

THE SUPREME COURT OF INDIA

WRIT PETITION (CIVIL) No. 260/2005

IN THE MATTER OF:-

Aruna Rodrigues & Ors.

...Petitioners

Versus

Union of India & Ors.

...Respondents

REJOINDER AFFIDAVIT OF BEHALF OF PETITIONERS

MOST RESPECTFULLY SHEWETH:-

I, Aruna Rodrigues, D/o Theresa Rodrigues, R/o Bungalow 69, Mhow Cantt., Madhya Pradesh- 453441, do hereby solemnly state and affirm as under:

1. That I am Petitioner No.1 in the Writ Petition mentioned above and am fully acquainted with the facts and circumstances of this case and am fully authorized to swear this affidavit on behalf of all the other Petitioners.
2. That the above Writ Petition has been filed by the Petitioners seeking to put in place a protocol that shall mandate the sound scientific examination of all relevant aspects of Biosafety before GMOs are released into the environment. At present, despite a wordy, unsubstantiated Counter Affidavit by the Respondents to the contrary, the evidence shows that GMOs are being released into the Indian environment without any proper scientific examination of their biosafety impacts. It is further submitted that the unprecedented release of GMOs into the environment is threatening agriculture and the countryside. This will lead to the contamination of the food chain and detrimentally affect biodiversity, in an irreversible and lasting manner.
3. That before giving a consolidated reply to the averments made by the Respondents, it is necessary to reply to the Preliminary objections raised

by them in their Counter Affidavit. The contention of the Respondents regarding WP 71/1999 is completely irrelevant to the facts and circumstances of the present case. However, it would be appropriate to apprise this Hon'ble Court about the real circumstances that lead to the dismissal of the abovementioned Writ Petition:

(A) That the Writ Petition No. 71 of 1999 was filed by the Research Foundation for Science, Technology and Ecology (RFSTE) on 04.01.1999 challenging the permission given by the Government to M/s Maharashtra Hybrid Seeds Company Limited (Respondent No. 2) to carry out multi-centric trials at 15 locations in 7 states without framing of proper guidelines, rules and systems for evaluating the Bio-safety and ecological and environmental impacts of genetically modified organisms used in crops. That through the said Public Interest Litigation the Petitioner Organisation sought to bring to the notice of this Hon'ble Court, among others the issue of unscientific "open field trials" of transgenic Bt. Cotton carried without any bio-safety considerations, and granted by following improper and illegal procedure.

(B) That during the pendency of the said writ petition GEAC in its 32nd meeting, which was held on 26.03.2002, gave conditional clearance for commercial release of three out of four of Mahyco's transgenic hybrids of cotton and on 05.04.2002 GEAC by formal order of the Ministry of Environment and Forest gave conditional approval for commercial release of Mech-12, Mech-162 and Mech-184 varieties of transgenic hybrids of cotton to M/s Maharashtra Hybrid Seeds Company Limited (Respondent No. 2 in the instant Special Leave Petition).

(C) That because of the aforementioned events the Petitioner organisation found it necessary to file an application for the amendment of the said Writ Petition for bringing these new

developments to the knowledge of this Hon'ble Court and also seeking a prayer quashing of the aforesaid decision to grant conditional clearance for commercial release of transgenic cotton.

(D) That when the said application came up for hearing before the Hon'ble Court the court was informed that an Appellate Authority has been constituted under Rule 19 of the "Rules for the Manufacture, Use, Import, Export and Storage of the Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" and that the Petitioner can agitate its grievances before the said Authority.

(E) That on 12.11.2002 this Hon'ble Court was pleased to pass an order directing the petitioner to approach the concerned Appellate Authority within four weeks; wherein the Appellate Authority shall entertain and decide on the same on merits.

(F) That RFSTE filed an Appeal bearing No. 2 of 2002 before the said Authority impugning the order of the GEAC dated 05.04.2002 by which it has given conditional approval for commercial release of Mech-12, Mech-162 and Mech-184 varieties of transgenic hybrids of cotton to M/s Maharashtra Hybrid Seeds Company Limited. However, the Appellate Authority on 08.10.2003 dismissed the said appeal on erroneous ground that adequate evaluations and tests were done by GEAC before giving the said impugned approval.

(G) That RFSTE aggrieved by the order of the Appellate Authority filed a Special Leave Petition No. 3762 of 2004 which is still pending before this Hon'ble Court.

(H) That as the SLP challenging the order of the Appellate Authority was by RFSTE, this Hon'ble Court vide its order dated 13/01/2004 dismissed the said Writ Petition as having become infructuous and further directed the Registry to preserve the

volumes of the said matter. The copy of the said order is annexed herewith as **Annexure S1**.

4. That the Respondents in their preliminary objections have also relied on the judgement and order dated 10.05.2002 passed by this Hon'ble Court in Writ Petition (Civil) No. 301 of 2002 titled Dr. P.M. Bhargava & Anr. Vs. Union of India and Ors. It is most respectfully submitted that the said Writ Petition was dismissed by this Hon'ble Court in limine vide its order dated 10.05.2002. However, it is submitted that the issues involved in the present case are different and these issues were neither considered nor decided in that case.
5. That the contention of the Respondents that the issues raised in the present Writ Petition are similar to the issues raised in W.P. (C) No. 115 of 2004 filed by the Gene Campaign is also not correct. It is most respectfully submitted that the issues raised in the present Writ Petition are different from the issues raised in the above said Writ Petition in the sense that the present Writ Petition is much more comprehensive and the prayers sought for in it are much wider than the prayers sought for in the abovementioned Writ Petition. It is submitted that vide the present Writ Petition the Petitioners have prayed to this Hon'ble Court to restrain respondents from allowing any agricultural imports until they are certified and labelled to be GM free and further to order a moratorium on any further release of any GMO's into the environment till each GMO has been subjected to all the required bio-safety tests, prepared according to the safety protocols mentioned in the Writ Petition, by agencies of independent expert bodies, and the results of which have been made public.
6. That the Respondents have filed a Counter Affidavit that indulges in blatant filibustering through irrelevant technical data being presented to this hon'ble court. They have also expressly denied any hazards from GM

crops, indeed have claimed many benefits from GE, including: reduction in pesticide and herbicide use, and therefore less chemical damage to the environment, better yields and better integrated pest management systems as a direct result of genetic engineering; that they have “acted with due care for the benefit of society” and have conducted extensive biosafety tests and have determined that neither Bt proteins nor Bt cotton are toxic to animals or humans or have negative environmental impacts. They have also claimed the application of “substantial equivalence” (SE) as a basis for health safety assessment, first employed by the US to GM foods, deeming them to be “as safe as their conventional counterparts”, and the similarity to “traditional breeding”. Both of these assumptions have been discarded as scientifically untenable, and are therefore, dangerously misleading and bogus claims that interfere with sound scientific studies to determine the safety of GM foods. These were first used by the US to facilitate the entry of GM foods on to the market without any safety testing, giving them GRAS (Generally Recognised As Safe) status, to promote the commercial interests of biotech at the expense of public health safety.

“This blanket GRAS exemption is based on the notion of ‘Substantial Equivalence’; it assumes not only the “safety of the transgenic protein but also the absence of any potentially harmful, unintended effects of transformation”. The US regulatory system is based on an interpretation of SE that uses it as the end point rather than the starting point of evaluation.

