brussels: European Commission

GREENPEACE Briefing

Genetic Engineering Briefing Pack
September 2002

The Precautionary Principle and GMOs: taking a scientific approach to risk

Genetically modified organisms (GMOs) are produced by transferring genes from one organism (usually an unrelated species) into another. The GMO may, for example, be a crop for food use, an animal to provide meat or a microorganism to degrade toxic waste. In these cases, the GE organism may be released into the environment where it can grow and multiply. Its foreign genes may transfer into related wild species or the GMO may behave unpredictably, become out of control and damage ecosystems. Any effects are likely to be irreversible. Our knowledge of how and when harm may arise is limited and surprises are likely.

When faced with such situations, how should decisions be made about whether and, if so, how to produce and use a GMO? One obvious approach is to apply the Precautionary Principle. This principle has been developed as a result of experiences with chemical and other forms of pollution with the intention of avoiding such harm arising in the future. The Precautionary Principle is intended to be a general rule in situations where there is the potential for serious or irreversible threats to health and the environment and requires action to be taken to avoid such threats even where definite proof of harm does not yet exist. It stops the lack of scientific certainty being used to delay preventive action[1,2,3]. From asbestos, PCBs and ozone depletion to mad cow disease, conventional risk assessments have failed and the lessons of waiting too long for proof of harm before taking action have shown that a rigorous precautionary approach is long overdue[4].

However, the Precautionary Principle is sometimes criticised as being unscientific, and stifling progress. This briefing reviews why precaution is so vital in relation to GMOs, how it demands a more rigorous approach to science and brings more democracy into decisions about whether or not to take risks and why it does not present a barrier to progress. Rather than a presumption that benefits for industry should take precedent, under a precautionary approach a voice is given to the environment, individuals and communities who stand to be affected if things go wrong.

GMOs: their potential to cause significant, irreversible harm

When organisms are genetically engineered, a package of genes is introduced which includes genes to switch on another 'gene of interest' (that makes a crop produce an insecticide or be tolerant to chemical weedkillers, for example) together with a gene to switch it off. A marker gene is also included because the GE process is very inefficient and only a small proportion of cells incorporate the foreign DNA. So a gene that gives an identifiable change, such as antibiotic resistance or florescence, is also included. All these genes may come from any species and bacterial and viral genes are commonly used.

The supporters of genetic engineering claim that the process is more precise than conventional breeding because it is known exactly what genes are added and, therefore, that their effects can be predicted. However, the GE process is not controllable and new

scientific research shows that gene function is much more complex than previously thought:

- **the position at which genes are inserted is random** – other genes may be disrupted and their function altered;
- **many copies may be integrated, additional fragments inserted, gene sequences rearranged and deleted**[5,6,7] – which may result in lack of operation of the genes, instability or interference with other gene function;
- **one gene does not code for only one function** – findings from studies such as the human genome project have shown that there are far fewer genes in higher organisms than was predicted – 30-40,000 in man rather than the 120-140,000 originally thought[8]. This means that genes or parts of genes may be involved in different functions, depending on how they are read and which other genes are involved. This undermines the assumption that adding a gene with one known function means that this is the only way it will behave in practice[9]. Indeed, the detailed functioning of DNA is not well understood. Scientific theories and understanding of the ways in which genes work is constantly developing, giving new insights on the complexity of gene function[10];
- **a package of genes is introduced for which there is no evolutionary precedent** – the introduced genes come from a mix of species which have never packaged together before. In a complex genome, how they will behave and interact over time is unknown.

The consequence of such complexity is that unpredictable effects are likely. Once released in the environment, it will not be possible to recall a living organism so any impacts are likely to be irreversible because organisms are self replicating. If the GMOs cross with related wild species, the genetic change may be incorporated in the natural gene pool and alter the path of evolution.

The kinds of impacts that may occur include:

- GE crops becoming more invasive, weedy and difficult to manage;
- wild plants acquiring the genes and so changing their characteristics and altering ecosystems. For example, if wild plants gain a gene to produce a protein toxic to a range of insects or other organisms, they may survive better than other plants;
- new toxins or allergens being produced as a result of interference with natural gene function or unexpected interactions between gene products;

There is evidence that things regularly DO go wrong with GMOs:

- Experiments to make potatoes resistant to insects using a lectin gene led to lowered levels of the plant's natural insect deterrent chemicals, glycoalkaloids. This was shown to be an unintended effect of the GE process itself, as the introduction of a different insect resistance gene had the same effect[11].

- Yeast which had been genetically engineered to improve alcohol fermentation unexpectedly had up to 30 times the concentration of methylglyoxal (a highly toxic compound) compared to the control non-GE strain[12].

- Researchers at Monsanto who were trying to increase the content of carotenoids (chemicals which are used to form vitamin A) in oilseed rape (canola) found that vitamin E and chlorophyll levels in the seeds were dramatically and inexplicably reduced[13].

- Other researchers trying to genetically engineer a carotenoid pathway in tomatoes found over-expression of a gene caused unexpected dwarfism in the plant[14].

- Monsanto's GE Roundup Ready soybeans have suffered unexpected crop losses in hot, dry weather due to stem splitting caused, most probably, by increased lignin[15]. The soybeans' phytoestrogen levels are also 12-14 % less than in conventional soybeans, which may mean that soy-based products derived from Roundup Ready soybeans would be less useful as sources of phytoestrogens which are thought to be beneficial in adult diets[16].

No independent monitoring takes place of the GE crops grown across the world so there

will be no early warnings of unexpected effects.

It is also becoming clear how unmanageable the risks of GE crops are. In Canada, volunteer oilseed rape weeds that are tolerant to three herbicides (Liberty, Roundup and Clearfield) were first identified in 1998, only 3 years after GE herbicide tolerant oilseed rape was first grown[17,18]. The problem has arisen because some seed is shed at harvest time, remains in the ground and germinates in future years. When the plants emerge in subsequent crops of a different species they are then unwanted weeds ('volunteers') which have to be removed by the farmer. This resistance to more than one herbicide is known as 'gene stacking' and arises through pollination of one herbicide tolerant variety by another. The emergence of super-weeds in Canada is driving up the use of other, more toxic chemicals. Both 2,4-D and paraquat (grammoxone) are being recommended by government agencies to control herbicide tolerant oilseed rape volunteers in Canada[19].

The unpredictable changes GE can cause, the difficulties there will be dealing with any problems and the potential for GMOs to multiply and grow mean that GMOs fall firmly within the scope of the precautionary principle. Conventional risk assessments, biased towards the interests of the biotechnology industry (see Box 1), are very unlikely to provide the degree of protection required.

How risk assessment fails the environment and human health

In a risk assessment of releasing a GMO to the environment, risk may be described by a seemingly simple equation:

Hazard x probability = risk

The hazard is the type of harm that might arise, a cancer or death of an animal, for example. The probability is how likely this is to happen, ranging from very low - such as one in a million, to high - such as one in ten. Probability, like hazard, is a complex issue covering a range of factors. For example, with gene flow from one plant species to another this includes how closely related the two species are, whether they flower at the same time, how far apart they grow, whether they are pollinated by insects or the wind and the prevailing weather. This is sometimes called 'exposure' in chemical risk assessment.

Risk assessment is often portrayed as a relatively straight forward process – simply identify all possible hazards, calculate the probability that they may arise, work out what the risk is, decide if it is acceptable and how to manage it. It sounds very scientific and impartial, but it's not. Initially conceived to deal with failures in machinery, it struggles with the complexity of the natural environment. Because it is this system that underlies the regulation of GMOs worldwide, protection of the environment and human health is being compromised.

There is now a well established critique of conventional risk assessment which has shown that the process is subject to scientific, social, political and economic judgements which tend not to be explicit[20]. These judgements are seen in:

- **which hazards are considered** – someone has to choose what to include and exclude. In the case of GMOs, the risk assessment focuses on the genetic change and generally excludes indirect effects and secondary impacts on organisms in the food web or implications for non-GE and organic farmers. It is this framing of the risk assessment that drives the outcome and reflects the interests of those designing the assessment;
- **calculating their probability** – there is always scientific uncertainty, and a choice has to be made. With GMOs it is unlikely that probability of an event happening can ever be calculated with any confidence as it covers a host of different environmental and ecological factors. It also depends on whether people follow the rules, which is often not the case;
- **what is an acceptable risk** – whether a potential impact is significant or not is a matter of social or even personal judgement – it depends on social, economic and cultural factors. Risk assessment conceals this and presents risk as something to be quantitatively measured by scientists and managed by experts to "acceptable" levels. The issue of genetic contamination of indigenous

maize varieties in Mexico will be viewed very differently by Mexicans, who bear the risk, and Americans whose corporations profit from GE maize;

- **dealing with ignorance and surprises** – when evidence is patchy or missing, deciding whether there may be a problem or not depends on informed prediction, using available information and drawing on lessons of the past in order to come to a reasoned but cautious decision. Risk assessment underestimates this problem, assuming that knowledge and understanding are sufficient to calculate risk, or will become sufficient in time if further research is commissioned.

The process is also constrained because only hazards that can be measured are commonly included in risk assessments. Long-term subtle changes in behaviour or fertility are not easily included. What might ultimately prove to be the most important changes may simply not be part of the assessment

Underlying the risk assessment of GE crops is an assumption that they form a positive development for agriculture[21]. Although rarely acknowledged in risk assessment, this bias shapes the way in which GMOs are evaluated. The odds are stacked in favour of the industry and against the environment and human health.

What does the Precautionary Principle mean in practice?

The Precautionary Principle was first used formally in German law in the mid-1970s. Since then it has been adopted as an approach to protection of environmental and human health in many other national, regional and international laws. The Cartagena Protocol on transboundary movements of GMOs is based on the Precautionary Principle and the principle has been endorsed by the European Commission. But what does it mean in practice? Too often, precaution translates into a conventional risk assessment as it has under the European Deliberate Release Directives[22] which leaves the pro-biotech bias in place (see Box 1).

The 'Precautionary Principle' builds on a series of straightforward and well-established ideas that[23,24]:

- '*prevention is better than cure*';
- '*the polluter should pay*';
- we should look for '*no regrets*' options;
- we should recognise the intrinsic value of non-human – as well as human – life.
- the *complexity* and *variability* of the real world limits the ability of scientific knowledge to predict;
- we must recognise the *vulnerability* of the natural environment;
- the *rights* of those who stand to be affected by an activity, must be prioritised rather than those who stand to benefit from it;
- there must be scrutiny of all available *alternatives* and an examination of *justifications* and *benefits* as well as risks and costs.
- *long-term, holistic and inclusive* perspectives are needed in environmental protection.

New techniques are being developed which allow these ideas to work in practice. Deliberative techniques, multi-criteria evaluation and other approaches provide new ways of conducting technology evaluation and must be brought into GMO assessments. Importantly, because a precautionary approach takes a much broader scope, it explicitly considers uncertainty and ignorance and evaluates alternatives. Policy analysts have concluded that the Precautionary Principle is more scientific than conventional risk assessment[25,23].

Precaution and GMOs: bringing science to the fore

Genetic engineering can change organisms in far reaching and unpredictable ways. Assessing their impacts and whether they are acceptable must take into account the complexity of ecosystems, scientific ignorance (the "unknown unknowns") and uncertainty. Conventional risk assessment denies the potential for surprises and narrows the scope of harm to be evaluated to a limited range of factors. It is often undertaken by a restricted group of specialists whose narrow expertise acts against a comprehensive approach. Whilst science is used in the assessment, the exclusion of wider criteria such as indirect impacts on agriculture and biodiversity and lack of attention to uncertainty is not scientifically justifiable.

A precautionary approach (see Box 2) does not stifle progress but can encourage innovation more widely by stimulating the search for alternatives and valuing diversity. In contrast, the demand for proof of harm before action is taken can lead to 'paralysis by analysis'[4], as old practices are defended to the bitter end.

Therefore, a precautionary approach introduces a more scientifically rigorous analysis, with a broader scope and wider range of experts. Precaution is involved at all steps in decision making in areas where action may lead to seriously harmful effects, from the practice of science and the research agenda, to regulation and governance. Because the threats of GE are so broad, and harmful impacts could be severe and irreversible, the precautionary principle must be strictly applied.

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Main Identity

From: "Jai Krishna" <jaikrishna.r@dialb.greenpeace.org>
To: <ravi@phmovement.org>
Sent: Thursday, June 29, 2006 6:53 PM
Attach: precautionay principle...GP stand.pdf; GM Accidents Report.pdf
Subject: FW: Genetically Modified foods

Dear Mr. Narayan,
This is Jai krishna from Greenpeace. I am writing this mail for divya, my colleague.

I hope you remember me- I was involved in the Kodaikanal- mercury pollution issue of the HLL.

I would be glad if you could give us some time tomorrow.

In tune with nature
greenjai

"You must be the change you wish to see."
- M.K.Gandhi

----Original Message-----
From: Divya Raghunandan [mailto:draghuna@dialb.greenpeace.org]
Sent: 29 July 2006 12:55
To: secretariat@phmovement.org; echatpun@vsnl.com; etddsf@vsnl.com; sumasaro@vsnl.com
Cc: Jai; Rajesh Krishnan
Subject: Genetically Modified foods

Dear Dr Ravi Narayan,Dr. Abhay Shukla,Dr. Amit Sen Gupta,Ms Sarojini,

Greenpeace has been campaigning against the use of Genetic Engineering in
agriculture and foods for over a decade. Our specific concerns with the technology and it's potential impact on the environment and the health of
all that consume GM foods or feed will hopefully be summarised in the 2 documents that you may find attached.

Our immediate concern stems from the fact that the Genetic Engineering Approval Committee(GEAC)housed within the Ministry of Environment and Forests is a week from deciding where GM brinjal with an insect resistant
gene from a soil bacteria(Bt)will be given permission for large scale field

Suggestions

i) Send links of Committee for some political mapping and strategy review

ii) Contact Naveen for NIAZ booklets plan and explain if GM Food issue is included. If not send suggestion and short paper for inclusion

iii) Follow up with Mure, Amb Satyagi, Anant, Chem Expert — AIDAN links and try to attend Hyderabad meeting

Head on with discussion with Jai and Divya on 30/6/06 12:30-1:30

NT - Please discuss

RN
30/6/06

3/JUL'06

- Discussed c Ravi. Sent to divya.

6/30/2006

trials(under 20 acre plots across the country). As shown in the case of Bt
Cotton GMOs in large scale field trials are impossible to contain. brinjal
is the first of a long list of
approvals.(http://www.greenpeace.org/india/press/reports/genetically-engineered-food-ho)

A number of recent lab reports with GM crops show unexpeced side effects on
lab animals (please see accidents report). Furthermore all over the world
risk assessment for GMOs is a huge challenge. At Greenpeace we believe that
the precautionay approach must be applied when the quantum or the nature of
the risk cannot be identified.

- On the 12th of July the GEAC will decide whether India is to have the first
GM food crop- Brinjal. By pressurising the GEAC to make public the biosafety
data and toxicological studies conducted by the company we have this data on
the GEAC website. The GEAc invites commentsfor all of us until the 7th of
July after which they will go on to decide the fate of GM brinjal.
http://www.envfor.nic.in/divisions/esurv/geac/brinjal_part-I.pdf

As eminent scientists, and medical professionals I do urge you collectively
and as individuals to review the data and raise any concerns that you see
fit.

- I would also request an appointment to meet with you either in Delhi or in
bangalore to see whether JSA would be able to put out a collective statement
by way of a press release or a submission to the health ministry on you
concerns of Genetically modified Food as the answer to the nations food and
health crisis.

Do look forward to hearing from your
Regards
Divya Raghunandan
Greenpeace
+91 9845535406

GMOs are Threatening Food Safety and The Environment

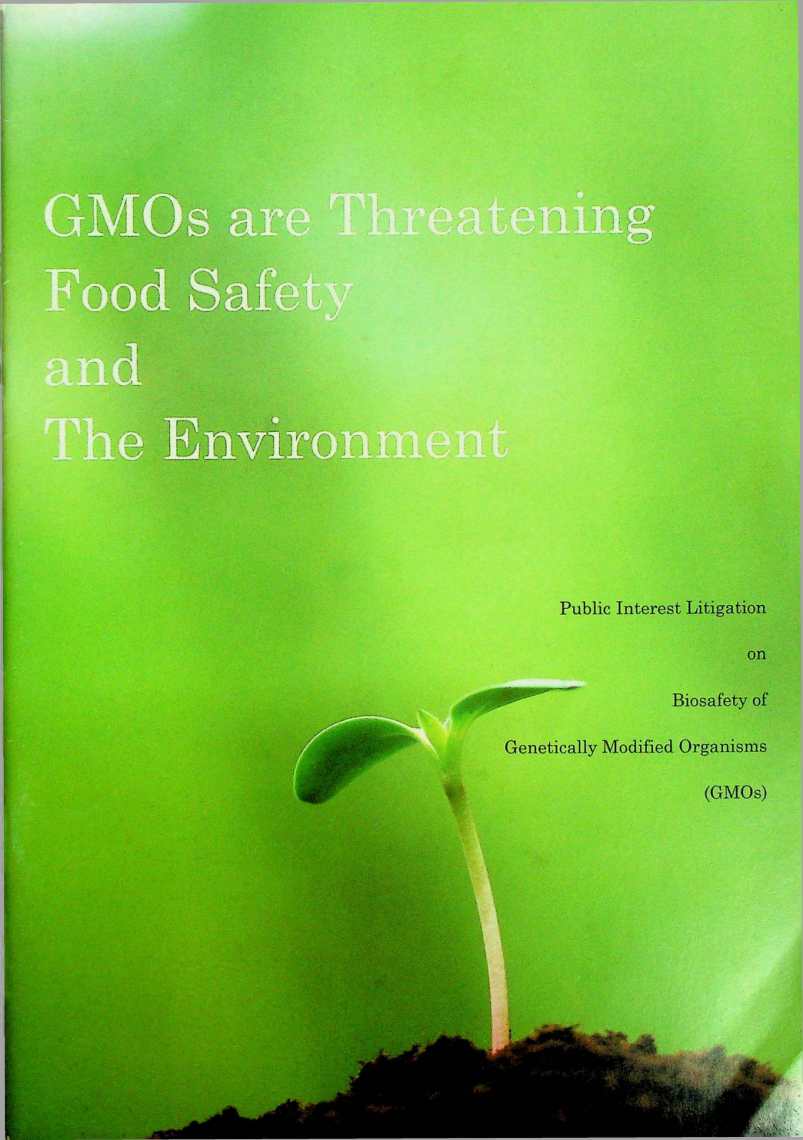
Public Interest Litigation

on

Biosafety of

Genetically Modified Organisms

(GMOs)



ecosystems around the world. It's estimated for every human being on Earth there are at least 2 hundred million insects. Maybe only one out of every thousand species of insects is a pest to human beings. It doesn't make sense to spray a chemical that kills all insects to get at the one or two that are a pest to human beings. The excitement and promise of science obliterated caution and duty and biologists, geneticists and ecologists did not say anything about their concerns over pesticides. Paul Muller won the Nobel Prize for medicine in 1948. But by the 1950s, bird watchers began to notice something funny was happening with birds. They were disappearing. Biologists went into a research huddle and discovered a phenomenon called **'biomagnification',** the ability of microorganisms to absorb DDT; they don't die, they concentrate it, and at each nutrition level of the food chains, it is concentrated. So when it gets to the fatty tissues of birds, or the breasts of women, the concentration of DDT is hundreds of thousands of times higher than the initial application of the chemical. So how could DDT have been managed when scientists didn't even know about 'biomagnification' until after the event? It also took 60 years to understand that DDT has oestrogenic effects. In terms of understanding the biology of species, Edward O. Wilson at Harvard (the leading authority on 9500 species of ants) says: *we probably know less than 0.1% of the species that exist.* We know perhaps a million and a half species out of may be 10 million (excluding the microbial world). 'Knowing' merely means that someone has given a species a name. That is all, no more than that.