“It is substantially lacking in rigour and cannot be used to declare a product as safe as its conventional counterpart, --- the transfection event used to create a GE plant generates unpredictable changes in gene expression that are going to be different in kind from those produced by traditional breeding;- --we do not understand the mechanisms of GE-induced changes in gene expression in sufficient detail to make an outcome prediction of the type that can be made when crossing two strains, such as wheat, that have been eaten safely for thousands of years --very few deleterious genes have been introduced into crops from

outcrossing, (ref. WP Annexure P17, Prof Dave Schubert: 'Safety Testing and Regulation of Genetically Engineered Foods). Prof Giles Seralini whose evidence is part of this submission is an expert on endocrine disruptors, a scientist who specialises in health effects of pesticides. He says that the hypothesis that an *"artificial genetic modification does not create more risk than unknown genetic effects possibly visible after classical hybridisation has not been demonstrated yet, but has been used to avoid labelling and long-term feeding studies with GMOs in north America"*. Furthermore, the assertion by the Respondents that no GM food has been approved for release in India is being used as proof of their ethical and upright approach to GM regulation *"on a step by step basis"* starting with approvals of Bt cotton, cotton by itself, being a non-food/feed product. This is a disingenuous statement; and it destroys the Respondents' own case in that it is an admission that Bt cotton therefore may well have negative health impacts if used for anything other than the production of cotton! Cottonseed cake is the second highest source of animal feed in the world, soy being the first. This is why these two GM products (along with GM corn also used as animal feed in the West) represent virtually the whole thrust of GM crops worldwide; and these are just the by-products! There is no mystery here. Its lucre. Cottonseed also produces oil. The Petitioners have already drawn this Hon'ble court's attention to the contamination of the food chain through cottonseed oil used commercially in India as well as milk, because cottonseed cake is used for animal feed. They have also provided evidence for the caution required on GM animal feed precisely because of the threat to human health through the contamination of the food chain. The Petitioners in their WP have provided extensive evidence of the impeccable sources of their data, i.e. world-renowned, independent scientists, who stand to gain nothing; many of whom on the contrary, have been vilified, slandered, and have lost their jobs for daring to speak out. For example, several years ago Dr. Arpad Pusztai showed that GE potatoes cause serious health

problems in rats, including tumours. This led to harassment by the Royal Society and the UK Government, which ultimately resulted in his dismissal from his academic position at the Rowett. The feeding study was peer reviewed and published in the Lancet despite institutional pressure not to do so. Since then, several other scientists have shown that different GE food crops cause similar problems and it was discovered that one of the companies that tried to discredit Pusztai withheld their own data showing that GE corn (a Bt variety) is toxic to animals. The Respondents however, on the other hand, have relied on secretive, industry-sponsored studies, which have not seen the light of day, and have referenced safety claims for GM crops made by other governments, especially the US and the EU Commission, which have an abysmal record of objectivity with regard to GM. The evidence for this is amply demonstrated in the WP. The Petitioners, however, crave leave of this Hon'ble Court to briefly narrate some of the studies annexed by them along with their Writ Petition, in order to clarify the issues and further reinforce the new evidence provided in this Rejoinder Affidavit.

Transgenic cotton is recognised by scientists to be a potentially toxic crop. Furthermore, the effects of GM crops are similar to that of pesticides. The Government's stance on safety flies in the face of extensive independent evidence to the contrary, provided in the WP and in this affidavit. It is further submitted that the Precautionary Principle has been comprehensively ditched by the Indian Government in the pursuit of GE which is wholly unwarranted by the scientific evidence and both government Regulators & GM crop developers cooperate to discourage the truth about GM biosafety impacts. For science to have credibility its experiments must be replicable by other labs, or the results must be discarded. Yet, requests by scientists for reinvestigation to confirm scientific results are routinely stymied and made difficult if not impossible, by the biotech industry through refusal of "reference material" and GM seed, which would enable scientists to continue work on safety

assessments. The industry goes to enormous lengths to eliminate any adverse research and uncomfortable finding, citing CBI (Confidential Business Information). Regulators accept these flimsy grounds and ignore the absolute priority that must be given to public health safety. For example, two years ago, when Prof Bela Darvas and his colleagues in the Hungarian Academy of Sciences revealed a massive buildup of Bt toxins associated with plantings of a GM maize called MON810, and indicated that they wanted to repeat and extend their research, Monsanto immediately shut off supplies of seeds and effectively killed off the research project. In 2005, when Dr Judy Carman asked Bayer Crop Science for 100g of GM InVigor canola seeds for field tests in Australia, the company simply ignored her request and made the research impossible. In the case of the Bt10 fiasco, Syngenta even refused to send to the EC reference materials needed by research laboratories for the development of a testing and monitoring programme. These facts, along with a list of bona fide 'scientists who were denied materials', have been provided by Dr. Brian John, co-founder, GM-free Cymru, and are appended as **Annexure S2 (Colly)**.

7. That the reason why we must proceed most cautiously with genetic engineering is because of the biological certainty of transgenic contamination. There is no turning back. Charles Benbrook, who was the former agricultural staff expert on the Council for Environmental Quality at the White House at the end of the Carter Administration, Executive Director of the Subcommittee of the House Committee on Agriculture, and Executive Director of the Board on Agriculture of the National Academy of Sciences, explains just how imprecise GE is in the following extract from 'An interview with Charles Benbrook on GE' by Arty Mangan'
"Anyone that's been involved in the discussion about genetically engineered crops has heard proponents claim that this is the most precise technology ever developed for the transformation of crops. For the most

part, this claim is made and not challenged. It is true that the molecular biologists that create a trans-gene do know precisely what that trans-gene is composed of, because they make it. In the regulatory submissions, for example, there will be a diagram of the trans-gene, exactly what genetic material is in different places, how they put it together, and what the function of the different parts of the trans-gene are. So that's the front end of the process. They do have precise control over that. Whereas in conventional breeding, when a plant breeder crosses two plants, they really don't have precise control or knowledge of how those genes combine in the next generation of a plant. So it's true that in terms of knowing exactly what gene you're trying to move into the plant, it is more precise. But it's not more precise. In fact it's fundamentally more imprecise, in that the techniques that are used to move the trans-gene into the crop are no more precise than a shotgun. They shoot into the cells thousands of particles that have the trans-gene coating and hope that one penetrates into the inside of the cell and gets picked up and stably expressed. They hope that it's only one, and that it gets expressed properly. But they have no way of knowing whether it does, and in fact they do know that it's likely that more than one of those particles actually leads to some expression, and some may lead to some partial expression; that somehow once they move these trans-genes in--despite the fact that they don't understand how many copies there are, they don't understand how stable they'll be, they don't understand how stresses are going to effect them--that they're not going to be influenced by the laws of evolution. It's an irresponsible leap of faith that has been underwritten by our universities, our government, by the companies and by people that know better. This is what drives a lot of people crazy. The scope of the fraud, ----that's being sold to the public about this technology is almost unprecedented." The above article and interview are appended as **Annexure S3 (Colly):** 'Experimenting with Life' by David Suzuki the eminent geneticist, award-

winning scientist, environmentalist and broadcaster, and 'An interview with Charles Benbrook on GE' by Arty Mangan'.