So how can anyone say that GMOs are safe for the natural world, for the biodiversity? With GM history is being ominously repeated with all the mistakes of the last 75 years. However this time round, the stakes are enormous. We must get it right pretty well the first time, because genetic manipulations are essentially irreversible and because the contamination of the natural environment is a biological certainty. And, whatever we do to the earth we do to ourselves because what we eat, we make into our bodies.

With CFCs, the lesson was repeated. CFCs seemed to be a miracle of organic chemistry, because they were chemically inert. And so they began to be used in massive amounts. Only years later did scientists discover the disastrous effects of these ozone-depleting substances on climate change, because of the very reason that CFCs are chemically inert; and they don't break down. They hang around and accumulate; in the upper atmosphere, ultraviolet light breaks chlorine-free radicals off CFCs, and **chlorine is a potent scavenger of ozone.** Then scientists discovered that there is something called the **ozone layer** and announced, that CFCs were degrading the ozone layer. How could CFCs have been managed, when no one could have anticipated what the effect would be ultimately?

So how can anyone say that GMOs are safe for the natural world, for the biodiversity? With GM history is being ominously repeated with all the mistakes of the last 75 years. However this time round, the stakes are enormous. We must get it right pretty well the **first time,** because genetic manipulations are essentially irreversible and because the contamination of the natural environment is a biological certainty. And, whatever we do to the earth we do to ourselves because what we eat, we make into our bodies.

The Hazards of Genetic Engineering are Inherent in the Technology

Genetically modified organisms are unnatural, not just because they have been produced in the laboratory, but because they can only be made in the laboratory, creating organisms and in ways that have never existed in the course of **3.8 billion years** of evolution. This technology is so powerful, crude but powerful, but the scientific ignorance of it is huge. Scientists concede that they do not understand the mechanisms of GE-induced changes in gene expression in sufficient detail. They do not know what to look for and these things are termed 'unintended effects'. Unintended effects are common in all cases where GE techniques are used. So on a whole range of issues, a great deal of research is required before they can predict an outcome. Independent scientists from all over the world have gone on record to say that GE crops and foods raise outstanding safety concerns and there should be a global moratorium on the release of these GMOs into the environment.

One of the most insidious *'unintended'* effects of GE is **Horizontal Gene Transfer (HGT).** It happens when genetic material moves between organisms, which is asynchronous with the process of reproduction of the organisms; so genes can also be transferred between ***distant species*** that would never interbreed in nature. For example, human genes are transferred into rice and those from pig, sheep, fish and bacteria are transferred into plants. *Thereafter, unintended HGT can take place from GE crops released into the environment.* Can we even begin to imagine where this might lead? There is strong evidence for HGT even though there have been literally, just a handful of clinical trials. One of the major omissions in present day GM risk analysis is that no attempt has so far been made to investigate an obvious link between GM food and intestinal tumour development. The grave implications and risks of HGT, for the **whole stream of life**, don't require a Ph.D in science to be understood. They include: new strains of antibiotic resistant bacteria, new viruses and bacteria arising from those introduced into the transgenic plants, random secondary insertion into other unrelated organisms, causing harmful effects including cancer, reactivation of dormant viruses, etc. For these reasons, concerns with HGT make the technology of GE highly unpredictable and also extremely dangerous and put in doubt the safety of the GE process itself. Yet it is being used to irrevocably change the fundamental molecular structure of the world's food supply and impact the biodiversity through un-recallable, self-replicating organisms.

Yet it is being used to irrevocably change the fundamental molecular structure of the world's food supply and impact the biodiversity through un-recallable, self-replicating organisms.

There Has Been No Safety Testing Anywhere

The US has initiated and promoted the commercialisation and spread of GM crops since the 1990s, because of a White House directive to "*foster the biotechnology industry*". It is also a fact that in order to facilitate the release of GM foods onto the market in the US, they are provided GRAS status, (Generally Recognised As Safe), a process, which contrary to popular belief, **means that the FDA does not formally approve a single GE crop as safe for human consumption,** a neat 'sleight of hand' method to get GM foods on to the market! It is a reasonable assertion that if the US had not

cleared GM foods and crops for market release, then no other country would have done so. There have been 10 years of commercialisation of GM crops in the US and Canada. They are sold in both these countries in the face of increasing consumer resistance to them and a demand for labelling as the public is only now discovering that they have been hoodwinked into believing that GM food and animal feed are safe. It is surprising that GM food has become part of the diet of millions of Americans and Canadians without their being able to exercise a democratic right of informed consent about their food choices, nutrition and health.

We may no longer ignore the growing evidence of dodgy science and shaky ethics surrounding the GM debate.

We in India can learn from these 10 years of commercialisation in America. There is a huge body of evidence that has emerged from these countries, of serious safety concerns with GM crops, despite severe hindrances to such data coming into the public domain. Independent scientists have been discredited, gagged or fired; there is substandard and even fraudulent testing and industry 'confidentiality' is given priority by governments over safety and public health and in this India is equally culpable. We may no longer ignore the growing evidence of dodgy science and shaky ethics surrounding the GM debate. In India, the only clarity about the GEAC approvals for the commercial planting of Bt cotton (GM cotton) is their very opaqueness. Farmers have suffered huge losses with no recourse to compensation. There have been substantiated reports of farmer suicides directly linked to Bt cotton because they have been economically ruined. Yet, on the basis of the GEAC approvals for commercial planting of Bt cotton, our farming community must rightfully expect that the government is trustworthy and has thoroughly examined the technology from every viewpoint; that theirs are not the 'killing fields' of experimentation. Unfortunately that trust has been betrayed. There are more illegal varieties of Bt cotton than legal with little sustained effort to stop them. This suggests that an official Nelson's eye is being turned to the issue of GM contamination. This is particularly worrying as no comprehensive health and environmental risk assessment has been carried out with Bt cotton, which is a potentially toxic crop. Even more worrying is the fact GM DNA has been shown to reach the milk of animals fed GM crops. Since the GEAC has made no attempt to segregate GM cottonseed from non-Gm cottonseed, the food chain is likely already contaminated. The biotechnology companies led by the 90% market leader, Monsanto, are known to frequently sabotage the regulatory structures in many countries. In India, Monsanto doctored an official report in South India on Bt cotton to circumvent claims for compensation, because of crop failures.

Environmental and Economic Impacts on the Farm

Weed scientists have warned for about a decade that heavy reliance on herbicide tolerant (HT) GM crops would trigger changes in weed communities and resistance, forcing farmers to apply **additional *toxic*** herbicides and/or increase herbicide rates of application. There is now incontrovertible evidence of this in the US, Canada and Argentina and it is accelerating, with the emergence of super pests and super weeds. Indian farmers who have grown Bt cotton for three years are being warned of resistance developing on their farms. This is of course, quite contrary to the claims made by the biotech industry, which has projected GM crops as the technocratic fix for pest and weed management.

We have in particular, looked at the experience of Argentina, which made a major switch to growing GM soy in the late 90s. Argentina's experience is a grim warning to India. By 2003, the warnings to the GM farming community were being fulfilled; GM soy growers registered a 10-fold

increase in the use of herbicides (compared to conventional farmers), in 5 years. There are changes to soil microbiology. Slugs, snails and fungi are moving into the newly available ecological niche. Charles Benbrook former Executive Director of the Board on Agriculture of the U.S. National Academy of Science says:

"Argentina faces big agronomic problems that it neither has the resources nor the expertise to solve. The country has adopted GM technology – based on the current use of RR (Roundup Ready, a herbicide made by Monsanto). I don't think its agriculture is sustainable for more than a couple of years".

Based on the evidence worldwide including India, farmers are being trapped on to a treadmill of 'unsustainability', of increasing pesticide and herbicide use and spiralling costs. GM crops are delivering a rising load of toxic chemicals into our food supply and into the environment. GE then is a noxious technology on the farm and impedes the transition to integrated pest management systems.

Based on the evidence worldwide including India, farmers are being trapped on to a treadmill of 'unsustainability', of increasing pesticide and herbicide use and spiralling costs. GM crops are delivering a rising load of toxic chemicals into our food supply and into the environment. GE then is a noxious technology on the farm and impedes the transition to integrated pest management systems.

There are other serious concerns with huge implications for India's food security. For 10,000 years farmers have preserved and created a diverse gene-pool through the traditional practice of saving and replanting seeds. But GE turns agriculture into an industry based on patents, which are paid for by the farming community, forcing farmers to buy seed each year. Drawing lessons from the American and Argentinian experience we focus on the following developments that have taken place:

- **Genetic engineering cannot create seeds from scratch. It is vital to understand that biotech companies need enormous quantities of seeds to engineer their patented manipulations and then supply GM seed to farmers, worldwide.** For the first time in history, one company, Monsanto, has unprecedented control of the sale and use of crops' seed and therefore germplasm, through their ownership of seed companies. This has been accomplished in three main ways:

  (a) control of germplasm through ownership of seed companies; (b) domination of genetic technology and seeds through patent acquisitions; and (c) breaking age-old farming tradition by forcing farmers to buy new seed each year. Monsanto has become a monopoly seed vendor controlling 90% of the GM seed sown globally.

- In America, the seed system is contaminated; Monsanto has put the diverse gene pools at risk by contaminating certified and traditional seed stocks, and by not permitting farmers to save seeds.

- American farmers are hard pushed to find high quality, conventional varieties of corn, soy and cottonseed. This represents a feudal system, which has turned agriculture into an industry where the corporations consolidate their hold over costly seeds and chemicals that increase farmers' spending on inputs. Meanwhile monopolies are created in corporate manipulated markets that include fewer buyers who demand the lowest possible prices for the outputs produced by farmers,

forcing them into a debt spiral. In 2003 Monsanto made $3.1 billion in pesticide sales and $1.6 billion in seed sales.

- **Organic and conventional farmers alike have lost their premium markets because their farms have been contaminated forcing them to join GM market streams.** The EU farming study confirms what independent scientists have warned. **At 0.1% of contamination, there can be no co-existence between GM and NonGM agriculture.**

The experience of both Argentina and America holds a grim warning that a new, untested technology like GM, vended monopolistically by multinational corporations poses a grave threat to world agriculture and food security. For India, as with the rest of the developing world, particularly with our small landholdings, it risks driving millions of small and medium farmers off the land. This is a doomsday scenario.

Food Safety And Food Security

Our health and nutrition are inextricably tied in with seed quality, variety and abundance. If farmers lose control over the seed supply, the diversity of the seed stock will be imperilled. **With GE foods and crops, the fundamental right to make food and health choices is removed entirely from the ambit of choice. This is so because transgenic contamination is irreversible.** Seed contamination offers genes and gene products surreptitious paths to new environments. In most cases neither seed sellers, nor farmers would be aware of the contaminant. You can imagine what would happen in India –we would quite simply be swamped It would take too long to speak about farmer rights, damages for contamination of farmlands and labelling, all of which are hugely important issues of fundamental democratic rights. On labelling, I just wish to add that there are very important reasons why consumers need to know what they are eating. (a) They need to know, so they know what to avoid. (b) Food allergies are a serious concern. (c) There are also religious and ethical concerns of particular relevance to India, since genes from animal sources are being incorporated into food products, including human genes into rice.

The experience of both Argentina and America holds a grim warning that a new, untested technology like GM, vended monopolistically by multinational corporations poses a grave threat to world agriculture and food security. For India, as with the rest of the developing world, particularly with our small landholdings, it risks driving millions of small and medium farmers off the land. This is a doomsday scenario.

World Consumers Want Non-GM Food & Animal Feed

But there are two other issues, which have priority today for Indian agriculture and farmer economics, which I need to emphasise because they point to the exact nature of what we are up against in the murky world of large business, and the corporate control over governments and international politics.

- The US has lost at a conservative estimate, around $4 billion in agri-exports to the EU because of GM trade restrictions and has taken legal action in the WTO. **Re-tooling the US grain and commodity infrastructure even if possible, would be prohibitively expensive. This is why ignominiously, UN food aid is GM;** why the pressure on India to open its agriculture to GM is so great that the biotech industry and government and private research institutions are experimenting with every conceivable vegetable and crop. We are perilously close to a full-scale GM onslaught.
- It is well to recognise that for the USA, the protection of its robust agricultural exports is dependent on a world that embraces GM crops; I call it the 'POLICY OF EQUIVALENT CONTAMINATION', to be achieved by any means possible. Then, contamination and consumer choice become irrelevant. Let's make no mistake about it. This is the agenda. This too is a pressure that must be successfully resisted.

For those who are unfamiliar with the format of a Suit, the 'Prayers' asked for, are at the end of the Petition on page 34. They are eminently logical and sane. By exposing an unaware population to serious risks that cannot be undone, the government stands accused of unconscionable offences against the Indian people. This joint petition before the Supreme Court indicts the Government of India for the declared intentions of its policy which: "mortgages the public interest, public safety and the environment, to the commercial interests of Biotech Corporations".

Aruna Rodrigues

Mhow Cantt.

With

Devinder Sharma	Rajeev Baruah	PV Satheesh
Delhi	*Mhow*	*Hyderabad*

Petitioners to the Public Interest Writ Petition in India's Supreme Court on GMOs

IN THE SUPREME COURT OF INDIA
(ORIGINAL CIVIL WRIT JURISDICTION)
Civil Writ Petition NO._____ OF 2005

IN THE MATTER OF:

Aruna Rodrigues and Others ...Petitioners

VERSUS

Union of India and Others ...Respondents

PAPER BOOK
FOR INDEX PLEASE SEE INSIDE

VOLUME - I

WITH I.A. No____ of 2005
(Application for ex-parte Interim Orders)

COUNSEL FOR PETITIONERS: PRASHANT BHUSHAN

IN THE SUPREME COURT OF INDIA
(ORIGINAL CIVIL WRIT JURISDICTION)
Civil Writ Petition NO._____ OF 2005

INDEX

LIST OF DATES & SYNOPSIS

1989	The Rules for Manufacture, Use, Import, Export and storage of Hazardous Micro-organisms and Genetically Engineered Organisms Or Cells, 1989 were brought into force under the Environment Protection Act, 1986. These rules were in response to a new technology of genetic engineering by which parts of the genes of viruses and bacteria or other organisms could be transmitted and inserted into the genes of unrelated organisms by carriers or vectors, which were usually viruses. These rules provided that no genetically modified organisms could be released to the environment by way of manufacture, import, etc., by any person without the specific permission of a Committee under the Ministry of Environment called the Genetic Engineering Approval Committee (GEAC).
1995 onwards	The Government started receiving applications from bio-technology companies engaged in the manufacture of genetically modified foods and crops to allow import and trial of various crops such as cotton, maze, corn, mustard, etc.
27.07.1998 and 05.08.1998	The RCGM (Review Committee on Genetic Modification), which is and a Committee in the Department of Biotechnology cleared the field trials of Bt Cotton by the company manufacturing this particular crop which it was seeking to commercialise. This clearance was given by a Committee under the Department which aggressively promotes this technology and is in violation of the rules of 1989 which provided that environmental release of genetically modified organisms could only be done by the GEAC under the Ministry of Environment.
1999	The Supreme Court delivered a judgment in A.P. Pollution Control Board Vs. M.V. Nayudu in which it was held that when a new technology or process can cause serious and irreversible harm to human health and environment, it is necessary that every possible precaution should be taken to ensure that there are no adverse effects to health or environment and that if the effects of certain things which are potentially hazardous to these are not known, it is necessary to wait till the effects are understood before releasing the potentially hazardous materials/technology into the environment.
October 1999	A leading Nutritionist and eminent Toxicologist Dr. Arpad Pustzai published his findings regarding the possibility and likelihood of horizontal gene transfer from genetically modified organisms, transfer of artificial genetic constructs from the target organism to the other organisms pose completely unknown hazards, since the effects of the transfer of genes to the new organisms would be completely unknown. Various studies also indicated that the marker genes used in the technology of genetic modification would increase antibiotic resistance to humans and other organisms which feed on these genetically modified organisms.
May 2000	More than 69 eminent scientists of the world from 79 countries released an open statement about the hazards that the release of genetically modified organisms pose to biodiversity, food safety, and therefore to human and animal health, and they demanded a moratorium on the environmental release of such genetically modified organisms in accordance with the precautionary principles. This statement was issued on the eve of U.N. Convention on Biological Diversity Conference in Nairobi in May 2000.
05.04.2002	The GEAC approved commercial release of Bt Cotton on the basis of some safety tests supposed to have been done by the commercial company producing this particular variety of genetically modified cotton. It is important to mention that these tests were essentially allowed to be done by the company itself and there was no transparency or public opinion released about these tests and no independent experts were allowed to critique the adequacy or otherwise of these tests.
April 2002	Mr. P.N. Bhargava, one of the most eminent Indian scientists in the field published a detailed article on the biosafety tests that must precede any genetically modified organisms. Most of the aspects were not considered for the examination of safety risks before any release of genetically modified organisms in the country.
June 2003	An Independent Science Panel consisting of expert independent scientists from 11 countries comprising the disciplines of agro-ecology, agronomy, biomathematics, botany, chemical medicine, ecology, epidemiology, histopathology, microbial ecology, molecular genetics, nutritional biochemistry, physiology, toxicology, virology, etc., published a report on the actual evidence of hazards posed by the genetically modified organisms which had been released and experimented across the world till that time. They concluded that genetically modified crops posed serious hazards of various kinds including the possibility of horizontal gene transfers, resistance to antibiotics, allergies, etc. The report also raised serious doubts about the adequacy of safety testing which was done prior to release of genetically modified organisms.
11.9.2003 onwards	Cartagena Protocol, other wise called the Bio-Safety Protocol for the U.N. Convention on Biodiversity came into force. The protocol, which was signed by large number of countries including India, provided that all participating countries must ensure the transfer, handling and use of genetically modified organisms in a manner so as to minimize risks to human health and environment and biodiversity. It also emphasizes the precautionary principle and provides that risk assessment must be made in a scientifically sound and transparent manner.