8. On the 13th March 2006, a tragic incident occurred in the UK that reinforces the truth about the uncertainty of genetic engineering and what are referred to as 'unintended effects'. Unintended effects are common in all cases where the GE technique is used. It is also a euphemism for ignorance. A drug trial catastrophe reflects upon the secretive open field-testing of pharm crops. There must be zero tolerance for transgenic contamination with such crops and therefore the implications of these field trials are very disturbing. The drug trial led to catastrophic injury to six human volunteers, one of whom may face up to a year or more in a coma. The drug being tested (TGN 1412) was a recombinant humanized monoclonal antibody being developed to treat diseases including leukemia and arthritis. The tests of the drug were being undertaken in Britain for a German biotechnology company (TeGenero). The six young men participating in the drug trial were healthy volunteers and were paid a small fee to participate in the experiment. It was the first time ever that humans had been exposed to such a drug trial. The drug trial went wrong after a single relatively high dose led to over-stimulation of the immune system leading to inflammation and organ destruction. Within hours they were critically ill. Yet the MHRA (Medicines and Healthcare Products Regulatory Agency) and the regulatory authorities in Germany, where the biotech company TeGenero is based, had both examined the data from the animal tests and allowed the human trial to proceed. When drugs are first tested on humans, doctors do not expect any response at all. But the six men who had taken the drug suffered a massive inflammatory reaction. Richard Gray, director of the University of Birmingham clinical trials unit, said: "It must have been a huge surprise to the people running the trial that something like this should happen. It is very, very rare indeed for something as catastrophic as this to happen." Molecular pharming (producing pharmaceuticals in transgenic crops) is turning into a new

battlefront in the imposition of recombinant crops. Governments appear to be prepared to side with corporations against the many people who do not wish to see the food supply contaminated with un-prescribed drugs. Exposure of humans without their knowledge or consent in secretive open field trials threatens the health, even the life, of those people and is a violation of their rights. "Such secretive field trials should not be allowed-- Such revelations may explain an array of mysterious maladies for which there has been no previous explanation. There is something disturbing about serious injury to young six volunteers who were paid a mere pittance to risk their lives for those producing drugs that are so costly that they can benefit the very rich alone. The secretive exposure of bystanders and neighbours to very hazardous recombinant plants to benefit corporations is equally disturbing" (Prof. Joe Cummins). A copy of the news report titled 'Relatives Fury over Calamitous Drug Trial' published in The Guardian on 16th March 2006; the report compiled by Prof Joe Cummins and the New Statesman report of the 3rd April 2006, 'Ziauddin Sardar Takes a Drugs Trial' are annexed hereto as **Annexure S4(Colly).**,

9. That, the Petitioners vide this Rejoinder Affidavit would also like to place on record some additional evidence that has recently emerged, covering a number of separate GE incidents. These firmly support and reinforce the contention of the Petitioners that GMO's are hazardous and are therefore not safe for human health or for the Environment. The evidence includes the current Bt cotton situation in India, which along with unapproved open field trials of Bt okra, rice and brinjal, clearly demonstrate the most serious of regulatory failures. It is most respectfully submitted that the new evidence confirms prima facie, deliberate intent on the part of the Regulatory bodies of the GOI including the DBT and GEAC to allow GM contamination in India. The biosafety violations are so serious that they

represent the highest betrayal of India's national interest including national food security. In this context, there is a chilling report by Jeffrey Smith, the well-known researcher who has studied the issues around genetic modification for nearly 10 years and the author of the international best seller on GM, 'Seeds of Deception'. Taken from the Introduction to this book but reproduced here from his monthly newsletter 'Spilling The Beans', it lays bare the very dangerous objective of Monsanto's supremacy over world agriculture, where "NATURAL SEEDS ARE VIRTUALLY EXTINCT". The Petitioners in their Writ Petition have already stated that the evidence thus far points firmly to the insidious intent of the biotech industry of which Monsanto is a monopoly market leader, to undermine by any and every means possible, national sovereign institutions and democratic governments. This plainly confirms it. Smith reveals:

"On May 23, 2003, President Bush proposed an Initiative to End Hunger in Africa using genetically modified (GM) foods. He also blamed Europe's "unfounded, unscientific fears" of these foods for hindering efforts to end hunger. Bush was convinced that GM foods held the key to greater yields, expanded US exports, and a better world. --- The message was part of a master plan that had been crafted by corporations determined to control the world's food supply. This was made clear at a biotech industry conference in January 1999, where a representative from Arthur Anderson Consulting Group explained how his company had helped Monsanto create that plan. First, they asked Monsanto what their ideal future looked like in 15 to 20 years. Monsanto executives described a world with 100% of all commercial seeds genetically modified and patented. Anderson Consulting then worked backward from that goal, and developed the strategy and tactics to achieve it. They presented Monsanto with the steps and procedures needed to obtain a place of industry dominance in a world in which natural seeds were virtually extinct. Integral to the plan was Monsanto's influence in government, whose role was to promote the

technology worldwide and to help get the foods into the marketplace quickly, before resistance could get in the way. A biotech consultant later said, 'the hope of the industry is that over time, the market is so flooded that there's nothing you can do about it. You just sort of surrender.'

That a copy of the reprint of the hard-hitting interview of Jeffrey Smith titled 'Spilling The Beans', dated Sept 2005 conducted by Noseweek, an influential South African investigative magazine, is annexed hereto as **Annexure S5**.

10. That the Government of India has recently concluded an ignominious agreement with the US. The recent visit by the US President and the agreement forged to open up GE for investment and promote biotech is now public knowledge and confirms the Petitioners' well-founded and expressed fears. In fact Monsanto has been elected to the Board of the 'Indo-US Knowledge Initiative on Agricultural Research and Education', which astoundingly elevates Monsanto, a thoroughly discredited company internationally, to an official member of the US delegation. This is therefore, now, clear and open acknowledgement of the US world agenda to promote the commercial agenda of the biotech industry (Monsanto being the 90% monopoly leader), with India as a major focus; and the Indian Government's willingness to further this agenda, covertly, without any public information; discussion or any safety testing whatsoever. The move will require India to invest initially about Rs. 400 crores over the next 3 years on collaborative research in farming, of which Rs 300 crores is earmarked for biotech. According to Suman Sahai, Convenor, Gene Campaign, the Americans have been aggressive in pushing for "a change in India's IPR laws (Intellectual Property Rights) to introduce patents on seeds and genes and do away with the provisions for protecting farmer's rights. A combination of physical access to gene banks and an IPR law that allows seed patents will deliver India's genetic wealth into American hands". A copy of the article titled 'Indo-US Agr. Agreement' is annexed

hereto as **Annexure S6**. This agreement demonstrates clear intent on the part of international agencies and national governments to oil the 'vehicles' that will deliver Monsanto's dire and resolute ambitions. It quite simply furthers the fulfilment of Monsanto's dark agenda with the active help of the Indian Government. This is a morally bankrupt and ethically deviant policy on GM; a tragically inappropriate tie-up, wholly detrimental to the national interest, which impacts sovereign issues of genetic wealth and IPRs, bio-safety, food security, farmer and consumer rights and public health. The Country now faces the unbelievable situation, which defies the most elementary logic, where Indian policy concerning these issues will be subject to even greater manipulation than at present, by private multinational biotech corporations that exist to make a profit. The company with its hand firmly on the rudder is MONSANTO! The Petitioners crave leave to repeat (from the evidence presented in the Writ Petition and new evidence as part of this Rejoinder), the track record of Monsanto, now the 'official' GE brand ambassador of the US.