January 2005 The U.S. Securities and Exchange Commission filed a complaint in the US Courts that Monsanto, a biotech company controlling a substantial share of genetically modified products worldwide, had bribed 140 officials of the Ministry of Environment between 1997-2000 in obtaining environmental clearance for their GM Cotton. Monsanto admitted this charge and paid penalty of US $ 1.5 million.

March 2005 The Royal Society for the Protection of Birds and the Centre for Ecology and Hydrology, Lancaster in the United Kingdom conducted a series of experiments, which showed that genetically modified organisms had adversely affected wild life and biodiversity.

5.4.2005 The Economic Times reported that the Government is planning import of large amount of soya from Argentina. These are likely to be genetically modified soya since large part of soya grown in Argentina is genetically modified soya. Argentina also have no labeling laws and, therefore, any import of soya from Argentina is likely to be either genetically modified or contaminated with genetically modified soya. Since GEAC has not allowed release or import of these soya, this import would clearly violate the rules of 1989.

SYNOPSIS

The above facts and circumstances clearly indicate the following:

- That genetically modified organisms posed serious hazards to human and animal health and to the environment.
- These hazards include risks of new kinds of allergies, greatly increased resistance to antibiotics, severe toxicity to humans, animals and micro organisms, resulting in serious import on human health, loss of wild life, biodiversity, etc.
- Apart from the above, the demonstrated possibility of a unintended transfer of these artificial genetic constructs from the target organism to the other organisms pose completely unknown hazards, since the effects of the transfer of genes to the new organisms would be completely unknown.

In these circumstances, the use of the technology of genetic engineering and the release of genetically modified organisms into the environment would clearly require the application of precautionary principle which mandates that every possible precaution must be taken to ensure that no harmful effects are caused to human and animal health and environment due to the use of new and unknown technologies and organisms. In particular, it requires that if the effects of certain technologies/ organisms are unknown and which are potentially hazardous, then the use of this technology and release of those organisms must wait until the hazards are properly understood and the effects known.

The experts worldwide agreed in the last decade that use of genetically modified crops and organisms has shown that these organisms and the technology is indeed very seriously hazardous and all kinds of problems have been documented in various scientific reports which have appeared in very prestigious and respected scientific journals and in the statements of very eminent and respectable scientists. On the other hand, it has also become evident that biotechnology companies, which have a commercial stake in the exploitation of this technology are aggressively pushing this technology and the release of these organisms. They have gone to the extent of bribing officials in third world countries for clearance and release. They also subverted the Food and Regulatory System of the USA to pronounce that these genetically modified organisms are substantially equivalent to natural biological organisms and, therefore, they do not need any clearance by the FDA for release. As a result, therefore, large number of genetically modified crops has been used in the U.S. without any prior safety testing. This has created an impression in many parts of the world that since such organisms are used in the U.S.A, they must be safe.

Despite the fact that in the Rules for Manufacture, Use, Import, Export and storage of Hazardous Micro-organisms and Genetically Engineered Organisms Or Cells, 1989 under the Environment Protection Act, 1986 provided that no genetically modified organisms would be released into the environment, without specific approval of a committee under the Ministry of Environment called GEAC, unfortunately, till today no proper system has been put in place to ensure that GMOs slated for release undergo proper biosafety tests by independent and scientifically competent bodies in a transparent manner. For this to happen, it was essential that GEAC laid down a protocol which prepares a list of biosafety tests which are required, particularly GMOs slated for release and that such tests thereafter done by independent scientific bodies and the results available for public scrutiny and critique by independent experts. However, no such system/protocol has been put in place with the result that these organisms are being currently tested essentially by the biotech companies themselves and whose results are not made available for public scrutiny. This has led to the situation whereby the future health of the people of this country and the environment has been placed at severe risk by a potentially explosive release of genetically modified organisms and crops without adequate and proper tests.

It is in these circumstances that the Petitioners are approaching this Hon'ble Court to ensure that a proper system is put in place which will ensure that this potentially hazardous genetically modified organisms are put through an adequate and proper safety tests by independent scientific agencies and whose results put to critique by independent experts so that the precautionary principle is adhered to before such organisms are released into environment.

IN THE SUPREME COURT OF INDIA
(ORIGINAL CIVIL WRIT JURISDICTION)
Civil Writ Petition No._____ OF 2005

IN THE MATTER OF:

1. Aruna Rodrigues,
   Bungalow No. 69
   Mhow Cantt,
   M.P. - 453441

2. Devinder Sharma,
   G-3/F, DDA Flats,
   Munirka,
   New delhi-110067

3. PV Satheesh
   Deccan Development Society,
   101, Krishnan Residency
   Road No. 5, Begumpet
   Hyderabad- 500016

4. Rajeev Baruah
   14, Signals Vihar,
   Mhow,
   Madhya Pradesh.

...PETITIONERS

VERSUS

1. Union of India
   Through its Secretary
   Government of India
   Ministry of Environment and Forests,
   Paryavaran Bhavan
   CGO Complex, Lodhi Road
   New Delhi- 110003

2. Union of India
   Through its Secretary
   Government of India
   Ministry of Science and Technology,
   Block II, CGO Complex, Lodhi Road
   New Delhi- 110003

3. Union of India
   Through its Secretary
   Government of India
   Ministry of Agriculture,
   Krishi Bhavan
   New Delhi

... RESPONDENTS

To,

The Hon'ble Chief Justice of India and His Companion Justices of this Hon'ble Court

MOST RESPECTFULLY SHEWETH:

This Writ petition is filed in public interest, regarding the Biosafety of Genetically Modified Organisms (GMOs), which are allowed to be released into the environment. The petitioners are concerned about the absence of proper scientific examination of Biosafety concerns. This petition seeks to put in place a protocol that shall mandate the scientific examination of all relevant aspects of Biosafety before such release. There is an increasing body of scientific knowledge and evidence, which points to the existence of serious hazards, and therefore safety concerns for human health and the environment. The reckless release of GMOs into the environment also threatens the agrarian structure of the country, will lead to the contamination of the food chain and detrimentally affect biodiversity, in an irreversible and lasting manner. It is submitted that this is a fit case to employ the Precautionary Principle, as enunciated by this Hon'ble Court in a catena of cases including M.V. Nayudu[1999 (2) SCC 718]. In view of the grave and irreversible harmful impacts resulting from the release of GMOs into the environment, the petitioners pray for a moratorium on the release of any GMOs into the environment until a comprehensive protocol for all required Biosafety tests of the GMO proposed to be released is put in place, under the regulatory and monitoring framework of the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989. Preceding such release, the protocol must insist on requisite Biosafety tests by independent expert bodies, whose results are made public, and the data to be published is provided in a manner that can be examined by the scientific community; it shall be accompanied by mandatory public notice and public hearing. The petitioners also pray for a labelling mechanism to ensure that the moratorium on the release of any GMO into the environment is safeguarded and effective. Such a mechanism is also necessary to protect the rights of agriculturists and consumers to grow and consume GM-free crops.

1. The Petitioners are public spirited individuals who on account of their vocation have the expertise, and access to information that reveal a grave and hazardous situation with regard to Biosafety concerns, developing in India due to release of GMOs into the environment. Petitioner No. 1 Ms. Aruna Rodrigues, is an economist and marketing management consultant with many years of international experience in project development and appraisal, and development economics; also solar PV applications (photovoltaics) and the energy-economics that are relevant to development She also has many years of Marketing Management experience in India in nutrition, foods and health foods. Petitioner No.2 Mr. Devinder Sharma is a trained agricultural scientist and writer. He is a Visiting Fellow at the School of Development Studies at the University of East Anglia, Norwich (UK) and at the University of Cambridge (UK), and was formerly a Visiting Fellow to the International Rice Research Institute, in the Philippines. Mr. Sharma also chairs an independent collective in New Delhi, called the Forum for Biotechnology & Food Security, that examines and analyses various policy decisions in the field Biotechnology and Food safety. Petioner No. 3, Mr. P.V. Satheesh is an internationally renowned developmental communication specialist and is a co-founder and General Secretary of the Deccan Developmental Society, an organisation which works with rural communities. He is the Chair of the Board of Directors, Genetic Resources Action International, [GRAIN], and , India Coordinator for the SANFEC, South Asian Network for Food, Ecology and Culture, a five country South Asian Network with over 200 ecological groups. He is also the founder Convenor of Andhra Pradesh Coalition in Defence of Diversity, a coalition of over 120 NGOs in AP. Petitioner No. 4, Mr. Rajeev Baruah is a management specialist and is involved in providing support to local farmers in Madhya Pradesh and Maharashtra to grow organic cotton following biodynamic farming principles. He is the Managing Director of Maikaal bioRe, a private service company involved with organic farming of cotton and other crops and provides basic support to farming communities in improving their standard of living. .Organic cotton for the export of cotton garments by definition means non-gm and farmers lose their organic status if soil samples show chemical or GM contamination.
2. Genetic Engineering (GE) or Recombinant DNA Technology, is a new technology that for the first time in history, is able to artificially manipulate and transfer genetic material between unrelated organisms. Transgenes are unusually complex combinations of genetic elements, which are unlikely to occur by chance in nature. The technology involves recombining i.e. joining together in new combinations, DNA that is often from different organisms, e.g. plant to animal, animal to plant and inserting them into the genomes of target organisms to make GMOs. The intended gene is incorporated into the genome of a crop using a vector containing several other genetic elements, including as a minimum, promoters which may come from plant or plant viruses, transcription terminators, reporter genes and antibiotic resistant or herbicide resistant marker genes. Cells modified by these techniques pass the new genes and their traits on to their offspring. GE however, is an imprecise technology as there is little control on where the new genetic construct will lodge within one or more of the target cell chromosomes. Furthermore, although for GM food safety, the intended gene is very important, the potential effects of the whole construct, i.e. the other genes may contribute substantially to the overall effect. In addition the protein produced from the gene of interest may interact in unpredictable ways. It is now known for example, that DNA does not always break down in the Alimentary tract. Such reference may found in the article by Arpad Pusztai titled "GM Foods: Potential Human Health Effects" attached to this Writ petition as **Annexure P 1.** GMOs are unnatural, not just because they have been produced in the laboratory, but because they can only be made in the laboratory, creating organisms and in ways that have never existed in the course of 3.8 billion years of evolution. These mainly untested and potentially hazardous GM crops are now spreading all over the world, creating irreversible risks for the environment and the hazards of GE raise outstanding safety concerns for human and animal health. Many of the

potential hazards are inherent in the GE process itself, which is not the case with traditional breeding. When the experts at the FDA undertook an extensive examination of genetically engineered food, they readily recognized the unique set of risks and clearly reported them to their superiors. This came to light when the FDA was compelled to give its files during the course of the lawsuit filed by Steve Druker. The statement of Mr. Druker and concerned scientists in the suit, is attached to this Writ Petition as **Annexure P 2**. FDA microbiologist Dr. Louis Pribyl, one of the scientists stated: "There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering ...." He added that several aspects of gene splicing ". . . may be more hazardous . . ." Scientists concede that with GE we are moving from science to applied technology and the science of GE has not kept pace with the technology. This technology is so powerful, crude but powerful, but the scientific ignorance of it is huge. Scientists do not understand the mechanisms of GE-induced changes in gene expression in sufficient detail. They do not know what to look for and these things are termed 'unintended effects'. Unintended effects are common in all cases where GE techniques are used. So on a whole range of issues, a great deal of research is required before they can predict an outcome. Yet, it is being used to irrevocably change the fundamental molecular structure of the world's food supply and impact the biodiversity through un-recallable, self-replicating organisms.

3. Sufficient scientific evidence has accumulated that GMOs are not safe. In May 2000 761 scientists from 79 countries expressed their concerns, in an Open Letter, about the hazards that the release of GMOs pose to biodiversity, food safety, and therefore human and animal health. The World Scientists, including among others, renowned geneticists Dr. David Suzuki, Canada and Dr. Prof. Ruth Hubbard, Harvard University, molecular biologists Prof. Jonathan King, MIT, Cambridge, USA and Prof. Gilles-Eric Seralini, Laboratoire de Biochimie & Moleculaire, Univ. Caen, France, onco-virologists Vladimir Zajac, of the Czech Republic and agronomist, Prof. Oscar B. Zamora from the University of Philippines, have demanded a moratorium on environmental releases in accordance with the precautionary principle. That this letter of the World Scientists, as early as May 2000, provides an impressive array of evidence of various hazards associated with the release of GMOs, raising serious safety concerns for the whole stream of life, including human and animal health. That this scientific evidence has emerged despite enormous pressure being put on independent scientists and other deliberate and difficult to override, blocks to transparency, which have hindered objective and independent examination of the issues and unfettered and truthful bio-safety testing. A copy of the statement of the world scientists to the UN Convention on Biological Diversity Conference in Nairobi on May 16-24, 2000 is attached to this Writ Petition as **Annexure P 3.**

FINDINGS OF THE INDEPENDENT SCIENCE PANEL

4. The Independent Science Panel (ISP) consists of expert independent scientists from eleven countries spanning the disciplines of agro-ecology, agronomy, biomathematics, botany, chemical medicine, ecology, epidemiology, histopathology, microbial ecology, molecular genetics, nutritional biochemistry, physiology, toxicology and virology. The panel includes world renowned scientists like Mr. Michel Pimbert, Agricultural ecologist and principal associate International Institute for Environment and Development, Prof. Bob Orskov OBE, Director of the International Feed Resources Union, Fellow of the Royal Society of Edinburg, Fellow of the Polish Academy of Science and Dr. Mae-Wan Ho Director of the Institute of Science in Society and a member of the roster of experts for the Cartagena Protocol on Biosafety. The ISP reviewed the evidence on the hazards and problems of GM crops as well as the proven successes of sustainable agriculture, and published its report in June 2003. The key findings of the ISP report are as follows:

- Regulations over the releases of GM crops and products have been highly inadequate.
- Few feeding studies have been carried out, but they raised serious doubts over the safety of the transgenic process itself, which are yet to be followed up by dedicated research.
- GM varieties are unstable; and this may enhance the horizontal spread of transgenes, with the potential to create new viruses and bacteria that cause diseases, and to disrupt gene function in animal and human cells.
- Many GM crops contain gene products known to be harmful. For example, the Bt proteins that kill insect pests include potent immunogens and allergens, and food crops are increasingly engineered to produce pharmaceuticals, drugs, and vaccines in the open environment, exposing people to the danger of inappropriate medication and their toxic side effects.
- Herbicide tolerant GM crops - accounting for 75% of all GM crops worldwide - are tied to the broad-spectrum herbicides glyphosate and glufosinate ammonium, and will likely increase their use. Both herbicides are systemic metabolic poisons linked to spontaneous abortions, birth defects and other toxicities for human beings and laboratory animals, and also harmful to wild life and beneficial organisms in the soil.
- GM crops have resulted in no benefits to the environment. Overall, there has been no reduction in the use of pesticides, while herbicide tolerant weeds and volunteers have emerged, and highly toxic herbicides have had to be brought back in use.