- Monsanto is the company that claimed that Aspartame was safe. It causes cancers and formaldehyde poisoning listed amongst 92 acknowledged health hazards on the FDA files, (produced in a court of law) and which is now the subject of a multi-million dollar law suit in the US
- It claimed PCBs were safe, DDT was safe, Agent Orange was safe. In 1966, for example, court documents in a case concerning Anniston residents in the US showed that Monsanto managers discovered that fish dunked in a local creek turned belly-up within 10 seconds, spurting blood and shedding skin as if dropped into boiling water. In 1969, they found fish in another creek with 7,500 times the legal PCB level. But they never told their neighbours, and concluded that *"there is little object in going to expensive extremes in limiting discharges --- We can't afford to lose one dollar of business "*. In fact, court documents revealed that the company withheld evidence about the safety of their

PCBs to the residents of the town that was being poisoned by their factory. On February 22, 2002, a court found Monsanto guilty on all six counts of negligence, wantonness and suppression of the truth, nuisance, trespass, and outrage. Outrage, according to Alabama law, usually requires conduct "*so outrageous in character and extreme in degree as to go beyond all possible bounds of decency so as to be regarded as atrocious and utterly intolerable in civilized society.*" A copy of the newspaper report published in The Washinton Post in Feb.2002 titled, 'Monsanto Held Liable for PCB Dumping' is annexed hereto as **Annexure S7**.

- In 2005, Monsanto paid a \$1.5 million fine to the US justice department for giving bribes and questionable payments to at least 140 Indonesian officials, trying to get their Bt cotton approved without an environmental impact study.
- Six government scientists testified before the Canadian Senate that a Monsanto official offered them a bribe of \$1-2 million, if they approved the company's GM bovine growth hormone (rbGH) without further study. One FDA scientist arbitrarily increased the allowable levels of antibiotics in milk 100-fold, in order to facilitate the approval of Monsanto's rbGH. She had just arrived at the FDA from Monsanto.
- In India, the Bt cotton fiasco is a documented story of cover-ups, doctored reports in AP, fraudulent advertising and claims on the performance of Bt, failed crops, scandalous overpricing, serious allergies among Bt cotton labourers and buffalos dying in MP and official enquiries by the State Governments of Maharashtra, & Andhra Pradesh into numerous farmer suicides, linked to Bt cotton's failure in both States.

11. Monsanto hasn't changed. It hides evidence of the toxic effects of its GM products, fudges and manipulates data and has refused to reveal the results of its own secret animal feeding studies which revealed serious abnormalities to rats fed GM corn, citing CBI (Confidential Business

Information). The evidence before this Hon'ble Court is unequivocal. Despite the great difficulties and enormous expense of undertaking independent studies, often without government support, but in fact in the face of official hostility and a pro-GM government agenda in the UK, EU, US, Canada, India (to state the major government examples), evidence has emerged of serious hazards connected with GM and scientists all around the world have called for a moratorium because of safety concerns on multiple dimensions of biosafety. In India, the proposed Indo-US cooperation amply explains why the Union of India in its Counter Affidavit is given to cover-up and deny the many failures of Bt cotton presented and documented by civil society and in the face of tragic farmer suicides specifically linked to the failure of Bt cotton. Perversely, it contrives to trumpet Bt cotton's success instead. The GEAC and DBT stand indicted of having misled the whole country on safety issues surrounding GM crops. This is the only possible explanation for the extraordinary sell out of India's agricultural sector along with the potential threat of India losing ownership of its own genetic resources, to US biotech corporations, led by Monsanto. There is a compelling urgency for action because of the pace at which things are developing, including the recent confidential ruling of the WTO on the 9th Feb. 2006, which ruled in favour of the US stating that the EU had imposed unfair TRADE restrictions on GM crops. It would be relevant to mention here that during the hearing conducted by the WTO, safety issues with regard to GMOs were not tackled. As a result of this ruling, the Petitioners feel that the drive to pressure India and bulldoze through any remaining restrictions on GM will accelerate further. A copy of the news report titled, 'WTO's decision on GM foods in Europe did not cover safety issues', of the Financial Express dated 2/10/2006 is annexed hereto as **Annexure S8.** .

SAFETY ISSUES & SAFETY TESTING PROTOCOLS

12. That, the new evidence presented herewith furthermore, further confirms and underscores the serious hazards of GM crops and effectively buries any equivalence of a GM food to its conventional counterpart. It is therefore imperative that there is the utmost commitment to a rigorous and transparent protocol of biological safety testing of GM foods. Two leading scientists Dr. Arpad Pusztai and Prof Dave Schubert who preside at the cutting edge of GM research have already provided health safety test protocols for GMOs. The studies conducted by them have already been annexed by the Petitioners along with their Writ Petition as Annexure P6 & P17. Dr. Arpad Pusztai is the acknowledged world authority on protein lectins, and the leading nutrition scientist and toxicologist in animal feeding studies, whose test protocols were to be adopted for the European Union. These now form part of his evidence to this Hon'ble Court, for India, along with a particular emphasis on Bt. Cotton, because of its relevance to our Country. Prof. Dave Schubert of the prestigious Salk Institute is head of the Cellular and Neurobiology Lab. His peer-reviewed document 'Safety Testing and Regulation of Genetically Engineered Foods' is likewise important material for guidelines for health safety testing protocols and deals at length with safety issues regarding Bt crops in particular. The Petitioners have already provided extensive evidence of how GE foods are currently regulated with particular reference to the US, EU and India. A thorough understanding of this is necessary, because claims about the safety of these crops are based largely on the assessments by government regulators, which in turn are based mostly on unpublished studies conducted by the biotech crop developer. Published, peer-reviewed studies are rare. Apart from cost considerations, one important reason for this is that independent researchers are routinely denied GE crop materials. Thus, the validity of a claim that GE crops are safe depends exclusively upon the quality of both the relevant corporate

science and the regulatory process. Both have been demonstrated to be very compromised.

13. There are very few established protocols for assessing potential human health impacts of GE crops and the guidelines provided in the Writ Petition filed by the Petitioners are a true landmark. A mere listing of procedures is of little use without a methodology. Prof Schubert focuses on the importance of allergenicity test guidelines as an example. *“Since 1996, various groups devised so-called “decision trees to assess the potential allergenicity of transgenic crop proteins. ---- however, until a 2001 report by an FAO-WHO expert consultation (FAO-WHO 2001), none of these decision trees specified test conditions”.* Thus biotech test results often vary markedly from tests conducted by independent researchers.

14. GM corn also includes Bt varieties and Bt corn for example exhibits other striking ‘unintended effects’ that mark their difference from natural, conventional counterparts. Bt corn MON810 and Bt11 events (Monsanto and Sygenta respectively) and their hybrids have significantly increased lignin in stem tissue (lignin is the woody component of plants and is non digestible). This finding accords with anecdotal evidence, reports from farmers that Bt corn is stiffer and less desirable to farm animals as fodder, Lignin, is derived from aromatic biomolecules, which are extremely important in both plants and mammals as building blocks for hormones and other bioactive substances. The lack of safety testing with Bt crops raises the question of what other metabolic intermediates have been affected by the GE process. Furthermore, the increase in lignin content of Bt corn was *“brought to light only 5years after market introduction”.* The lack of targeted testing for other bioactive substances--- and the failure to apply non-targeted techniques such as metabolic profiling and long term

animal feeding studies, highlight the serious gaps in human health assessment of Bt corn.

15. The chief justification for approval of Bt crops "in the absence of crucial data", and one that has been actively employed by the Respondents' is that Bt sprays have a history of safe use and so Bt crops are presumed to be as safe as well. This presumption is unjustified for several reasons:

- First, Bt sprays do cause allergic symptoms
- Secondly, there is likely much greater chronic exposure to Cry proteins in Bt crops than in sprays ---- the Cry proteins in sprays break down within several days to two weeks upon exposure to UV light, while this is obviously not the case with Bt crops, which produce the toxin internally in grain and other plant tissues;
- Thirdly, Bt sprays are only toxic to insects with alkaline gut conditions ---. Bt crops on the other hand, are generally engineered to produce the Bt toxin, which is active without processing. There is also evidence that Cry toxins (of Bt crops) are more immunoreactive than Cry protoxins;
- Finally, the trend to increased Cry protein expression (high dose) to slow down development of pest resistance to Bt crops, has been shown to have one thousand times more cry protein in kernels and may increase consumers' dietary exposure to Bt proteins. Thus Bt crops cannot be judged safe.

16. Prof Schubert goes on to provide significant detail of just what is required from a health safety test protocol, and why:

- There are three features whose presence especially in combination, is regarded as sufficient evidence to reject the pertinent GE crop, or at least trigger additional testing. They are: amino acid sequence homology to a known allergen, digestive stability and heat stability. Industry procedures used to measure digestive stability frequently employ highly acidic conditions and a very large excess of pepsin

relative to test protein, conditions that favour the most rapid possible digestion. Under the authoritative allergenicity testing protocol recommended by international experts at the FAO/WHO, digestive stability tests are to be carried out at a higher pH (2.0) and in specified SGF (simulated gastric fluid).

- Another example involves employing bacterial surrogate proteins, which means that there is no testing of the plant product that is actually consumed. This is indicative of just how easy it is to fudge test data, test results, and undertake deliberately flawed studies in the absence of laid-down parameters and test protocols.
- Molecular characterisation studies: to reveal 'unintended' effects. One such study on MON810 (Monsanto's Bt corn) revealed such an unexpected transfection event, which creates the potential for production of fusion protein. In general, Freese and Prof Schubert believe *"that the presence or potential presence of a novel fusion protein in a GE crop should trigger a mandatory review for potential human health or environmental impacts"*.

17. Further, Prof. Schubert outlines three non-targeted safety-screening procedures for GE Foods to address the issues including the potential for GE to introduce novel allergens into food crops, which has received significant attention as a safety issue. The elementary medical truth is that allergies are notoriously difficult to pinpoint, but in the absence of labelling, post-market epidemiological studies are simply impossible. *"It is necessary to have stringent labelling of GE products, as well as the ability to trace the GE material to its origin"*. For Respondents therefore to stake a claim for the safety of GM foods based on the absence of such reported health impacts is precisely to tout the industry line. It is clearly devious, is not intended for the ingestion of scientists but to mislead the general public and this Hon'ble Court. Among others, experts at the FAO and WHO have also formulated an authoritative decision- tree testing protocol

to identify novel allergens. The importance of this particular protocol is that it represents a consensus among international experts and serves as the basis for the *Codex Alimentarius* international food safety standards and for the first time specifies detailed test parameters. The testing procedures to be combined with standard crop testing procedures, to determine if a new GE product falls within the accepted norm of safety of current food crops, as recommended by Prof Dave Schubert are:

- (a) The Ames test for mutagenicity
- (b) Metabolic Profiling for toxic and nutritional compounds
- (c) Extended animal feeding studies for carcinogenic, reproductive, and other adverse effects
- (d) Allergenicity testing

The FAO-WHO also recommends consideration of post market surveillance, in analogy with the final phase of drug testing, to capture allergic responses that may be missed with pre-market testing (FAO-WHO, 2001 as referenced by Schubert). The Petitioners have already annexed the study conducted by Prof. Schubert alongwith the Writ Petition as Annexure P17 titled: 'Safety Testing and Regulation of Genetically Engineered Foods'.

- 18.** In 'GMO in Animal Nutrition: Potential Benefits and Risks', Dr. Arpad Pusztai and Susan Bardocz have taken the protocols further. They have reviewed previously published animal studies and have examined them critically in the light of a suggested but *always evolving testing protocol* in which the "*safety of GM crops is established from the effects of GM ingredients on the physiology, pathohistology, immunology and bacterial flora of the gastrointestinal tract of young animals and the metabolic consequences of these effects*". It is clear from this review that "*most GM and parent line crops fall short of the definition of "substantial equivalence" and that this concept is a serious impediment to health safety analyses of GM foods. Thus novel biological concepts and methods to probe into the*

safety of gene splicing are needed". This is urgently required because the biological testing of GM feeds as presently carried out is "*rather limited in scope and mainly aimed at finding out the best conditions of commercial animal production*". Furthermore, concerns with 'unintended effects' and the importance of the analyses of such effects, highlights the inadequacy of the current methods. This has also been recognised in the Codex Alimentarius guidelines 2003, an international consensus of a minimum set of guidelines for the conduct of GM food safety. Dr. Pusztai goes on to say:

"More sophisticated analytical methods need to be devised, such as mRNA fingerprinting, proteomics, secondary metabolite profiling and other profiling techniques. However, and most importantly, there is an urgent need to develop comprehensive toxicological /physiological /nutritional methods which will equally be applicable, to scientifically examine the veracity of the claimed benefits of genetic manipulation and screen for its unintended and potentially deleterious consequences for human/animal health. The center of this effort should be the physiology of the alimentary canal, since this is the first contact point of exposure to any food/feed including those which have been genetically modified, to establish in scientific terms the SHORT- AND LONG-TERM CONSEQUENCES OF THE EXPOSURE".

19. That, judging from the almost total absence of published data in peer-reviewed scientific literature, the "*safety of GM foods rests more on, trusting the assurances given by the biotechnology industry than on rigorous and independently verified risk assessment*". A copy of the abovementioned article titled 'GMO in Animal Nutrition' by Arpad Pusztai and Susan Bardocz published in the book titled "Biology of Nutrition in Growing Animals" is annexed hereto as **Annexure S9**.