A copy of the Report of the ISP is attached to this Writ Petition as **Annexure P 4.**

5. Since its publication, all the major findings of the ISP report have been further corroborated. Furthermore, 10 years of commercialisation of this technology in the US and Canada, and more recently, Argentina, has produced an increasing flow of evidence of the serious hazards connected with GMOs. These hazards include:

- Genetically engineered insulin (so-called human insulin) was claimed by its manufacturers to be one hundred percent safe; but thousands of diabetics have suffered serious adverse side effects from this product, including 50 suspected

deaths and this despite the fact that far stricter rules apply to GE drugs than to GE agricultural and food products

- Transgenic contamination (contamination of the natural environment by GMOs) by more than one method, including wind blown and by cross- pollination, is an established fact, beyond dispute and there can be no co-existence between GM and non-GM crops. Extensive transgenic contamination has occurred in maize landraces (crops grown by traditional farmers from wild species) in remote regions of Mexico, despite an official moratorium that has been in place since 1998. The fact of transgenic contamination is so important precisely because of the serious nature of the hazards connected with GMOs; Furthermore, given that there is de-facto, zero tolerance of pharmaceuticals in food, this means that once pharma-crops are grown, they will get out.
- Both of the two human clinical studies carried out and published till date, provide strong evidence of HGT from food to humans. Thus, it was shown that fragments of GM DNA were incorporated into the bacteria resident in the gut of human volunteers who were previously given a single meal containing GM soybean, something entirely unexpected. On this analogy, had this meal contained a GM plant that had been engineered using an antibiotic-resistance marker gene in the construct, the gut bacteria could have been made resistant to that particular antibiotic by horizontal gene transfer, opening the way for the spread of antibiotic-resistance to medically important bacterial species, making infections very difficult to treat.
- The very few nutritional and toxicological studies carried out on ingested plant GM DNA, provide information on the potential nature of the hazards of GM foods/feeds. These include: wasteful growth of gut tissues and bacterial proliferation, development of intestinal tumours, depression of the body's immune system, interference with the normal development of vital organs of the body (liver, kidneys, sexual organs, etc.) and reproduction. The seriousness of these effects cannot be overemphasized because the harm will be the most pronounced in the young, the old and in people with intestinal disorders.
- Plant GM DNA has been shown to reach the milk of cows fed GM crops; the danger to infants and children will be disproportionately high. Thus, the GOI approvals of Bt cotton in States like Gujarat, MP and Punjab, which are the milk-producing heartlands of India, raise concerns of serious health issues, because cottonseed products like oil and cottonseed cake are used extensively in human and animal nutrition. This raises the possibility of the contamination of milk, and milk-derived products, including processed foods.
- Bt cotton is a potentially toxic crop whose toxins/anti-nutrients such as gossypol, cyclopropenoid fatty acids, or the potent carcinogenic aflatoxins produced by contaminating fungi, are well known to accumulate in the subcutaneous fatty tissues of consumers. "In the absence of conclusive evidence for the lack of toxicity, responsible GM regulatory authorities must prevent the cultivation, commercialisation and food use of GM cotton and its products
- Feeding rats with diets containing genetically modified (GM) potatoes affected their growth, organ development and immunity (unintended effects).
- Another unintended effect is that Bt corn hybrids descended from Monsanto's MON 810 and Sygenta's Bt 11, both have markedly increased levels of lignin in stem tissue which may make the corn less digestible. There is some suggestion that given a choice between equivalent feeds, domesticated animals will eat the non-GM feed.
- Finding the same unintended effect in the above two different transformation events suggests that *the GE process itself*, is responsible for the increase in Lignin levels and perhaps other undetected effects. The increased lignin content of Bt corn was brought to light only 5 years after market introduction. The failure to carry out the required testing highlights the serious gaps in the human health assessment of Bt corn.
- Plant-generated GE pesticides have potential health impacts as well as environmental impacts. For example, several Cry proteins in Bt products could be a source of allergens and antibodies.
- Random, unintended effects including unexpected toxins and allergens in food plants and cancer in mammalian cells have arisen from the inherently random, uncontrollable nature of the process of GE
- The cauliflower mosaic virus (CaMV), the viral promoter that is in practically all transgenic plants, has similarities with the human hepatitis B virus. As all genomes of living species contain dormant viruses, there is a potential for the CaMV promoter to reactivate them, raising cancer concerns
- Thus, hazards from GM crops released into the environment may spread more readily through HGT because GM constructs are specifically designed to cross the interspecies barrier. Apart from the above list, these hazards include the reactivation of dormant viruses, the creation of new viruses and super viruses and the spread of drug and antibiotic resistance marker genes to pathogens, making infections untreatable or at least very difficult to treat.
- Significant amounts of transgenic DNA is found to survive most commercial processing or in the gut of mammals. Thus, GM plant materials used in silage and manure from animals fed with GM feed has a greater likelihood of containing fragments of DNA bearing antibiotic resistance genes.
- GM crops grown in the UK were not only harmful to beneficial insects like ladybirds but could also indirectly harm other and higher life forms, including mammals, domesticated or wild animals, birds and ultimately man, both in the short- and long-term.
- The three-year UK farm-scale trials were the largest study ever to evaluate, the ecological effects of GM crops. Released on March 21 2005, the study indicated that GM crops damage wild life and farmland bird populations would fall even further if the crops were widely planted. Birds are a primary indicator of environmental health.
- Glyphosate and Glufosinate the herbicides used with Herbicide Resistant/Tolerant (HR/HT) GM crops account for 75% of all GM crops worldwide. Both are systemic metabolic poisons with a wide range of harmful effects.

- GM lines are notoriously unstable, do not breed true and do not perform consistently in the field. Evidence is emerging of yield drag, susceptibility to disease and other problems.
- 9 years of US Dept of Agriculture data, shows conclusively, that GE crops have led to an increase, not decrease in herbicides and pesticide use, involving millions of pounds, demolishing the basic claim by biotech companies that GM crops were such a boon to farmers because their use would lead to less herbicide and insecticide use and the management of pests and weeds would be so much easier.
- Resistance is growing, leading to super pests and super weeds; even triple herbicide-tolerant oilseed rape weeds (volunteers) that have combined transgenic and non-transgenic traits are now widespread in Canada. A similar problem has emerged in the US, which may take over from Australia as the No1 'resistant' country to Monsanto's RR. Indian farmers who have grown Bt cotton for three years have been warned of resistance developing on their farms. Thus GM crops trap farmers onto a treadmill of highly toxic and increasing pesticide and herbicide use; it is therefore by definition, a noxious technology on the farm, with significant safety concerns for health and for the environmental. It also impedes the use of and transition to, safer integrated pest and weed management systems by farmers.

THE IRRESPONSIBLE CLEARANCE OF GMOS BY THE US FDA AND IT'S IMPACT ON REGULATION IN OTHER PARTS OF THE WORLD.

6. An impression been fostered in the minds of people that GM crops are safe and in fact offer a technological solution to food shortages. This impression has been created because of the extensive use of GM foods in the US, that therefore, they must have gone through an approval process by the regulatory authorities in the US, including the US FDA. However, nothing could be further from the truth. This is demonstrated in the evidence provided below:
7. The FDA openly acknowledges it has been operating under a policy "to foster" the biotechnology industry. A memo by former FDA Commissioner David Kessler, who described the agency's policy as "consistent with the general biotechnology policy established by the Office of the President", said, "It also responds to White House interest in assuring the safe, speedy development of the U.S. biotechnology industry." Reference in this regard made in the article "Eating Genetically Engineered Food is Gambling with Your Health" by Jeffery Smith, Director of the Institute for Responsible Technology and author of "Seeds Of Deception", published in the website www.NewWithViews.com dated 24.01.2004 is attached to this Writ Petition as **Annexure P 5.**
8. That, GM foods would not have come onto the market if the facts about their unique risks had been acknowledged and if national laws had been honoured. Their introduction depended on a systematic cover-up and deliberate deception by both the biotech industry and the Government of the United State, to push a commercial agenda for spawning a multi-billion dollar industry for the United States. This continues today and is the reason why GM foods continue to be aggressively marketed in more and more countries. The US clearance of GE foods and crops for commercial release has given them a flawed stamp of legitimacy and hoodwinked the public into believing that they are safe. If the US had not done so, then no other Country would have allowed their introduction. That India has clearly been influenced by the US clearance of GE crops, as is evident from the manner in which it has given approvals for the commercial cultivation of Bt crops and other permissions, because there is a complete absence of any genuine biosafety testing protocol in India.

The US Review Process Means That Contrary to Popular Belief the FDA Has Not Approved a Single GE crop As Safe for Human Consumption

9. Theoretically, transgenic proteins in foods fall under the food additive provisions of the FFDCA (Federal Food, Drug and Cosmetic Act). Food additives must undergo extensive pre-market safety testing including long-term animal studies, unless they are deemed to be, 'generally recognised as safe' (GRAS). The FDA's own records indicate that because the process of genetic engineering can induce unpredictable side effects, its resultant products are not even recognized as safe among the agency's own scientists let alone by a consensus in the scientific community. It is important to emphasize that the extent of the disagreement clearly precludes GRAS status. As both the FDA's regulations and the federal courts make clear, general recognition of safety can only be imputed if there is an overwhelming consensus in the community of qualified experts. While unanimity is not required, a significant disagreement prevents a determination that consensus exists. Even so, the FDA has left it to the biotech industry to decide whether or not a transgenic protein is GRAS and so exempt from testing. (FDA Policy, 1992). Thus, the FDA's policy presumes every genetically engineered food is as safe as its conventional counterpart unless demonstrated otherwise, inviting a strong presumption of 'substantial equivalence' (SE). Biotech industry and government officials have testified to the great influence exerted by the industry on the formulation of this policy, which was designed to give speedy clearance without having to go through formal approvals before market release of GE crops and foods, while at the same time reassuring consumers that GE foods have passed government review. According to Henry Miller, in charge of biotechnology at the FDA from 1979-1994: "In this area, the US government agencies have done exactly what big agribusiness has asked them to do and told them to do". This is quoted by David Schubert, Head of the Salk Institute's Cellular and Neurobiology Lab, in his peer reviewed document 'Safety Testing and regulation of GE Foods', in the Journal "Biotechnology & Genetic Engineering Reviews. The article is attached to this Writ Petition as **Annexure P 6.** The main study that attempted to demonstrate the safety of a bio-engineered food through standard toxicological testing, failed conspicuously to do so; that product was "Flavr Savr Tomato". So, although GRAS exemption was intended to permit marketing of substances whose safety has already

been demonstrated through sound testing, the FDA is now using it to circumvent testing and uses it instead to expedite product approvals, at the expense of public health. This amounts to a 'scientific sleight-of-hand' in the use of GRAS exemption for GE clearances. It is emphasised that the FDA does not require the testing of any GM food before it is released on the market and that it has consistently ignored the warnings and advice of its own scientific experts in clearing GE crops and foods for market release. The irresponsibility of the FDA is adequately documented in the Statement of Steven M. Druker, who represented nine scientists who were plaintiffs in the Law Suit challenging FDA policy on genetically engineered foods. The Statement of Steven M. Druker and the list of Scientist-Plaintiffs are already attached to this Writ Petition as Annexure P 2. The FDA's irresponsible clearance of GE Foods Is also documented by David Schubert in his peer–reviewed paper, 'Safety Testing and Regulation of GE Foods' already annexed to this Writ Petition as Annexure P6.

SIGNIFICANT HAZARDS FURTHER EXPLAINED: EXPERIENCE WITH " FLAVR SAVR" TOMATO, STARLINK AND Bt 10

10. Flavr Savr tomato was the first GE food reviewed by the FDA. It went through standard toxicological testing to demonstrate the safety of a GE food, which it failed. The report prior to 1999 submitted to the US FDA revealed harmful effects on rats fed on GM tomatoes. Several of the rats developed erosions (early ulcers) of the lining of the stomach similar to those seen in the stomach of older humans on aspirin or similar medication. (Some rats died and were replaced). Substantial life threatening haemorrhage may occur in humans from these early ulcers. Reference of this can be found at page 38 of the report of the Independent Science Panel already attached to this Writ petition as Annexure P4. Yet the FDA approved the product anyway on the ground that it is GRAS (Generally Recognised As Safe), but it was subsequently taken off the market. The FDA ignored the advice of senior scientists of the FDA itself on the need for further safety testing. Instead, FDA officials claim that Flavr Savr passed muster so well that the rigor of its testing will not have to be repeated for other bio-engineered foods. This evidence can be found in the statement of Mr.Steven Druker, already annexed to this petition as Annexure P2.

Experience with StarLink

11. In 1997/98, the EPA had approved StarLink (corn engineered to contain a Bt. toxin pesticide which produces the now banned Cry9C insecticidal protein) for animal feed, but not human food. In 2000, it was found in taco shells that set in motion widespread product recalls and an expensive chain of events of testing and diverting contaminated lots of grain. The cost of the impacts ran into hundreds of millions of dollars. The USDA (US Department of Agriculture) ended up by bailing out seed companies involved in the effort to contain the contaminants. The Starlink episode "involved crops planted on less than 0.5% of US corn acreage, yet the product ended up contaminating grain throughout the food system. Also affected were the seed stocks of at least 63 small and medium-sized companies. Banned StarLink genes still contaminate the seed supply. In fact, a most recent study of February 2005, backed by the international group Friends of the Earth found that samples of UN World Food Program shipments collected in Guatemala included StarLink, the banned corn long since pulled from the market in the United States because of concerns it could provoke allergic reactions. Reference can be found in the report of the Union of Concerned Scientists titled "Gone to Seed" annexed to this Writ Petition as **Annexure P 7**. The StarLink episode should serve as a timely warning to India of how easily GM contamination of food crops can happen and how virtually impossible it is to clean up contamination from the system. In view of this, the DBT approval of Cry 9C for experiments on cabbages and cauliflower (which is the same as Starlink) in experiments by Bayer (owners of Aventis Crop Science which engineered StarLink) is surprising. A collection of documents prepared by an organisation called Green Peace India documenting this evidence is attached to Writ Petition as **Annexure P 8 (colly.)**. Seed contamination would exacerbate this problem by making it even more difficult for growers and food companies to know the exact composition of the products they buy and sell. Commingling is being reported with regard to Indian cotton, BT cottonseed commingling with non-GM cottonseed, as the GOI has no mechanism in place to prevent this. Products like StarLink that are not intended for use in food raise the highest level of concern. They are unlikely to be reviewed for food safety at all and many such farm and industrial crops are likely to produce bioactive and toxic compounds. StarLink was denied approval for food use because its Bt toxin failed screens for digestibility and heat stability. Starlink raises the question of whether other Bt toxins that were screened might nevertheless be allergens. Scientists accept that without a better understanding of food allergenicity, this question cannot be adequately answered. The failure to remedy and rectify such a critical research need is a major flaw in the US regulatory process for GE food. Reference to this can be found in foot note 54 of Annexure P 7, already attached to this Writ Petition.

Sygenta Bt10

12. In a variation of the above incident, in April 2005, imports of US corn were banned at UK ports following the discovery that the US has been illegally exporting a banned GM maize, Bt10 to Europe for four years. Bt10 also has an antibiotic resistance marker conferring resistance to antibiotics The Bush administration failed for three months to inform European customers about the banned maize. The scandal was only admitted on 22 March, after its exposure by the scientific magazine Nature Biotechnology. Reference to these facts is made in the article published in the Independent dated 17 April 2005 attached to this Writ Petition as **Annexure P 9**.

UNINTENDED EFFECTS INCLUDING HORIZONTAL GENE TRANSFER(HGT)

13. The GE process itself is achieved through Horizontal Gene Transfer (HGT) because it moves genetic material between organisms, which are asynchronous with the reproduction of the organism, so genes can also be transferred between distant species that would never interbreed in nature. For example, human genes are transferred into rice and those from pig, sheep, fish and bacteria are transferred into plants. Thereafter, secondary, unintended HGT can take place from GE crops released into the environment and several serious examples of this insidious hazard connected with the GE process are provided below as evidence of the grave risks they pose for human and animal health and for the environment, including: new strains of antibiotic resistant bacteria, new viruses and bacteria arising from those introduced into the transgenic plants, random secondary insertion into other unrelated organisms, causing harmful effects including cancer, reactivation of dormant viruses etc. For these reasons, concerns with HGT make the technology of GE highly unpredictable and also extremely dangerous and puts in doubt the safety of the GE process itself.

Insufficient scientific knowledge and research on HGT

14. Horizontal transfer of transgenes and antibiotic resistant marker genes from genetically engineered crops into soil bacteria and fungi has been documented in the laboratory. Dr. Jack Heinemann, Director of the New Zealand Institute of Gene Ecology, University of Canterbury, speaking about one form of HGT says: "the question of HGT from transgenic plants to soil micro-organisms is not 'will it happen' but 'when and where will it happen'"; and "it is very possible that the relevance of HGT to assessing the risk of genetically modified organisms will be more important than can be extrapolated from present data". This reference is in this regard can be found in a statement by Mr. Jack Heinemann to Petitioner No.1, Aruna Rodrigues daetd 29.03.2005 is attached to this Writ Petition as **Annexure P 10**. At present, there are significant limitations on research on HGT, that have lead to underestimating the frequency of HGT. Jack Heinemann, an authority on HGT, an Associate Professor at the University of Canterbury, and the Director of the University's New Zealand Institute of Gene Ecology, in his statement has stated that HGT has not been studied to a sophistication, that is, to within a reasonable fraction of the scale with which gene technologies have developed. "An increasing body of scientific evidence supports the suggestion that the capacity to detect and monitor GMOs is below what is sometimes claimed. It also falls short of what would be necessary for the purposes of containing GMOs in some environments or eliminating them from others. The assessments about frequency and importance of HGT are premature at present. Mr. Heinemann has stated that more research is needed to even develop the appropriate tools to monitor at the necessary levels of sensitivity. Further, in a study with co-author and expert Dr. Terje Traavik, published in the reputed journal "Nature: Biotechnology", August 2004, they also stated that analysing the sensitivity of the current techniques for monitoring HGT from GM plants to soil micro-organisms, they felt that it could have an environmental impact even at a frequency that was approximately trillion times lower than what the current risk assessment literature assumes it to be. They concluded that current methods of environmental sampling to capture genes or traits in a recombinant are too insensitive for monitoring evolution by HGT. Since there is critical risk to health and environmental safety and the scientific uncertainty surrounding the environmental application, the authors recommend a slow down of genetic modification till new approaches of monitoring emerge. A copy of the article titled "Problems in monitoring horizontal gene transfer in field trials of transgenic plants" published in Nature Biotechnology, September 2004 , is attached to this Writ Petition as **Annexure P 11.**

Resistance to antibiotics through marker genes

15. That during the process of genetic modification, to identify the modified cells, and for this reason only, an extra gene called a 'marker gene' is added. This is a passenger gene and it is carried along with the one for improvement, growth, pesticide resistance or whatever desired characteristic one is trying to introduce into the genetically modified cell. This is how GM cells are sorted from non-GM cells. Many marker genes used in commercial crops currently on the market, are antibiotic resistance genes and they work by producing a chemical that reacts with antibiotics to protect the GM cells from the harmful effects of the antibiotic Therefore many GM products contain a gene that produces the desired trait and something that overcomes the antibiotic (an 'anti-antibiotic').. This leads to resistance of the specific organism to antibiotics, which gives rise to grave concerns to human and animal health.
16. There have been several cases of GM crops that contain antibiotic resistant genes. The case of GM corn/ maize in the European Union, developed by the company Syngenta, is an effective illustration of this. The European Union has called for an end to cultivation of several genetically modified varieties including Syngenta Bt. 176 corn, for the reason that it could generate resistance to antibiotics. A copy of the press note downloaded from the internet detailing the event is attached to this Writ Petition as **Annexure P 12.**
17. Various studies have found that DNA from GM material can persist in the environment and is not completely broken down by processing, decomposition or digestion.. Antibiotic resistance genes may escape from both silage and manure to bacteria in the gut and in the environment. GM animal feed serves to greatly increase the potential for new strains of antibiotic resistant bacteria, a hazard, which adds to the growing global threat of multi-drug resistant bacteria. Furthermore, antibiotic resistance genes have the potential to spread in our environment via horizontal gene transfer, to other bacteria, making it very dangerous. A copy of the article titled "GMOs: Genetically Modified Food and Animal Feed What Have We Learned", authored by Dr. Harsh Narang, a leading expert with more than thirty years of field research behind him and who held a crucial position as a government scientist at the United Kingdom Public Health Service Laboratories, is

attached to this Writ Petition as **Annexure P 13**.

18. The UK Ministries of Agriculture Fisheries and Food (MAFF) too, has recommended that: "In view of the potential health impacts due to the secondary horizontal transfer of transgenic DNA on livestock and human beings, all current animal feed should be withdrawn immediately. Steps should be taken to ensure that no GM material is fed to animals directly or incorporated into commercial animal feed". A copy of the article that reports the study is attached to this Writ Petition as **Annexure P 14.**
19. Recent studies have proved that the GM plants containing viral inserts (as transgenes or promoters) may lead to HGT, which makes it an inherently hazardous technology. The study by Jonathan Latham, PhD and Ricarda Steinbrecher, PhD on HGT published as a Technical Report titled "HGT of viral inserts plants from GM plant to viruses" is attached herewith as **Annexure P 15.**

Other Safety Concerns with GM Foods

20. GM Food Raises Serious Safety Concerns. In the only systematic investigation on GM food ever carried out in the world, 'growth factor-like' effects were found in the stomach and small intestine of young rats that were not fully accounted for by the transgene product and were hence attributable to the transgenic process/construct. This was the finding of the multi-centre collaborative research conducted by the public-funded Rowett Institute of the UK, under the co-ordinatorship of Dr. Arpad Pusztai, a leading nutritionist and an eminent toxicologist. At the start of this project in 1995, there wasn't a single paper published in peer-reviewed scientific journals on the biological evaluation of GM foods. These effects could not be replicated by supplementing the parent line potato diets with GNA, the natural gene product, given at the same level as expressed in the GM potato. The conclusion therefore seems inescapable that it was not the GNA but the genetic technology itself that caused the harm. According to Dr. Pusztai, "one of the major omissions in present day GM risk analysis is that no attempt has so far been made to investigate this obvious link between GM food and intestinal tumour development. Further, " full reproductive experiments (are required) in which the reproductive performance of both male and female rats fed on GM- versus non-GM diets should be monitored for several generations because any problems with reproduction could have disastrous consequences for the environment. Despite official denials by the USDA that this had nothing to do with GM but that it was caused by a mould contamination of the corn, curiously, the same problem did not seem to occur with non-GM corn". A copy of the peer-reviewed article published in the Lancet titled "Effects of diets containing GM potatoes expressing Galanthus nivalis lectin or rat small inetstine" is dated October 1999 attached to this Writ Petition as **Annexure P 16.**
21. Various studies also demonstrated that GM crops grown in the land were not only harmful to beneficial insects like ladybirds but could also harm other and higher life forms, including mammals, domesticated or wild animals, birds and ultimately man, both in the short- and long-term. When GM crops are grown widely it will be unavoidable that both domestic and wild animals will have to ingest them. As most of first generation GM crops have been developed using the same unpredictable gene transfer technology as that used for GM potatoes, it can be expected that the health damage found with these could also generally occur with other GM crops. Consequently, animal health will be massively compromised leading to a major disruption of the ecological steady state balance. This is so because the problems encountered in the study of 'growth factor-like' effects on young rats, was attributed most likely, to the CaMv (cawliflower mosaic virus) viral promoter, a promoter spliced into nearly all GE foods and crops and may hence be general to all GM food. Evidence suggests that the CaMv 35S promoter might be especially unstable and prone to horizontal gene transfer and recombination with all the attendant hazards: gene mutation, cancer, re-activation of dormant viruses and generation of new viruses. This promoter as mentioned, is present in most GM crops being grown commercially today.
22. That it is relevant that Pusztai was fired from his job after an extremely distinguished career of 35 years in this Institute, due to pressure from the GM industry. No further follow-up studies have been done to ascertain whether GM foods in the market create the same damaging effects as those observed by Pusztai.
23. In a significant study on the potential human health effects due to GE foods, Dr. Pusztai and two other scientific experts in the field Susan Bardocz and Stanley W.B. Ewen stated that, "from the results the conclusion seems inescapable that the present crude method of genetic modification has not delivered GM crops that are predictably safe and wholesome"... "we need to consider that these GM feed, ration-fed animals will eventually be consumed by humans and there is absolutely nothing known about the potential hazards (if any) on human health of this indirect exposure to GM food. There is an urgent need to come up with novel scientific methodologies to probe into the compositional, nutritional/ toxicological and metabolic differences between GM and conventional crops if we want to put this technology on a proper scientific foundation and also to allay the fears of the general public. We need more science and not less. For proper safety assessment our first concern ought to be to establish on a case-by-case basis the impact of components of GM foods on the digestive system, its structure and metabolism, because the way our body will respond to GM foods will be pre-determined at this level. According to The Royal Society (1999) we need 'to refine the experimental design of the research done to date'." A copy of the report is already attached to this Writ Petition as Annexure P1.
24. The statement of Dr. Arpad Pusztai recommends that a minimum of the enumerated investigations must be carried out in the areas of allergenicity, toxicity and nutrition viz.,
    a. the comparison of the GM and isogenic lines should include investigation with novel and up-to-date analytical techniques, such as proteomic analysis (2D electrophoresis and mass spectrometric analysis of relevant components),
    b. a full biochemical, nutritional and toxicological comparison of the *in planta* produced Bt toxin with that of the

original used for the transformation must be done

c. microarray analysis of all novel RNA species in the genetically modified plant must be performed

d. full molecular biological examination should be carried out with particular attention to the possibility of secondary DNA insertions into the plant genome

e. a full metabolomic NMR, etc analysis of the transformed plant is obligatory

f. variation in the amounts of gossypol, cyclopropenoid fatty acids and other toxins related to these should be investigated in Bt cotton grown under different agronomic conditions

g. the stability to degradation by acid or pepsin or other proteases/hydrolases of GM products, foreign DNA, including the gene construct, promoter, antibiotic resistance marker gene, etc, must be established in the gut of animals *in vivo*, and not *in vitro* as done presently.

h. with GM lectins, including the Bt-toxins (*Bacillus thuringiensis* toxin) the presence/absence of epithelial binding in the gut should also be demonstrated by immunohistology.

i. the nutritional, immunological, hormonal properties and allergenicity of GM-products must be established with the gene product isolated from the GM crop and not with the recombinant material from *E. coli* as these two may be substantially different.

25. Dr. Pusztai stated that GM food is unlikely to be highly poisonous and instantaneously deadly. "Toxicity" is therefore an unhelpful and loose concept and in contrast, nutritional studies in which GM crop-based diets are fed to young growing animals should reveal their possible harmful effects on metabolism, organ development, immune and endocrine systems and gut flora which together determine the safety of the GM crop are the most appropriate. Therefore for the next stage in the regulatory risk assessment process an animal testing protocol based on methods already used in animal feedstuff evaluation is necessary. A copy of the statement of Dr. Pusztai for this honourable court titled 'Gaps in the current safety assessment of GM crops/foods – the way forward' is attached to this Writ Petition as **Annexure P17**.

Contamination of milk due to GMOs

25. Recently, Greenpeace, Germany, highlighted the results of a study from the Research Centre for Milk and Foodstuffs in Weihenstephan, Bavaria, which was reportedly "kept under lock and key for three years". It contains the results of a farmer's milk samples that tested positive for GM DNA from Roundup Ready soy and Bt 176 maize. A copy of the article that refers to this incident titled Twin Biosafety Briefings: DNA in GM food and feed" by Dr. Mae- Wan Ho is attached to this Writ Petition as **Annexure P 18.**

26. That the implications for India are particularly relevant. Given the strong evidence for GM DNA in animal feed, including GM cottonseed in animal feed and secondary horizontal gene transfer, the serious risk of GMO contamination of the food chain and its consequences for public health as a result of the GOI approvals of Bt cotton for commercial planting is very grave. Thus, commingling of BT cottonseed cake in animal feed, particularly for milch cattle and the potential for contaminating milk and the next link, processed milk foods, including infant foods, milk powder, butter, cheese etc, is a most immediate danger and a widespread route to the potential contamination of our food chain at this time, with impacts across the whole of India.

27. The significant example of the genetically altered hormone called recombinant bovine growth hormone or rBGH and its serious health effects on cows highlights the problems connected with animal health. Besides, their milk may contain a substance that has been implicated in human breast and stomach cancers. rBGH and its effects are dealt with in a later part of the petition; but it has already taught us a lesson about how a GM hormone can have a devastating effect on both animal and human health and it is one of the most disturbing cases of biotechnology gone haywire.

GM CROPS AND THE ENVIRONMENT

Evidence for Transgenic Contamination:

28. The proven contamination of Mexican corn landraces (traditional maize crops in Mexico from wild species) has raised deep concern among scientists about the consequences of transgenic contamination, precisely because there are such outstanding safety concerns linked with the technology of GE, as has been enumerated in the foregoing sections of this Suit. In November 2001, Berkley plant geneticists Ignacio Chapela and David Quist presented evidence of transgenic contamination of the landraces. The report was published in Nature, but subsequently withdrawn under pressure. Dr. Chapela was discredited and his university tenure terminated. Subsequent research by scientists confirmed that the contamination was much more extensive that previously suspected. 95% of the sites sampled were contaminated, varying from 1%-35%, averaging 10%-15%. The issue of the Mexican landraces is particularly important for a number of reasons: (a) Mexico has in place a moratorium on GM crops (since 1998). Therefore the contamination of the landraces could only have occurred from GM corn crops originating from the US; (b) The rapid dispersal of transgenes to Mexico only a few years after their first commercial use in the US must serve as a dire warning to India of how easily transgenic contamination can take place and with what impacts, because Mexico is the centre of corn diversity and Teosinte, the crops wild progenitor grows alongside in Mexican cornfields. Whatever novel genes are found in Mexican 'landraces' are also likely to be transferred into the Teosinte plants via pollen. Reference in this regard can be found in footnote 83 & 86 of the report of the Union of Concerned Scientists titled Gone to Seed, already attached to this Writ petition as Annexure P 7. This is particularly relevant to India as it is the centre for rice diversity; (c) The GM companies involved have refused to provide molecular information or probes for research, which would sort out which are the

parties liable for the damages caused. (d) Even more serious than the issue of contamination is the possibility that because the transgenic constructs were unstable, (the unstable CaMV), they could be fragmenting and scattering throughout the genomes; this is known to cause DNA rearrangements, deletions, translocations and other disturbances, which could destabilise the genomes of the landraces, driving the landraces towards extinction (All the transgenic maize constructs that might have been responsible for the contamination contained the CaMV 35S promoter, which was why the promoter could be used to test for transgenic contamination).

29. Transgenic contamination is not limited to cross-pollination. New research shows that transgenic pollen, wind-blown and deposited elsewhere, or that has fallen directly to the ground, is a major source of transgenic contamination. Such transgenic DNA was even found in fields where GM crops have never been grown, and soil samples contaminated with pollen were demonstrated to transfer transgenic DNA to soil bacteria. The source of the aforementioned information the report of the Independent Science Panel already attached to this petition as Annexure P 4. The ISP had stated unequivocally "that transgenic contamination is unavoidable and there can be no co existence between GM and Non-GM agriculture. Most important of all, GM crops have not proven safe"— "and if ignored could result in irreversible damage to health and the environment"

GM crops harmful to Wildlife

30. Significantly, a four-part series of experiments conducted over 3years by the Royal Society for the Protection of Birds and the Centre for Ecology and Hydrology, Lancaster in the United Kingdom, concluded that GM crops could be more harmful to many groups of wild life than their conventional equivalent. A copy of the news story titled "The end of GM crops" in the Independent dated 22.03.2005 reporting the studies are attached to this Writ Petition as **Annexure P 19.** The experiment confirms the fact that Bt. proteins, incorporated into 25% of all transgenic crops worldwide, have been found harmful to a range of non-target insects, worms and amphibians. Some of them are also potent immunogens and allergens.

31. In a significant field experiment reported recently, scientists from the University of Pittsburg, found that glyphosate and the Roundup herbicide that contain it, and is used on most herbicide resistant crops is lethal to amphibians. "The most shocking insight coming out of this was that Roundup, something designed to kill plants, was extremely lethal to amphibians," said Relyea, who conducted the research at Pitt's Pymatuning Laboratory of Ecology. "We added Roundup, and the next day we looked in the tanks and there were dead tadpoles all over the bottom." A copy of the press note of the University titled "Herbicide runoff is lethal to Amphibians" dated 04.04.2005 is attached to the Writ Petition as **Annexure P 20.**

GM crops and increasing herbicide use

32. That the reality has been contrary to the claims of the GM industry that GM crops lead to a major reduction in pesticide use. Scientific data shows that overall, GM crops have led to an increase in pesticide use, financially hurting farmers and harming the environment. The report of the Independent Science Panel, mentioned earlier and annexed to this petition effectively documents this. Further, the technical report of Dr. Charles Benbrook, former Executive Director of the Board on Agriculture of the U.S. National Academy of Science for seven-years, further corroborates and confirms this evidence. Dr Charles Benbrook in his latest technical report, drawing on 9 years of US Dept of Agriculture data, has concluded that the use of GM crops in the USA hasled to an overall increase in pesticide use involving an amount of 122 million pound since 1996. A copy of the press note downloaded from the internet titled "Benbrooke report on pesticide use on GM crop in the first nine years" dated 25.04.2004 is attached to this Writ Petition as **Annexure P 21.**

33. Argentina's experience in this regard is a warning to India. Argentina used to be one of the world's major suppliers of wheat and beef, but the wholesale shift to mainly GM soy of half of the arable land, i.e. 11.6 million acres changed all that. Roundup Ready (RR) soy growers were using more that twice as much herbicide as conventional farmers and in 2003 used an estimated 150 million litres or a 10fold increase in 5years. The warnings to GM soy growers has fallen on deaf ears but are now being fulfilled, including changes to soil microbiology. Slugs, snails and fungi are moving into the newly available ecological niche. Charles Benbrook says: "Argentina faces big agronomic problems that it neither has the resources nor the expertise to solve. The country has adopted GM technology - "based on the current use of RR I don't think its agriculture is sustainable for more than a couple of years". Argentina demonstrates a grim lesson that the new and untested technology of GM provided by multinational companies increases a country's vulnerability and agriculture and food security are seriously threatened and undermined. A copy of the news report titled "Argentina's Bitter Harvest" in the New Scientist dated 17.04.2004 is attached to this Writ Petition as **Annexure P 22.**

34. The increase in herbicide use on HT crop acres should come as no surprise. Scientists have always known that resistance would occur. Weed scientists have warned for about a decade that heavy reliance on HT crops would trigger changes in weed communities and resistance, in turn forcing farmers to apply additional herbicides and/or increase herbicide rates of application. The ecological adaptations predicated by scientists have been occurring in the case of Roundup Ready crops for three or four years and appear to be accelerating.

35. In March 2000, the WWF published one of the most extensive reviews relating to GE crops titled "Transgenic Cotton: Are There Benefits for Conservation?". The review concluded, that the technology has been "misrepresented in ways that suggest, that genetic improvement can take the place of management and skill in solving pest problems. This may explain in part why farmers have so readily adopted the technology to the degree that they have". Reference in this

regard can be found in review on the report on the WWF review titled "GM Cotton - No Reduction In Pesticide Use" dated 28.11.2000 attached to this Writ Petition as **Annexure P 23.**

The Need for safety Testing

36. That it is clear that genetic engineering is fundamentally different from traditional breeding. Expert scientist Dave Schubert (head of the Salk Institute's Cellular and Neurobiology Lab) has strongly advocated mandatory safety testing for genetically engineered food in the USA because of the fundamental difference between genetic modification and traditional breeding and citing various adverse effects. Such tests are equally necessary for India, for the release of any GMO into the Indian environment. It is matter of grave concern that there are very few established protocols for assessing the potential health impacts of GE crops. David Schubert says: "instead one finds loose guidelines that in most cases only list certain tests or procedures without specifying how they are to be conducted". "As a result biotech companies have been free to devise procedures of their own choosing that often vary markedly from tests conducted by independent researchers". David Schubert and William Freese outline a peer-reviewed safety-testing protocol, which addresses the unique risks posed by the GE process and better protect public health. In the absence of such studies, it is not possible to identify errors or intentional deception and get at the facts about the safety of GM foods. A copy of the peer-reviewed article by William Freeze and David Schubert published in Biotechnology and Genetic Engineering Reviews is already attached to this Writ Petition as Annexure P 8.