20. This has also been recognised in the Codex Alimentarius guidelines 2003, an international consensus of a minimum set of guidelines for the conduct of GM food safety. The Codex Alimentarius (Latin word for “food law” or “food code”) is a collection of international standards for food safety and consumer protection. It is maintained by the Codex Alimentarius Commission, a body established jointly by FAO (The Food and Agriculture Organization of the United Nations) and WHO in the years 1961-1962 to protect consumers’ health and to ensure fair practices in the international food trade. The Codex Alimentarius covers all foods, whether processed, semi-processed or raw, which are sold directly to the consumer. In addition to standards for specific foods, the Codex Alimentarius contains general standards covering matters such as food labeling, food hygiene, food additives and pesticide residues, and procedures for assessing the safety of foods derived from modern biotechnology. It also contains guidelines for the management of official (i.e., governmental) import and export inspection and certification systems for foods. It would be relevant to mention here that India is also member of Codex Alimentarius Commission. The FAO-WHO, 2001 was the first attempt by an expert consultative international body to identify tests and specify test conditions and standards for biotech safety testing protocols to facilitate rigorous review. It also formulated an authoritative decision-tree testing protocol for the potential for GE to introduce novel allergens into food crops. These formed the basis for the subsequent *Codex Alimentarius*, 2003, a set of international food standards for safety testing of GE plants: ‘Guideline For The Conduct Of Food Safety Assessment Of Foods Derived From Recombinant-DNA Plants’, which for the first time specifies detailed test parameters. These guidelines support the Principles for Risk Analysis of foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as source of food, and that have been modified by modern biotechnology to exhibit new or altered

expression of traits. The document does not address animal feed or animals fed with feed or environmental risks.

21. The Codex 2003 is based on the principle that the safety of foods derived from GE plants *“is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects”*. This is a clear recognition of the risks of GE. The Codex in fact makes a specific point of noting that:

“It is recognised that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts”. The concept of ‘substantial equivalence’ according to the Codex fully supports the evidence of independent scientists who have demonstrated that GE foods are not substantially equivalent to their conventional counterpart; that this concept has been completely misused and misrepresented and has been erroneously applied as the end point in safety assessment in order to facilitate their market release. The Codex goes on to say that SE *“is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart”*,. The safety assessment approach of the Codex falls within the risk assessment framework of Section 3 of the ‘Principles for the Risk Analyses of Foods Derived from Modern Biotechnology’. The Guideline describes the recommended approach to making safety assessments of GM plants and identifies the *“data and information that are generally applicable to making such assessments”*. Thus the goal of *“each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value --- including through food processing”*. It endorses the view of Prof Seralini and that GM plants

must be tested like chemical pesticides. This is also because of the proven ability of microorganisms to absorb pesticides, and concentrate it in each nutritional level of the foodchains, a phenomenon called biomagnification; so that by the time it gets to the fatty tissues of birds or the breasts of women the concentration is hundreds of thousands of times higher than the initial application. DDT is the infamous example. The Codex speaks in terms of *“accumulation of pesticide residues, altered metabolites, -- toxic metabolites, contaminants or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account”*. Pusztai’s evidence to this Hon’ble Court in the WP specifically states that Bt cotton is a potentially toxic crop whose toxins and 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 tissue. Finally, like Dr Pusztai and Prof Schubert, the Codex concludes that safety assessment is an evolving science which must be reviewed in the light of new scientific information that *“calls into question the conclusions of the original safety assessment: --- as scientific knowledge and technology evolves, other methods and tools may be considered ----“* The Codex Alimentarius ‘Guideline For The Conduct Of Food Safety Assessment Of Foods Derived From Recombinant- DNA Plants’ is annexed hereto as **Annexure S10**.

22. The above evidence highlights the laxness that prevails internationally, by national regulators and the biotech crop developer, in current health safety testing in the absence of specified protocols and the degree of rigour and transparency that is required to ensure that safety testing is undertaken according to the evolving best science and practices, which alone will ensure that the public are not guinea pigs in the experiment with GM crops. Other ecological and biosafety aspects, farming economics, farmer rights and development are even more complex and will require much more work to determine their impacts. Various studies on environmental

impacts thus far demonstrate clear and serious problems. It is therefore surprising that, in the light of the comprehensive evidence of sound science against the safety of GM crops, and the demonstrated absence of health safety testing of Bt crops in particular, leave alone the much wider and complex issue of biosafety testing, the Union of India is able to make un-judicious, even sweeping, and thoroughly unsubstantiated claims about the BIOSAFETY of Bt cotton in India. This is not merely astounding it is irresponsible and an attempt to mislead this Hon'ble Court. Fortunately, so blatant a falsehood is easily perceived. The following example serves to clarify the essential untruth of their stance. The Petitioners focus on one of the more significant sources used by the Respondents to bolster their assumptions about the safety of GM foods. Reference is made to their reliance on the EU Commission report, referenced on pg. 21 of the Counter Affidavit, subtitled 'EU Commission'. It refers to 81 EC supported research projects over 15 years with 400 scientific teams at a cost of Euro 70 million. The Petitioners in reply present the following facts and clarification:

- In 2001, the EC identified 81 EC-funded research projects on GE organisms that were in progress, but not conducted.
- An accurate assessment in 2003 of peer-reviewed literature on the health safety of GM foods and feeds, by Pryme & Lembcke (2003), found only 10 "in vivo" studies. Of these only 5 were independently funded. The authors found that more scientific effort and investigation was necessary before GE foods could be considered unlikely to cause long-term human health problems.
- In the comprehensive analyses by Pusztai in 2005, annexed along with this Rejoinder Affidavit as Annexure S9 'GMOs in Animal Nutrition' that number was raised to 19. Most of these are industry-sponsored and are criticized as superficial and poorly designed, as Pusztai clarifies: *"relatively short-term animal feeding/production experiments, particularly as they are presently carried out, do not contribute much to*

GM safety"; --- "so also, the failure to distinguish between a scientific study and an animal production exercise". The above Review was written under the sponsor's explicit instructions to leave out all production studies from the review as "these may be of some value to commercial animal production but have limited scientific value".

- Again, as Prof Schubert has amply clarified and exposed in his peer-reviewed article in 'Biotechnology and Genetic Engineering Reviews' (annexed along with the Writ Petition as Annexure P17), "numerous health risks of GM foods are not being tested for", and cited "serious deficiencies in both regulatory oversight and corporate testing procedures"
- The eminent geneticist and environmental commentator David Suzuki said it more clearly: "Any politician or scientist who tells you these products are safe is either very stupid or lying. The experiments have simply not been done".
- Furthermore, with regard to the growing criticism of EFSA, (European Food Safety Authority), as a deeply compromised watchdog of food safety, several of the EU's 25 environment ministers at their last meeting in March, accused EFSA of failing to take independent and national studies into account for its GMO risk assessments and of not allowing proper access to its research. Europe's Parma-based food safety agency, which conducts scientific risk assessments of GMO products awaiting EU approval, echoed similar criticisms made last month by the bloc's environment ministers. On the 5th April 2006, Europe's environment chief Stavros Dimas in a news conference, attacked the EU's top food safety agency on Wednesday for flawed risk assessments of genetically modified (GMO) crops and foods, saying: "There are questions like whether scientific opinions rendered by EFSA have relied exclusively on information provided by companies that look at short-term effects", and "EFSA cannot give a sound scientific opinion on long-term effects of GMOs. There are also questions on whether

GMO companies are providing the right information to the European Commission”.