PRECAUTIONARY PRINCIPLE

37. Such compelling evidence suggests that the technology of GE is a fit case for the application of the Precautionary Principle. The precautionary principle necessitates that if there are reasonable scientific grounds for believing that a new process or product may not be safe, it should not be introduced until we have convincing evidence of reasonable certainly of no harm. The principle can also be applied to existing technologies when new evidence appears, suggesting that they are more dangerous than what society had previously expected; as in the case of cigarettes, CFCs, greenhouse gasses and now GMOs. Then, it requires that we undertake research to better assess the risk and that in the meantime we should not expand our use of the technology and should institute measures to reduce our dependence on it. If the dangers are considered serious enough, then the principle may require us to withdraw the products or impose a ban or a moratorium on further use.

38. This Hon'ble Court in A.P. Pollution Control Board versus M.V. Nayudu [1999 (2) SCC 718] held that that precautionary principle is applicable to India. The principle mandates that when a new technology or process can cause serious and irreversible harm to human health and the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context, the proponent of the novel and uncertain activity rather than the public should bear the burden of proof. As, if one is embarking on something new, one should go ahead only and until one is reasonably convinced that it is safe. Pushing forward with untested, inadequately researched technologies, and insisting that it is for the society to prove conclusively that they are harmful before they can be stopped, is self defeating and extremely dangerous.

39. That this is a fit case to employ the Precautionary Principle. There is adequate scientific evidence in terms of research carried out in various parts of the world, to at least doubt the safety of the process of Genetic Engineering. That this evidence has emerged despite active efforts by the GM industry to stifle independent scientific research and systematically dismantle regulatory mechanisms in various important countries in the world including India. Hence, it is submitted that it is in the public interest that the precautionary principle be employed and a moratorium be ordered on any further release, till there is reasonable certainty of the safety of such releases, through independent scientific studies. That it is submitted that such studies would in the normal course take a number of years, akin to the scientific studies mandatory before the approvals given for pharmaceuticals. It is submitted that such a moratorium should also be accompanied with isolation, destruction and recall of the GMOs that have already been released, to the extent that is possible. It is instructive that the proponents of the technology also refuse to accept liability. The implication therefore is, that, if the technologies turn out to be hazardous, as in many cases they have, the rest of society is left to pay the penalty.

FLAWED CORPORATE TESTING & FLAWED CLEARANCES UNDER THE US REGULATORY SYSTEM

40. In its official statements, the FDA carefully avoids vouching for the safety of GE foods, which is consistent with its voluntary review process. Clearly, however, this is not the case with communications with food additives or drug companies. In these cases, the agency conducts an exhaustive review or a full set of required studies on the product, then, either approves or rejects it on its own authority. The following represent significant examples of flawed testing procedures by biotech companies which are ignored by the FDA: (a) GE companies rarely test the transgenic protein actually produced in their GE crops but instead they make use of a bacterially-generated surrogate protein. Says David Schubert, "testing for a bacterial protein should not substitute for testing the plant-expressed proteins" for various important reasons and that "immunologic differences between the plant-produced and bacterial surrogate proteins could haves serious medical consequences". The Starlink case used a surrogate protein, and so does MON810, which was approved and about which more will be said; (b) Inherent to the process of GE is the creation of 'unintended effects' including "over-expression" of the gene and excess lignin production etc., as explained earlier in this Suit. These issues were recognised by FDA scientists in the early 1990s but their recommendations to require appropriate

testing were overruled; (c) Neither the EPA nor the FDA demanded characterisation of the novel Bt fusion protein apparently produced by Mon810; the records point to deliberate deception, cover-up of the true facts of the case. This is a particularly troubling example because the US FDA responsible for food safety has "fundamentally flawed molecular characterisation data on such a widely planted GE crop"; (e) the EPA plays a critical role in the introduction of HT plants by raising or establishing tolerance levels for herbicide residues on crops. In 1992, Monsanto successfully petitioned the EPA to raise the tolerance levels for glyphosate residues on soybeans from 6 to 20 ppm (EPA rule, 1992). This anticipated the introduction several years later of glyphosate-tolerant soybeans, which use higher levels of glyphosate than conventional soybeans. Reference to these facts may be made in peer reviewed article of William Freeze and David Schubert already attached to this Writ Petition as Annexure P 6.

41. Biotech companies frequently deny access, or allow strictly conditioned access, to data on crop materials on the basis of confidentiality, making it impossible for regulatory authorities and independent researchers to verify or review test claims on the safety of GE crops and foods. The following incident is a good example of how dangerous and flawed the regulatory process is, even in Europe with Governments seeming to side with the industry in opposition to their own scientists' advice on safety assessment. In 2003, the French commission for bioengineering, the CGB refused approval to Monsanto's MONS 863 corn because of a study showing rats developed several abnormalities. (The EFSA European Food Safety Authority overturned this decision). Gerard Pascal, Director of Research at the National Institute of Agronomic Research, is reported by Le Monde as saying, "...what struck me in this file is the number of abnormalities. I never saw that in another file." In April last year, Greenpeace asked the German regulatory authority for the report (which it only became aware of from the Le Monde story). The supporting Monsanto dossier held by EFSA, and the report on a 90-day rat feeding study, are treated as secret, as is a review document by Dr Arpad Pusztai, commissioned by the German competent authority. His review has not been released and he is effectively "gagged" and prevented from either revealing his findings verbally or issuing copies of his report. Monsanto has refused to release the government body from the confidentiality agreement it had signed. This facts can be referred in article titled "Evaluating the acceptability of GM crops: the scope for autonomy in developing countries" by Erik Millstone in the Journal SciDev in January 2005 is attached to the Writ Petition as **Annexure P24**. These facts point to the importance for India to ensure that there is full disclosure by law of product material and data for examination by the scientific community of each GMO that is required to be tested according to the laid down biosafety testing protocol.

Flawed Clearances of Two Products with Dangerous Health Risks: The Cases of Recombinant Bovine Growth Hormone and Aspartame

42. Two examples nail the US FDA for its failure to safeguard the health of the US public and point conclusively to just how compromised is this much- vaunted US institution and watchdog of public health: they are recombinant bovine growth hormone or r BGH and Aspartame, the 'sweetner' used in nearly all foods and soft drinks, promoted as a healthy alternative to sugar. Both are Monsanto products. Aspartame is not necessarily genetically engineered, and it is not known when it is and when it isn't; but its inclusion demonstrates very starkly just how irresponsible and untrustworthy the FDA has become and how keen it is to toe the industry line, to the exclusion of its prime role as a health regulator.

43. **Recombinant Bovine Growth Hormone** (rBGH or rBST) is a genetically engineered drug produced by the Monsanto Corporation. It is injected into dairy cows and induces them to increase milk production by 5-15. The FDA approved Monsanto's genetically engineered cattle drug, Bovine Growth Hormone (rBGH), despite being in possession of a substantial amount of scientific information on the grave dangers it presents to human and animal health. The confidential files of Monsanto submitted to the FDA in 1987, revealed evidence of widespread pathological lesions, infertility, and chronic mastitis of cattle given the drug. Also, cows hyper-stimulated by repeated rBGH injections, were found to be seriously stressed.

44. The above data was leaked to the public as a result of which, in 1990, the House Committee of the U.S. Government carried out an investigation and charged "that Monsanto and the FDA have chosen to suppress and manipulate animal health test data — in efforts to approve commercial use" of rBGH. This charge is also consistent with the Committee's 1986 report, "Human Food Safety and the Regulation of Animal Drugs." The report concluded: "The FDA has consistently disregarded its responsibility—has repeatedly put what it perceives are interests of veterinarians and the livestock industry ahead of its legal obligation to protect consumers—jeopardizing the health and safety of consumers of meat, milk— –". Even so, despite the damning evidence against the use of the drug, the FDA did not refuse clearance of rBGH and, in 1994 approved the commercial use of Posilac, Monsanto's trade name for rBGH. Overwhelming evidence had already compelled Monsanto to insert a label, which states that the use of Posilac "is associated with increased frequency of use of medication in cows for mastitis" and some 20 other adverse health effects. Reference may be made of these facts from articles attached to this Writ petition as **Annexure P 25 (colly).**

45. Acting on this cumulative evidence, the European Commission entrusted a team of internationally recognized experts to examine the issues. The report of the experts concluded that "avoidance of rBGH dairy products in favour of natural products would appear to be the most practical and immediate "dietary intervention to . . . (achieve) the goal of preventing cancer". A copy of the press report on the facts titled "Monsanto's GM drug stil threatens Public Health" dated 05.02.2005 downloaded from the internet is attached to this Writ Petition as **Annexure P 26.** Based on this evidence, all 25 nations of the European Union have banned rBGH, as have Canada, Australia, New Zealand and Japan. In fact, most industrialized nations of the world have disallowed its use. The U.N. food safety organization, Codex Alimentarius, had declined to

declare the drug safe three times.

46. Aspartame is the generic name for the brands 'Nutrasweet' and 'Equal'. Given clearance by the FDA in 1993, a $350-million class-action lawsuit has now been filed in order to prove how deadly aspartame consumption truly is to the human body. Also included in the lawsuit, is the central role, played by Donald Rumsfeld, current United States Secretary of Defence, in helping to get aspartame approved through the Food and Drug Administration. A close examination of the process for approving aspartame by the FDA provides an example of how powerful corporations are influencing once trusted institutions. The documentary "Sweet Misery, A poisoned World" is annexed to this Writ Petition. Loaded with compelling interviews, this powerful examination includes:

i) Archival footage from G.D. Searle, the producer of aspartame, and federal officials to describe the amount of propaganda and "dirty tricks" big business used to push aspartame on the market.

ii) Key dialogue with Arthur Evangelista, a former Food and Drug Administration investigator, who exposes how far major conglomerates went to legalize the use of aspartame in the United States, and the resulting domino effect on its use in other countries.

iii) Consumer attorney jim turner's candid report of his exchange with Donald Rumsfeld. Rumsfeld was the ceo of SEARLE, and, at the same time, part of Reagan's transition team when the FDA's board of inquiry was overruled to allow the marketing of aspartame as a food additive, until this time aspartame was unanimously rejected by the FDA.

47. Not long ago, aspartame was on a Pentagon list of bio-warfare chemicals submitted to Congress — yet this lethal product remains on grocery shelves. Aspartame complaints represent 80-85% of food complaints registered with the FDA. So-called "diet" products containing the chemical sweetener aspartame can have multiple neurotoxic, metabolic, allergenic, foetal and carcinogenic affects. The FDA's own report has recently come to light, prized from their reluctant grip. It is a self-confessed list of 92 documented symptoms triggered by aspartame from 4 types of seizures to coma and death. In Operation Desert Storm, US troops were 'treated' to liberal quantities of aspartame-sweetened beverages, which 'cooked' in the Saudi Arabian desert to temperatures over 86 degrees F. Many of them returned home sick with symptoms characteristic of formaldehyde poisoning. In a 1993 act that can only be described as "unconscionable", the FDA approved aspartame as an ingredient in numerous food items that would always be heated to above 86°degrees F (30°Degrees C). Much worse, on 27 June 1996, without public notice, the FDA removed all restrictions from aspartame allowing it to be used in everything, including all heated and baked goods.

48. The Aspartame clearance by the FDA is a prototype of the GM clearance in three respects: (a) it reveals one of the most pervasive, insidious forms of corporate 'negligence' since tobacco (b) Like the tobacco story, it horrifically attempts to put the burden of proof with regard to toxicity on consumers (c) safeguarding Public Health is the FDA's raison detre, but curiously, this is no longer the priority or focus of their actions and objectives. Credible evidence validates corporate fraud, greed, manipulation to further Industry and commercial interests and in the case of GE, an "admitted agenda", as part of a White House directive "to foster the biotech industry" including aggressively pushing the corporate biotech agenda on to other countries through patent monopolies and the resulting dominance of world markets.

49. Further corroboration of the fact that the FDA is a seriously compromised institution, was provided by no less than Dr David Graham, Associate Director for Science and Medicine in the FDA's Office of Drug Safety. His straight forward remarks about the relationship between the regulators and industry was part of his evidence before a hearing of the US Senate Committee on Finance. His remarks have been recorded in and were recently quoted by the Fourth Report of Session 2004–05 of The House of Commons, Health Committee of the UK: ""There was little doubt that, even in the best-resourced regulatory bodies, the pressure on individual employees may become intense when problems arise…The FDA has become an agent of industry. I have been to many, many internal meetings and, as soon as a company says it is not going to do something, the FDA backs down. The way it talks about industry is 'our colleagues in industry'… it is rather because the body is entirely geared towards concentrating on approving drugs, doing little once they are on the market". A copy of the relevant excerpts of the Report of the Committee is attached to this Writ Petition as **Annexure P 27.**

SABOTAGE OF REGULATORY STRUCTURES BY GM COMPANIES

50. That Monsanto, the 90% market leader in GE products, has a track record of sabotaging regulatory regimes of many third world countries, including bribing Government officials to get clearances for the release of GMOs. This was established in the U.S. Courts in the case of Monsanto's business dealings in Indonesia. To achieve this task a consulting company, on behalf of Monsanto, paid huge bribes to Indonesian environmental officials. Monsanto wanted to increase acceptance of GMO crops in Indonesia. Monsanto has admitted to paying over $ 750,000 in bribes to more than 140 Indonesian Government Officials and members of their families between 1997 and 2002, financed through improper accounting of its pesticides sales in Indonesia. Monsanto has also accepted that $50,000 was paid to senior environmental ministry in 2002 in a bid to by-pass environmental controls on GM cotton. Monsanto was subsequently fined $1.5 million by justice department, payable to U.S. Government. The copy of the complaint filed by the United States Securities and Exchange Commission in January 2005 and copies of the newspaper reports has been annexed herewith as **Annexure P 28 (colly).**

51. Monsanto has also been found tampering with data in Andhra Pradesh where Bt. cotton has failed drastically. According to Greenpeace, Andhra Pradesh, one of the most proactive states in safeguarding the rights of cotton farmers, responded

to the increase in farmer suicides by introducing a Memorandum of Understanding, with the primary aim to arbitrate cases involving seed companies and farmers and to provide quick relief to the latter. Repeated failure of Bt. cotton in the state in 2002-03 and 2003-04 caused the government to make Monsanto-Mahyco accountable to the farmers for losses in Bt. cotton. While the data in the original report reveals the comprehensive failure of Bt Cotton in Andhra Pradesh, a second, visibly tampered-with version exaggerates the yields, thereby reducing Monsanto's compensation burden by nearly Rs. 2 Crore. The fact that data has been so clearly manipulated in this case raises serious doubts about the authenticity of any data that GEAC would use to review Bt Cotton. The copy of these documents which clearly indicate how Monsanto has been manipulating data collected by the Government of Andhra Pradesh, as were procured by Greenpeace have been annexed herewith as **Annexure P 29 (colly).**

52. That the decision of the GEAC (Genetic Engineering Approval Committee), the regulator that is responsible for approvals for the commercial release of GMOs, in the matter of the clearance of Bt cotton in India, conflicts with its own stance and is inexplicable; thereby revealing not only a genuine lack of clarity in the mind of the regulators but also the abject opaqueness of the process of regulation. The GEAC by its order dated 18.10.2001 directed the destruction of the entire standing crop of transgenic Navbharat- 151. In this case Navbharat-151 seeds were found to be transgenic cottonseed and was being sold without bio-safety clearances. GEAC vide its above mentioned order directed the uprooting and burning of the entire crop, and also directed that the cotton and the seeds harvested by the farmers from Navbharat-151 be recovered along with the plants and burnt; seed production plots were to be destroyed along with the breeding lines, hybrids, and any seed material available with Navbharat Seeds Company. Most importantly, such severe directions, including the uprooting and burning of the entire standing crop were passed solely on the ground that the seeds are transgenic and represent an untested technology, and hence is extremely unsafe. Having admitted the hazards of the technology of transgenic seeds, it is inexplicable that, the required Biosafety tests are not carried out independently by the regulator. That within five months of passing severe restrictions and asking for uprooting and burning of the entire standing crop, the GEAC gave permission for commercial release of Bt. cotton to MAHYCO, the Indian subsidiary of Monsanto. A copy of the order of the GEAC dated 18.10.2001 is attached to this Writ Petition as **Annexure P 30.**

53. Even the circumstances surrounding the initial approvals of Bt. Cotton in India are highly dubious. The Review Committee on Genetic Monitoring (RCGM), under the Department of Biotechnology, is a body that did not have the jurisdiction to grant permission for release of GMOs into the environment, and is under a department, which is primarily responsible for promotion of such untested Biotechnology. It was originally the RCGM who illegally permitted the release of the GMOs into the country for the first time. It was only when there was a public outcry over the serious illegality of these clearances, attempts were made to then get the release of such GMOs cleared, retrospectively.

54. In this regard, the recent report by a major US financial risk assessor, Innovest is instructive on the manner in which the Biotech companies and government regulators have sabotaged bio-safety regulatory structures. It states that "It is understandable that the US Government has essentially taken the industry position on GE safety and labelling.... US Government support for GE crops appears to stem from the fact that the crops are mostly US-developed and that GE companies have made substantial financial contributions to US politicians and political parties. This is not said as a criticism of politicians, but rather of the campaign finance-system, which allows politicians to accept money from the firms they are supposed to regulate. Money flowing from GE companies to politicians as well as the frequency with which GE company employees take jobs with US regulatory agencies (and vice versa) creates large bias potential and reduces the ability of investors to rely on safety claims made by the US Government. It also helps to clarify why the US Government has not taken a precautionary approach to GE and continues to suppress GE labelling in the face of overwhelming public support for it."

55. That it is the recognition of these issues that forms the basis of the refusal of Insurance companies to underwrite the risks entailed by this technology. Agricultural insurance policies of most insurance companies in the world, including NFU Mutual, the UK's largest agricultural insurer, specifically exclude cover for "any liability arising from the production, supply, or presence on the premises of any genetically modified crop, where liability may be attributed directly or indirectly to the genetic characteristics of such crop".

56. That the influence that the GM industry has managed to exert over regulatory structures is insidious for the subtle ways which are employed, which include regulator 'education', awareness etc. For example in India and many other developing countries, organisations which are substantially funded by the biotech industry have sought to influence regulatory and other decision making processes by conducting "awareness" and "educational" programmes. The Press report of activities in India in January 2001, of an organisation that calls itself the Einstein Institute for Science, Health and the Courts, based in the United States of America, well illustrated this point. The Report in The Hindu dated 05.01.2001 is attached to this Writ Petition as **Annexure P 31.**

57. That the Government of the United States of America has been a handmaiden to the GE Industry is clear from the manner in which various developing and developed countries have been arm-twisted to take a pro-GM stand. In April 2004 Angola expressed apprehensions for the safety of its citizens health and environment due to GM food aid. The World Food Programme, of the UN and clearly influenced by the US effectively denied food aid to Angola, with the objective of coercing the Government of Angola to retract its decision of banning import of GM products. The press note that points to these facts titled "GM Food Aid pressure on Angola again" dated 26.01.2005 is attached to this Writ Petition as **Annexure P 32.**

58. That it is submitted that the current basis typified by the US system of a "voluntary consultation" process is non-

rigorous and undefined, with regulations that are haphazard. It works to entrench the FDA as the handmaiden of the biotech industry. In the US, the provision of and process under GRAS status through which GE products are cleared, is unacceptable and dangerous. What is crucially required instead, is a safety-testing regimen that will detect potentially harmful changes in GE foods and crops and their environmental impacts, through a mandatory, science-based, testing protocol by independent agencies. The Independent Science Panel, consisting of scientists from eleven countries, encompassing disciplines of agro-ecology, agronomy, biomathematics, botany, chemical medicine, ecology, epidemiology, histopathology, microbial ecology, molecular genetics, nutritional biochemistry, physiology, toxicology and virology, wrote an open letter to the Commissioner of the FDA in late 2004. The letter is cogent with reasons on why a "voluntary consultation" is inappropriate and unsatisfactory for checking contamination: and exhorts the FDA to undertake a mandatory science-based review process designed to guarantee that GM crops are safe for food and feed. A copy of the letter of the Independent Science Panel is attached to this Writ Petition as **Annexure P 33.**

59. That it is relevant and significant, that the regulatory structure in India has similarly opted against the path of a mandatory science-based review process designed to guarantee the biosafety of GM crops. That such irresponsible action in the name of regulation has created the erroneous impression that GMOs are safe.

DEVELOPMENTS IN THE EUROPEAN UNION

60. That the European Union has legislated Directive 2001/18/EC, which provides for protection of human health and environment in Europe from adverse effects that may be caused by the deliberate release into the environment of the GMOs. This Deliberate Release Directive (Directive 2001/18/EC) came in to force 17th April 2001. The Directive has set out a system of clearance for such releases, where approval on biosafety grounds, is a prerequisite. The Directive requires uniformity in safety standards for all domestic countries under the jurisdiction of the European Union. A copy of the EC Directive 2001/18 is attached to this Writ Petition as **Annexure P 34**.

61. Following the Directive, the European Commission has also legislated two regulations to implement the provisions of the Directive viz., Regulation (EC) 1830/2003 dated 22 Sep 2003 concerning 'traceability' and labelling of GMOs and the traceability of food and feed products produced from GMOs, as well as Regulation (EC) 1829/2003 dated 22 Sep 2003 on genetically modified food and feed. Copies of the two Regulations are attached to this Writ Petition as **Annexure P 35** and **Annexure P 36** respectively. Further the Federal Republic of Germany has amended its GE Act bringing its legal structure in line with the Directive. A copy of the "Information on the Amendment to Germany's Genetic Modification Act" downloaded from the official website of the Government of Germany, the only available material accessible in English, dated nil, is attached to this Writ Petition as **Annexure P 37.**

INDIA'S OBLIGATIONS UNDER INTERNATIONAL AGREEMENTS

62. The Cartagena Protocol on Biosafety for the Convention on Biodiversity, was adopted in 2002 and came into force on 11 Sep 2003. It is a binding International agreement on Biosafety. India is a signatory and is bound to implement its provisions. Art. 1 of the Protocol lays down the objective to contribute to ensure adequate levels of protection in the field of safe transfer, handling and use of Living Modified Organisms (LMOs or GMOs) that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account the risks to human health. A.2(2) stipulates, that parties to ensure, that the development, handling, transport, use, transfer, and release of LMOs is undertaken in a manner that prevents or reduces risk to biodiversity.

63. Further, A. 10 (6) (Precautionary Principle) necessitates that the lack of scientific certainty due to sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party from taking a decision, as appropriate, in order to avoid/ minimise potential adverse effects. According to Para 9(h) of the Annex III of the Protocol, the parties are bound to to consider information on the location, geographical, climatic and ecological characteristics, including relevant information on biodiversity and centres of origin of the likely potential receiving environments. Annex III of the protocol includes, *inter alia*, the general principles of risk assessment: (i) Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice as well as guidelines developed by relevant international organisations. According to Art. 26 of the Protocol parties may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use, specially, with regard to value of biodiversity to indigenous and local communities. According to A. 23(iii) of the Protocol parties shall consult the public in the decision making process regarding LMOs; while Article (iv) mandates that parties shall make decisions available to the public, but respecting confidential information. Further, A 21 (6) prescribes that the information about a summary of the risk assessment cannot be made confidential. A copy of the Cartagena Protocol is attached to this Writ Petition as **Annexure P 38.**

64. The U.N. Convention on Biological Diversity (CBD), 1992 *inter alia* requires that the contracting parties shall domestically regulate or manage the risks associated with the use and release of LMOs resulting from Biotechnology and which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biodiversity, and the risks to human health [A. 8(g)]; introduce appropriate procedure to require impact assessment of proposed projects likely to have significant adverse effects on biodiversity and to allow public participation in the procedure where appropriate [A. 14]. Further, Article 19 (3) of the CBD had urged parties to consider the need for and modalities of a protocol setting out appropriate procedures in the field of the safe transfer, handling and use of any LMOs that may have adverse effect on the conservation and sustainable use of bio-diversity. A copy of the U.N.

Convention on Biological Diversity is attached to this Writ Petition as **Annexure P 39.**

65. Despite the eroding effects of the insidious relationships between research, regulation and industry, strong public pressure has nevertheless, forced numerous regions of Europe and other parts of world to declare themselves, GM free. Over 58 countries have enacted Biosafety laws to restrict import and commercialisation of GM products and/or require labelling of food containing GM ingredients. More than 100 regions and 3500 sub-regions in Europe, the most important market for such products, have declared themselves GMO-free, and have demanded new European laws to protect them from GM contamination.

TRANSGENIC CONTAMINATION OF THE SEED STOCK IS IRREVERSIBLE AND DANGEROUS AND WILL PRECLUDE CHOICE

66. With the inevitable contamination of the seed stock, which is certain to take place with GE crops, recovering the original genetic stock will be impossible. Thus, Seeds are foundational. If GE should fail, then seeds will be the only recourse; but it will be too late because under the US regulatory system, agencies do not analyse GE crops for food safety, until there is alarming evidence of a safety hazard emerging from the field as happened in the case of Starlink. This is also the process that India has followed with approvals given for Bt. Crops. This means that transgenic crops are potentially available to contaminate the seed supply long before any tests have been made or a decision taken about their safety. In Canada and the US, as a result of 10 years of the commercialisation of GE crops, the whole seed system is contaminated. Dr. Lyle Friesen of the University of Manitoba tested 33 samples of pedigreed, oilseed rape seed stock and found 32 contaminated. The Union of Concerned Scientists (UCS), a non-profit partnership of scientists has in its Report, 'Gone to Seed', sounded the alarm bells ringing on seed contamination, because "the value to the food supply of the seeds entrusted to our generation cannot be overstated" –and that "nothing is more fundamental to agriculture and our food supply than seeds". A study based on tests conducted by two respected commercial laboratories using duplicate samples of seeds of six traditional varieties each of corn, soybeans and canola, found that in one lab fifty percent of the corn and soybean, and hundred percent of the traditional canola varieties tested transgenic; while in the other laboratory, transgenic DNA was detected in 83 percent of the traditional varieties of each of the three crops. The Starlink episode given in evidence in the early part of this Suit, demonstrates just how easily contamination can happen and how difficult and expensive any damage control exercise is, without any surety thereafter that the system has been cleaned up. This petition has provided evidence that Starlink is still in the US system. A copy of the UCS report "Gone to Seed" is already attached to Writ Petition as Annexure P 7.

67. Genetic engineering cannot create seeds from scratch. It is vital to understand that biotech companies need enormous quantities of seeds to engineer their patented manipulations and then supply GM seed to farmers, worldwide. For this purpose they have bought out virtually every major seed supplier in the US so that sourcing seeds from non-gm sources is getting increasingly difficult for US farmers. Seed contamination offers genes and gene products surreptitious paths to new environments. In most cases neither seed sellers, nor farmers would be aware of the contaminant. In India where there has been no mechanism instituted by the GOI to segregate Bt cotton from non-GM cotton, the risk of seed contamination seems inevitable.

US Transgenic Contamination of Farmlands and Seeds: The Implications For India

68. In the US, much of the non-engineered grain and oilseed is contaminated with varying levels of genetic sequences derived from GE varieties, as mentioned in paragraph 81. This would not matter if export customers were willing to eat GE foods. But this is not the case. In the first official test of public opinion in the National GM Debate in the UK, 80% of Britons are opposed to GM crops and only 2% will eat GM food. (London Times, 25th Sept. 2003). Worldwide, 90% of the world's consumers are demanding mandatory labelling of GE foods; the logical conclusion being that people want to know so that they can avoid buying them. Even in the US, there is increasing consumer rejection of GM foods. Several polls in the USA have shown that a significant percentage of people - up to 58% - would not eat GM foods if they were labelled as such. In the past year, 79 towns in Vermont passed resolutions against GMOs while the State government passed a seed-labelling bill, the first of its kind in the USA. In California, Mendocino County passed the first law in the USA to ban GMO releases into the environment; and other counties have followed suit.

69. That in the light of this, the US is aggressively marketing GE foods in other countries and promotes GM food by actively blocking labelling laws that prohibit or require foods to be labelled for GM content. For example, the EU is facing enormous pressure by the US to relax its rules with regard to establishing minimum thresholds for unintended or technically unavoidable traces of GM content in US imports. The fact is that at 0.1% of GMO contamination, co-existence of GM and Non-GM cultivation would not be possible. A study commissioned by the European Union was conducted to ascertain the question of consumer choice in the presence of GE crops, because consumers are demanding a "reasonable degree of choice between GMO and non GMO derived products, keeping in mind that different modes of agriculture are not naturally compartmentalised." The study was done for three crops, for which GM crops are available in the European Union, oil seeds for seed production, maize for feed production and potatoes for consumption. The conclusion reached was that "it is virtually impossible to have coexistence with thresholds in the region of 0.1% in any of the scenarios concerned". A copy of the summary of the findings of the report of the European Union titled "Coexistence in European Agriculture" is attached to this Writ petition as **Annexure P 40.**

The Right To Choose: Farmer and Consumer Choices

70. That it is clear from the evidence provided, of the many ways that contamination does take place, that for India, the only way to safeguard and implement a moratorium on the release of any GMO into the environment, until adequate biosafety tests demonstrate safety beyond reasonable doubt, is with concurrent mandatory labelling for "no GM content" for imports sourced from countries which produce GM crops and foods. The route for example to the contamination of India's seed stock, will be through the import of seeds for planting and via bulk commodity imports which are made up of viable seed.

71. We eat for nourishment and vitality and the food we eat is made into our bodies. Our health and nutrition are inextricably tied in with seed quality, variety and abundance. This is what farmers have traditionally provided and in India, continue to provide. With GE foods and crops, the fundamental right to make food and health choices is removed entirely from the ambit of choice. This is so because transgenic contamination is irreversible. Therefore, both the moratorium and labelling must be concurrent mandatory requirements. There are other very important reasons why consumers need to know what they are eating. (a)They need to know, so they know what to avoid. (b)Food allergies are a serious concern. (c)There are also religious and ethical concerns of particular relevance to India, since genes from animal sources are being incorporated into food products, including human genes into rice.

72. That, farmers have the right to save seed for sowing in the next season, which a patent-based regime of GM seeds, controlled by multi-national biotech corporations, will effectively deny. That, farmers also have the right to respond to consumer choice and produce food according to what the market demands. It is pertinent in this connection that the India Economic Survey 2004-5 asked the question whether India can afford to grow GM crops. Referring to the exports of oil cake for feed, the survey said that its growth was sustained and increased on account of its non-gm content. The animal feed market is enormous and demand is growing for non-gm soy and cottonseed cake. Most of the world's 70 million acres of GM crops is for this purpose and this market is already being seriously threatened by the option of non-gm feed. India is one of the few countries that can meet this demand. It is for this reason that the Parliamentary Standing Committee on Agriculture, on 25 April 2003 asked the Union Government to re-evaluate the economic viability of Bt. Cotton. A copy of the news report titled "Bt. Cotton remains highly controversial in india" dated 01.05.2003 is attached to this Writ Petition as **Annexure P 41.**

73. That Indian farmers therefore, have as never before, an economic opportunity and comparative advantage created by the GM fiasco, to respond to a domestic market, as well as a robust and expanding global market demand for organic products including medicines, which are critical for Indian systems of medicine, as well as non-gm conventional crops of food and feed, because the world does not want to eat GM food. This choice must be retained as a fundamental right and for better farming prospects and livelihoods. The key organic standards by definition mean non-GM. Pressure is growing as demonstrated above, for animal feed to likewise, be non-GM. Without a moratorium and mandatory labelling as defined, farmer rights to save seed and choose what they want to grow will be effectively denied, along with the unravelling of India's agriculture, which is essentially based on small holdings; and India's food security will be threatened. American farmers are in a serious crises and the process by which GM has de-stabilised farming in the USA is adequately described in the press note of the ISIS titled "Monsanto vs Farmers" dated 28.04.05 attached to this Writ petition as **Annexure P 42.** The recent response of Renate Kuenastof, the German Consumer Protection Minister, during an interview she gave to Spiegel International in the context of the banned US GM corn variety into Germany, is key evidence of and an accurate pointer to the trends in consumer choice round the world in so far as GM food and feed is concerned and how she sees Germany's role in responding to this choice:

"Organic farming has already created 150,000 jobs in Germany alone. A study by Ernst & Young showed that there are only 2,000 jobs in the sector of agricultural genetic engineering. And our clear-cut requirements — security, labelling, and traceability — have already created an economic advantage, especially in the export sector. Throughout the world, consumers are weary of genetically modified products. Producers know this. For many, abstaining from these products is already paying off". Reference to this may be made from the interview with the German Minister posted as press note dated 18.04.2005 attached to this Writ petition as **Annexure P43.**

74 That the Indian Government has made various moves to import GM products into India. That various processed foods with GM ingredients like US corn, Canadian mustard etc are already available in India. A news report of the statement of Mr. Sharad Pawar, the Union Agricultural Minister on the move to import GM oil seed titled "India may import GM oil seeds" dated 18.01.2005 is attached as **Annexure P 44** to this Writ Petition. The Government is also reported to be planning to import 5.2 million tonnes of vegetable oil in the year ending in 2005. Dealers estimate that soy oil imports this year will total 30-35% of the total edible shipments, including 350,000 to 400,000 tonnes from Argentina and Brazil, in April and May alone. A copy of the news report in the Economic Times titled "Soya oil imports eat into demand for palm oil" dated 05.04.2005 is attached to this Writ Petition as **Annexure P45.** It is very clear that the Government has not only ignored concerns of Biosafety, but also has no plans to require, that only GM free products will be allowed into the country. The Soy from Argentina based on the evidence provided in this Suit will by definition be either GM Soy or contaminated soy. This is because, In a short space of a few years, Argentina has converted 50% of its arable land (11.6 million acres) to growing GM soy, is without regulatory safety testing or labelling mechanisms (The US and Argentina together account for 84% of the GM crops worldwide). India has no scientific facilities to test for GM contamination levels, especially for those that do not survive the development process, as they cannot be tested with PCR-based tests (polymerase chain reaction).

75 That GE projects have been undertaken on more than twenty crops in the country including Brinjal, Cabbage, Caulifower, Blackgram, Chickpea, Groundnut, Muskmelon, Rice, Okra, Cotton, Potato, Sorghum, Sugarcane, Tobacco, Sunflower, Tomato, Corn/Maize, Wheat, Chilli and Banana. An inclusive list of such GE foods and crops are attached to this Writ petition as **Annexure P 46**.