Additional references for this evidence are provided in **Annexure S11(Colly)**: ‘Dr. Arpad Demolishes Monsanto’s Claims that GMOs Have Been Proven Safe’; ‘Why opposition to GM Crops is based on Sound Science’; ‘Reply to Spin’ by Jeffrey Smith and a Reuters Report of the 5th April 2006, ‘EU Environment Chief attacks Commission for Flawed Health Safety Checks’.

23. The Respondents in their Counter Affidavit have stated that, “*the commission has today published a report....*”. The report specifically states that there are no new risks to human health or the environment from GM crops and that “*the precise technology (of GE) and the greater regulatory scrutiny probably make them even safer than conventional plants and foods*”. Since the Petitioners are neither aware of the date nor the report, because it has not been referenced as it should have been, it would be useful in the interest of food safety, not just in India but internationally and the truth, to be provided the relevant references.

24. That, further the Petitioner would also like to place on record new critical evidence, which comprises of:

- ❖ The current and updated situation of Bt cotton in India
- ❖ Field trials of Bt okra, Bt Brinjal and Bt Rice
- ❖ The proposed plans of the Gov. of India to import large quantities of soy products from the USA and continued imports of soy oil in the form of crude and refined oil from both the US and Argentina. It is accepted that in both countries, up to 85% of the soy is either GM or contaminated with GM and its import into India is therefore illegal. In view of the importance of soy to the Indian context, the Petitioners have highlighted in the summary provided below, and elsewhere, specific

hazards related to GM soy, why it is a *particular* health risk.

- ❖ Monsanto's Bt Corn 863;
- ❖ Super weeds in UK Farm Trials.
- ❖ Russian tests on rats fed GM soy;
- ❖ 10 years of research terminated on a GM Pea;
- ❖ Bt Resistance Scientifically proven for the first time;
- ❖ Significant added evidence on the dangers associated with the cauliflower mosaic virus (CaMv).

The new evidence provided in this Rejoinder Affidavit underpins the sense and rationale of the Petitioners plea for GM-free imports and labelling which are complimentary measures for an effective and meaningful moratorium. Before addressing the new evidence contained in this Rejoinder Affidavit, it would be useful and pertinent to provide a recapitulation of the major findings contained in the Civil Writ Petition referred to above and provide new references where relevant that augment and validate these findings.

25. That, the Petitioners in their Writ Petition have cited annexed reports, which clearly substantiate their contention that no GM crop has ever been formally approved as safe for human consumption by the FDA, which facilitated their entry into the market through a 'sleight of hand' manoeuvre that provided GM foods GRAS status. Their global spread has been spearheaded by the US, including through such US spellbound institutions like the WTO and even the UN in the form of GM food aid. Governments mostly, including the EU Commission, EFSA (The European Food Safety Authority), the UK and French Governments have shown unprecedented willingness to toe the US line and similarly foster the multi-billion dollar biotech industry for their own political ends, with scandalous cover-ups and lies, overriding extremely serious public safety health considerations. The Indian Regulatory Authorities of the Government of India have outdone

even these 'achievements', demonstrating significant laxness in their approvals of Bt cotton for commercial release in India, and post Bt cotton monitoring is conspicuous by its absence. The potential health impacts through the contamination of the food chain through milk and oil are particularly serious, as village communities have traditionally used cottonseed cake as animal feed and feed for milch cattle to obtain a better fat content in milk. Furthermore, in India, cottonseed oil is also used for human consumption. However, no proper safety testing is being done on these GE crops before they are allowed to enter human as well as animal food chains.

- 26.** The evidence underscores the fact that as the time element increases with the commercial release of GM crops, there is a significant rise in the number of serious health effects being reported worldwide, including environmental and other biosafety impacts. Thus far, there has been a marked difference between 'independent' and industry-generated reports and studies. The independent reports observed health concerns; the industry-related or industry-supported studies did not. Of the former, there have been only a handful: an analysis of all peer-reviewed animal feeding safety tests on GM foods, published in *Nutrition and Health* in 2003, found only 10. Another comprehensive analysis published in October 2005, refers to 19. Most of these are industry-sponsored and are criticized as superficial and poorly designed. The peer-reviewed article of Prof. David Schubert in *Biotechnology and Genetic Engineering Reviews* already extensively covered above (reference is made to Annexure P17 of the Civil Writ Petition) exposes numerous health risks of GM foods that are not being tested for, and cited "serious deficiencies in both regulatory oversight and corporate testing procedures." His recent stinging and unambiguous response to Bradford et al on the misuse of scientific language, to promote 'themselves' (biotech), details abundantly, the use of

'genetically modified language' to obscure the serious hazards surrounding GE crops:

"I, and hundreds before me, pointed out that [the claim that GM plants are no different from classically bred plants] is unambiguously not the case. I used specific references to show that many of their statements were misrepresentations of scientific fact. In their reply to my comments they used several new rhetorical techniques in addition to the standard ones such as taking statements out of context and misquoting sources. Of greatest concern is the new lexicon that has been evolving in the plant biotechnology industry over the last decade... Perhaps the most curious aspect of all is that plant biotechnology is complaining about a regulatory system that was written by their lawyers (Eichenwald et al., 2001) and at least with respect to the FDA is voluntary and lacks safety testing requirements altogether (as referenced by Dave Schubert: Gurian-Sherman, 2003; Freese & Schubert, 2004). Although they have what they asked for, they are still complaining about it".

A copy of the abovementioned reply given by Prof. Schubert and Gurian Sherman is annexed hereto **Annexure S12**.

27. That HGT (horizontal gene transfer) and other 'unintended effects' are now well established scientific facts. It would be useful to clarify again, that the Genetic Engineering process itself is achieved through HGT because it moves genetic material between organisms, which are asynchronous with the reproduction of 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, secondary, unintended HGT can take place from GE crops released into the environment. In the only human study conducted, it has clearly been shown that a transgene from GE SOYA can survive passage through the

small intestine and can transfer its DNA to the microflora of the small intestine (Netherwood et al., 2004). This trial confirmed findings of HGT in similar animal studies. The significance and importance of this in animal husbandry cannot be overemphasised in view of the general practice of including antibiotics in animal feed.

The genetically engineered Bt-toxin is even a thousand times more concentrated than the spray. The spray degrades in the sunlight in a few days, but the GM variety is produced by every cell of the maize/cotton, around the clock, and eaten by animals and the cottonseed oil, by the consumer. Mice exposed to Bt-toxin developed an immune response equal to that of cholera toxin, developed a greater susceptibility to allergies, and developed abnormal and excessive cell growth in their small intestines. Farm workers exposed to even the low dose Bt spray showed evidence of allergic sensitivity, and blood tests showed an immune response. Preliminary evidence found that thirty-nine Philipinos living next to a Bt maize field developed skin, intestinal, and respiratory reactions while the maize was pollinating. Tests of their blood also showed an immune response to the Bt. Toxin. Now, there are documented allergies in MP as well, showing mild to sever allergies to farm workers employed for cotton picking.