76 That all these aforementioned projects in India have been carried without any meaningful examination of the Biosafety implications of their release.. The statutory framework for the regulation of such release is provided by "Rules for the Manufacture, Use, Import, Export and Storage of the Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989" under the Environment Protection Act, 1986. That no guidelines or practice have been stipulated by the GEAC, the body responsible for clearances, to conduct independent scientific examination of the Biosafety implications of the release of GMOs. A copy of the "Rules for the Manufacture, Use, Import, Export and Storage of the Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989" is attached to this Writ Petition as **Annexure P 47.**

77 According to Dr. P. M. Bhargava, the world eminent bio-scientist, who also founded the Centre for Cellular and Molecular Biology based in Hyderabad, the following tests are absolutely necessary for any meaningful Biosafety risk assessment before the release of any GMO into the environment:

- Molecular characteristics of the GMO with complete information on the site and sequence of every genetic change that has occurred in the GMO.
- Details of the technology, with all steps clearly stated, that was used to effect the above-mentioned genetic changes (intentional and unintentional).
- Automated karyotyping and gross chromosomal analysis.
- Details of plasmids, transposons or insertion elements introduced.
- Properties of the products of gene(s) considered to be introduced (allerginicity; toxicity; will it lead to resistance to a micro-organism or pest?).
- Growth characteristics of the GMO (comparison with the starting host organism).
- Nutrient, soil, climatic and other requirements of the GMO (comparison with the host or wild type).
- Nutritional and toxicity studies with the organism or its product that may be intended to be used as food.
- Dispersal patterns of the GMO where applicable, and comparison with those of the starting organisms.
- Gene flow from the GMO under normal ecological conditions.
- If the GMO is a plant, the viability of hybrids (comparison as above).
- If the GMO is a plant, its biomass productivity.
- Gross chemical composition of the GMO.
- Details of any structural or surface changes in the GMO.
- Impact on ecology in controlled field trials.
- Reproductive inferences if any.
- The manner and mode of the use of the GMO (When and where will it be grown, harvested and processed? If it is to be grown in the containment facility, what are the chances of its escape?)

A copy of Dr. Bhargava's article, "GMOs: Need for Appropriate Risk Assessment System" dated April 13 2002, is attached to this Writ Petition as **Annexure P 48.** That most of these aspects were not considered for the examination of safety risks before any release of the aforementioned GMOs in India.

78. Thus what is required in a proper regulatory regime for approval of GMOs, is the following:

a. The regulatory authorities must prepare a list of the biosafety tests that are required, for each GMO that is to be examined.

b. The above list of tests should be prepared in a transparent manner with an opportunity for independent experts and citizens to have their say, before the safety protocol is finalised.

c. That independent expert bodies and scientists must carry out these tests and adequate GM materials must be provided by the biotech companies, to the scientists, to enable them to carry out the necessary tests.

d. The test results must be open to public scrutiny and independent experts must get an opportunity to respond. The data given out must be in a manner that can be used by the scientific community.

79. Instead of this, however, the current practice is the following: The commercial company itself is asked to do some testing, the adequacy of which has not been put up for public scrutiny. The test results are also not available for public scrutiny and to top it all most of the testing is done by the same biotech company that has a commercial interest in the approval of the GMO. This is entirely without logic and is a clear conflict of interest.

80. That even for technologies which have been tried and tested, and found to be far safer than Genetic Engineering, for instance Hydro-electric projects, the statute mandates a public notice and public hearing before an Environmental Impact Assessment is completed. Hence, it is arbitrary and unreasonable not to have a mandatory public notice and Public Hearing before approvals for the release of GMOs are granted. That the rules do not provide public access to such critical information, or allow public participation in decision making processes, and are in direct contravention of the ruling of this Hon'ble Court in Research Foundation for Science, Technology and Ecology v Union of India [2003 (9) SCALE 303]:

"Clearly the Right to Information and Community Participation necessary for protection of Environment and Human Health is an inalienable part of Article 21 and is governed by the accepted environment principles. The Government and

the authorities have to motivate the public participation by formulating the necessary programmes".

81. However, instead of strengthening the regulatory system, for such an inherently hazardous technology, the Department of Biotechnology, of the GOI, has issued a draft National Biotechnology Development Strategy that proposes to weaken it in order to promote the industry. A copy of the draft strategy of DBT is attached to this Writ Petition as **Annexure P 49** . Responding to this, a large and prominent group of people representing independent scientists, farmer groups, NGOs, organisations, and concerned citizens have signed on a detailed statement, which severely criticises the DBT for a strategy paper that completely mortgages public interest, public safety and the environment, to the commercial interests of Biotech Corporations. A copy of this letter is attached to this Writ Petition as **Annexure P 50.**

82. This Writ petition is filed on the following among other

GROUNDS

A) Release of GMOs into the environment without a Protocol and a transparent, independent, credible and publicly accessible system of testing of the GMOs for Biosafety and environmental hazards is a violation of the Precautionary Principle. This Hon'ble Court had declared in A.P.Pollution Control Board versus M.V. Nayudu [1999 (3) SCC 718]:

"There is nothing to prevent decision makers from assessing the record and concluding there is inadequate information on which to reach determination. If it is not possible to make a decision with 'some' confidence, then it makes sense to err on the side of caution and prevent activities that may cause serious or irreparable harm. An informed decision can be made at a later stage when additional data is available or resources permit further research."

As a result of more than ten years of commercialisation of this technology, ample evidence has emerged from many countries to raise serious doubts about its safety for human and animal health and the environment. That this evidence has been placed on record by independent scientists as well as regulators despite active efforts by the GM industry not only to stifle such research, but also to systematically dismantle regulatory mechanisms in various important countries in the world including India. Such evidence has firmly established the potential impacts of the hazards on the biodiversity. Since genetic manipulations are essentially irreversible, there is a critical need for India to get it right the first time that a GMO is released into the environment.

B) That any release of GMOs into the environment without the requisite scientific testing for bio-safety concerns would be unconstitutional. Since enumerated evidence clearly demonstrate that release of GMOs have, at the very least, the potential to cause grave and irreversible harm to health of human beings and ecology, such indiscriminate releases would violate the fundamental right to health and environment under Art. 21 of the Constitution. This Hon'ble Court has held in a number of cases that the Right to life under Art. 21 includes the right to a healthy and safe environment. This Hon'ble Court in *Virender Gaur v. State of Haryana* [1995 (2) SCC 577] had held that:

"Article 21 protects the right to life as a fundamental right. Enjoyment of life... including the right to live with human dignity encompasses within its ambit the protection and preservation of environment, ecological balance free from pollution of air and water, sanitation, without which life cannot be enjoyed. Any contra acts or actions would cause environmental pollution. Environmental, ecological, air, water pollution etc. should regarded as amounting to violation of Article 21." That it is amply clear that the Rules notified in the year 1989 and the Guidelines framed thereunder are not sufficient to provide requisite safeguards to the Environment as well as Human and Animal health, and have therefore, rendered themselves unconstitutional. These rules and guidelines must be modified so they are consonant with the present scientific knowledge and experience, as well as the requirements under the U.N. Convention on Biological Diversity (CBD), 1992 and the Cartagena Protocol, the binding international instrument in the realm of Biosafety. A failure to take into account such overwhelming scientific evidence that cast doubts on the safety of the technology would be arbitrary and unreasonable.

C) It has been held by this Hon'ble Court in the case of Gramophone Company of India v. B.B. Pandey [1983 (2) SCC 534] and Visakha v. State of Rajasthan [1997 (6) SCC 241] that international treaties signed by India can be read into the domestic law of the country provided that they are not in conflict with any statutory provisions in the country. The U.N. Convention on Biological Diversity (CBD), 1992 require that the contracting parties shall domestically regulate or manage the risks associated with the use and release of LMOs resulting from Biotechnology and likely to have adverse environmental impacts that could affect, the conservation and sustainable use of biodiversity, and the risks to human health [A. 8(g)]; introduce appropriate procedure to require impact assessment of proposed projects likely to have significant adverse effects on biodiversity and to allow public participation in the procedure where appropriate [A. 14]. Further, Article 19 (3) of the CBD had urged parties to consider the need for, and modalities of, a protocol setting out appropriate procedures in the field of the safe transfer, handling and use of any LMOs that may have adverse effect on the conservation and sustainable use of bio-diversity. Such releases of GMOs may result in irreversible damage to Biodiversity with grave implications for food security and devastation of the livelihood of farmers; especially since India being the centre of origin/ diversity of major food crops including rice. Since India is a signatory to the CBD and its provisions are not in conflict, but in fact in aid of the domestic laws, India is bound by its provisions.

D) That India is a signatory and is bound by the provisions of Cartagena Protocol, the binding International agreement on the matter of Biosafety. The Protocol aims to ensure adequate levels of protection in the field of safe transfer, handling and use of LMOs, (Living Modified Organisms) that may have adverse effects on the conservation and sustainable use of biodiversity, taking into account the risks to human health. The protocol, under A.2(2), stipulate parties to ensure that the development, handling, transport, use, transfer, and release of LMOs is undertaken in a manner that prevents or

reduces risk to biodiversity. Further, A. 10 (6) (Precautionary Principle) stipulates that a lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party from taking an appropriate decision, to avoid/ minimise potential adverse effects. According to Para 9(h) of the Annex III of the Protocol, the parties have to consider information on the location, geographical, climatic and ecological characteristics, including relevant information on biodiversity and centres of origin of the likely potential receiving environments. Annex III of the protocol includes, *inter alia,* the general principles of risk assessment: (i) Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice, as well as guidelines developed by relevant international organisations. According to Art. 26 of the Protocol parties may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use, specially with regard to value of biodiversity to indigenous and local communities.

E) That the Cartagena Protocol also stipulates that parties shall consult the public in decision-making processes regarding LMOs [Art. 23 (3)]; and shall make all relevant decisions available to the public, albeit respecting confidential information. Further, the Cartagena Protocol through Art 21 (6) stipulates that information about a summary of the risk assessment cannot be made confidential. It is clear from the aforementioned provisions of the Cartagena Protocol that India is required to not only put such a safety protocol in place, but also that such a protocol would mandate openness, transparency and public participation. The decision to release GMOs in India without any access to the public, information regarding the kind of safety tests conducted, the results of the test and an opportunity to the public to critique the tests is a violation of this provision of the Cartagena Protocol.

F) That Article 21 of the Constitution also mandates that a public notice and public hearing be held in tandem with Scientific Risk Assessment before any release of such GMOs. Even for technologies that have been tried and tested, and found to be far safer than Genetic Engineering, for instance hydro-electric projects, the statute mandates a public notice and public hearing before an Environmental Impact Assessment is completed. Hence, it is arbitrary and unreasonable not to have a mandatory public notice and Public Hearing before clearances for such releases are granted. Further, such public notice and mandatory public hearing would facilitate proper and transparent functioning of regulatory bodies responsible for risk assessment and clearance. The existing rules do not provide public access to such critical information, or allow public participation in decision-making process. Hence, they are in violation ve of Article 21 as held by this Hon'ble Court in Research Foundation for Science, Technology and Ecology v Union of India [2003 (9) SCALE 303]: "Clearly the Right to Information and Community Participation necessary for protection of Environment and Human Health is an inalienable part of Article 21 and is governed by the accepted environment principles."

G) To ensure the effective functioning of the Protocol, and a meaningful employment of the precautionary principle it is important that a labelling mechanism of GM food and GM products are put in place. It also requires that the import of any biological organism, food or animal feed is prohibited unless they have been tested and certified and labelled to be GM free. The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989 mandate specific permission of the GEAC before import of any substances or products which contain GMOs etc. GM products and food are wantonly imported without any regulation whatsoever by the GEAC. There are no facilities to ascertain the transgenic nature of the imported food and food products, before such goods are allowed inside the country; this is especially important in cases where such imports are from countries like Argentina and the U.S.A. There are no legal requirement in these countries to have GM labelling. Secondly, the reckless and wanton release of GMOs in various commercial crops, have genetically contaminated even non GM products. Hence, it would be only reasonable to conclude that products from such countries, where there is a history of wanton release, and where exist no labelling mechanism, are GM products or at least contaminated by GMOs. For instance in the case of Argentina, by the year of 2002, 11.6 million acres, which is half of Argentina's arable land was planted with Soya, almost all of it GM. There would be very little chance that the Soya imported from Argentina would be GM free. Enforcement agencies in this country are under an obligation to strictly enforce environmental laws. Hence, for such a strict implementation of the said rules would require (i) a strict implementation of a ban on import of products that are not labelled as GM free and (ii) an immediate blanket ban on products from such countries that wantonly release GMOs and have no effective internal labelling mechanisms.

H) Allowing GM food and crops to be sold in India without a requirement of labelling violates the fundamental right to choose. Such action violates the right of a producer to choose non- GM, and violates the right of consumer to chose to consume non-GM. Such a right is inherent in Article 21 of the Constitution.

83. The petitioners have not filed any similar petition in this Court earlier.

PRAYER

The petitioners therefore, pray that in the facts and circumstances of the case, this Hon'ble Court may be pleased to issue appropriate writs or directions to:

A) Direct the Union of India not to allow any release of GMOs into the environment by way of import, manufacture, use or any other manner unless the following precautions are taken.
   (a) a protocol for all the required bio-safety tests of the GMOs proposed to be released is prepared by the GEAC after processes of public notice and public hearing.
   (b) The GMO has been subjected to all the required bio-safety tests, prepared on the basis of the required Biosafety tests on the basis of the above protocol, by agencies of independent expert bodies, and results of which have been made public.

B) Direct the Union of India to ban the import of any biological organism, food or animal feed unless they have been certified and labelled to be GM free, by the exporting country.

C) Direct the Union of India to put in place rules to ensure that it shall be compulsory for any dealer or grower selling GMOs to label them as such.

D) Pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

PETITIONERS

Through
Prashant Bhushan
(counsel for the petitioners)

IN THE SUPREME COURT OF INDIA
(ORIGINAL CIVIL WRIT JURISDICTION)
I. A. No. /2005
in
Civil Writ Petition NO._____ OF 2005

IN THE MATTER OF:

Aruna Rodrigues and Others ...Petitioners

VERSUS

UNION OF India and Others ...Respondents

APPLICATION FOR EX-PARTE INTERIM STAY ON BEHALF OF THE PETITIONERS

To,
The Honourable Chief Justice and his companion judges of the Supreme Court of India: —
Most respectfully sheweth:

1) The petitioners have filed the accompanying writ petition seeking to put in place a protocol that shall mandate the scientific examination of all relevant aspects of Biosafety before such release. The petitioners are concerned about the absence of proper scientific examination of Biosafety concerns in the country. There is an increasing body of scientific knowledge and evidence, which points to the existence of serious hazards, and therefore safety concerns for human health and the environment. The reckless release of GMOs into the environment also threatens the agrarian structure of the country, will lead to the contamination of the food chain and detrimentally affect biodiversity, in an irreversible and lasting manner. It is submitted in the Writ Petition that this is a fit case to employ the Precautionary Principle, as enunciated by this Hon'ble Court in a catena of cases including M.V. Nayudu[1999 (2) SCC 718]. In view of the grave and irreversible harmful impacts resulting from the release of GMOs into the environment, the Writ petition pray for a moratorium on the release of any GMOs into the environment until a comprehensive protocol for all required Biosafety tests of the GMO proposed to be released is put in place, under the regulatory and monitoring framework of the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989. The Writ petition also prays for a labelling mechanism to ensure that the moratorium on the release of any GMO into the environment is safeguarded and effective. Such a mechanism is also necessary to protect the rights of agriculturists and consumers to grow and consume GM-free crops. The petitioners crave leave to refer to and rely upon the content of the accompanying writ petition for the purpose of this application.
2) From the facts and circumstances mentioned in the petition it is clear that the petitioners have a very strong *prima facie* case and every hope of succeeding in this Hon'ble Court. That various moves to import GM products into the country have been mentioned in the writ petition. The statement of Mr. Sharad Pawar, the Union Agricultural Minister on the move to import GM oil seed dated 18.01.2005 is attached to the Writ Petition. The Government is also reported to be planning to import 5.2 million tonnes of vegetable oil in the year ending in 2005. Dealers estimate that soy oil imports this year will total 30-35% of the total edible shipments, including 350,000 to 400,000 tonnes from Argentina and Brazil, in April and May alone. The Soy from Argentina based on the evidence provided in the writ petition will by definition be either GM Soy or contaminated soy. This is because, in a short span of a few years, Argentina has converted 50% of its arable land (11.6 million acres) to growing GM soy and is without regulatory safety testing or labelling mechanisms (The US and Argentina together account for 84% of the GM crops worldwide). India has no scientific facilities to test for GM contamination levels, especially for those that do not survive the development process, as they cannot be tested with PCR-based tests (polymerase chain reaction). It is very clear that the respondents have not only ignored concerns of Biosafety, but also have no plans to require, that only GM free products will be allowed into the country.
3) Such imports are *ex- facie* violative of the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989. The Rules mandate specific permission of the GEAC before import of any substance or product which contain GMOs etc. There are no facilities to ascertain the transgenic nature of the imported food and food products, before such goods are allowed inside India; this is especially important in cases where such imports are from countries like Argentina and the U.S.A. There are no legal requirement in these countries to have GM labelling. Secondly, the reckless and wanton release of GMOs in various commercial crops, have genetically contaminated even non GM products. Hence, it would be only reasonable to conclude that specific produce from such countries, where there is a history of wanton release of GMOs, and where exist no labelling mechanism, are GM produce or at least contaminated by GMOs. For instance in the case of Argentina, by the year of 2002, 11.6 million acres, which is half of Argentina's arable land was planted with Soya, almost all of it GM. There would be very little chance that the Soya imported from Argentina would be GM free. Enforcement agencies in our country are under an obligation to strictly enforce environmental laws. Hence, for such a strict implementation of the said rules would

require (i) a strict implementation of a ban on import of products that are not labelled as GM free and (ii) an immediate blanket ban on products from such countries that wantonly release GMOs and have no effective internal labelling mechanisms.

4) That apart from the aforementioned mandatory requirement under the Rules such imports seriously affect the health and safety of citizens of this country. There is a grave danger of seed contamination arising out of such imports.

PRAYER

It is therefore prayed that during the pendency of the accompanying writ petition, this court may be pleased to:

A) Direct the respondents not to allow agricultural imports until they are certified and labelled to be GM free,

B) Order, ex-parte, a moratorium of any further release of any GMO into environment till such time a protocol in consonance with Prayer A (a) of the Writ petition is put in place, and

C) Pass any other orders as this court may deem fit and proper.

PETITIONERS

Through
Prashant Bhushan
(counsel for the petitioners)

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