The StarLink incident well documented in the Writ Petition, involved recalls and an attempted cleanup amounting to hundreds of millions of dollars and it is still contaminating the system, even though only 1% of the corn sown in Iowa was StarLink. This was a dire warning of the disastrous consequences of GM contamination because of lax controls regarding segregation and ensuring the security of the seed system. In India the Government does not consider that segregation is even an issue! It is also proven that there can be no co-existence between GM and non-GM crops because transgenic contamination of the natural environment is a biological certainty.

28. That the Petitioners have clearly shown through the evidence presented to this Hon'ble Court that the GOI and its regulatory authorities have primarily relied upon assumptions about the safety of genetic engineering, the main one being the unscientific and therefore, fully discredited notion of substantial equivalence, for their claims about the safety of this technology. They also rely upon their own studies and/or those of the crop developer, a demonstrated conflict of interest. Nor have they undergone the scrutiny of honest science or the peer review process. Their performance and submission to this Hon'ble Court are replete with flagrant misrepresentation of facts, and a total disregard of negative market feedback about Bt cotton, even to the point of tyranny. The word is employed reluctantly but with deliberation by the Petitioners because of distraught and agonised Indian farmers whose lives have been blighted by a blighted cotton crop called Bt. Their absolute refusal to consider the overwhelming evidence of honest science, from scientists of international eminence, of serious hazards connected with GM is proof of an amoral and abject commitment to the dark objectives of an industry bent on profiteering and commercial gain at any cost. Monsanto leads this pack. Monsanto is also the company with 70 years of a dark history and an even darker dream as described earlier. It has a history of sabotaging regulatory regimes of many third world countries, including bribing Government officials to get clearances for GMOs. Further deeds shed further light.

About Monsanto: More Lies, & Fraud –a menacing entity:

29. Monsanto omitted incriminating data altogether from its 1996 published study on GM soybeans. When the data was recovered later by an investigator, it showed that GM soy contained significantly lower levels of protein and other nutrients, and toasted GM soy meal contained nearly twice the amount of a lectin that may block the body's ability to assimilate

other nutrients. Furthermore, the toasted GM soy contained as much as seven times the amount of trypsin inhibitor, a major soy allergen. Monsanto named their study, "*The composition of glyphosate-tolerant soybean seeds is equivalent to that of conventional soybeans.*"

30. In February 2006, more than 90 Texas cotton farmers have sued Monsanto Co. and two affiliated companies, claiming they suffered widespread crop losses because Monsanto failed to warn them of a defect in its genetically altered cotton product. The lawsuit, which was filed in federal court in Marshall, Texas, seeks an injunction against what it calls a "*longstanding campaign of deception,*" and asks the court to award both actual and punitive damages. The farmers claim there is evidence that the promoter gene inserted into the cotton seeds in the genetic modification process does not work as designed in extreme high heat and drought conditions, allowing herbicide to eat into plant tissue, leading to boll deformity, shedding and reduced yields. The plaintiffs claim Monsanto knew this but did not disclose it so the farmers would continue to buy and use Monsanto's Roundup herbicide. A copy of the news report titled, 'Texan Farmer Sue Monsanto' published by Reuters Business News is annexed hereto as **Annexure S13**.

31. Monsanto consistently reported increased yields on GM soy, canola and cotton, whereas farmer reports and independent studies show decreases. In India, the new evidence is replete with their continuing shenanigans, aided by a willing Regulator and has been listed separately below.

BT COTTON IN INDIA

32. Monsanto and the biotech industry have consistently put out one set of statistics on the success of Bt cotton in India, a version which the GEAC and DBT appear to agree with. The GEAC approved six new varieties of Monsanto-derived Bt cottonseed for commercial use in the fertile northern states of Punjab, Rajasthan and Haryana, and eight new varieties have

approval for large-scale trials in these states. This greatly extends the area given to GM cotton - which had previously been restricted to six central and southern states - in spite of the overwhelming evidence of harm caused to farmers' livelihoods by the GM varieties, because of lower yields, continued (not reduced) pesticide use and the unsound economics of Bt cotton. And concurrently, large-scale trials have been expanded for Bollgard II (BGII) a product of Monsanto that encodes for 2 Cry proteins. Indian farmers were warned that resistance on their farms to the Bt transgene was growing, especially in Gujarat one of the first States to plant Bt cotton in 2002. Formal field research by the Scientists at the Central Institute of Cotton Research clearly demonstrated this fact. Now there is "unequivocal evidence" of resistance to the Bt transgene in two different studies in Australia and Hungary. The fallout with regard to Bt Cotton has been so great, with every national and regional paper providing coverage that the truth can no longer be disguised. The Maharashtra State Govt. has agreed on paper, compensation to farmer losses as a result of the failure of Bt cotton, putting an official seal of acceptance on its non-performance.

33. Despite clear evidence to the contrary, it is strange that Monsanto consistently reports increased yields everywhere not just in India, on soy, canola and cotton. In India, for example, Bt cotton yield was by up 58% on a country wide basis, resulting in a 60% increase in farmers' incomes; and in Andhra Pradesh, 46% with a 65% reduction in pesticide costs which gave a 42% increase in income to farmers. A notorious piece of research by Martin Qaim (University of Bonn) and David Zilberman (University of California, Berkeley) was published in *Science*, claiming outstanding (80%!) yield increases from Monsanto's GM cotton; and projected the results as relevant to farmers throughout the developing world. The paper drew a storm of protest, as it derived all its data from Monsanto and its findings were completely at odds with the reports coming from Indian farmers. Dr Devinder Sharma, a food policy expert, and co-petitioner to the

WP called Qaim and Zilberman's paper a "scientific fairytale". Similarly, Doug Gurian-Sherman Senior Scientist at the Centre for Food Safety in Washington has caught the misinterpretations on Bt cotton yields in India spot on by exposing the dishonest and artful wrong allusions. He says *"This kind of spin is typical of proponents of GE crops, who don't seem to have enough confidence in their technology to make accurate and realistic arguments"*. The copies of the abovementioned documents titled, 'In Defence of Bt cotton' and 'India's Bt cotton fraud' is annexed hereto as **Annexure S14 (Colly)**

34. Like studies on food safety, independent studies on Bt cotton show decreases in yields, growing pest resistance and farmer bankruptcies. Monsanto resorts to its old tricks of fraud, cover-up and some new angles with advertising, which include Bollywood and religious endorsements and dancing-girls for spin, hype and 'hula'. For example, in advance of a deadline for a decision on licence renewal in March 2005, Greenpeace and the Sarvodaya Youth Organization released two versions of a report on Bt cotton prepared by the Joint Director of Agriculture of Warangal District, Andhra Pradesh (AP). The data in the original report, commissioned under a memorandum of understanding between the AP government and Monsanto-Mahyco, revealed a comprehensive failure of Bt cotton in AP. The second, visibly tampered-with-version, exaggerated the yields, thereby substantially reducing Monsanto's compensation to farmers. The study by the government of Andrah Pradesh found a decrease in yields of about 18%. When they told Monsanto to pay about US\$10 million compensation to the farmers, the corporation refused and was kicked out of the state altogether.
35. That agricultural scientists Dr Abdul Qayum and Kiran Sakkhari have conducted the first ever sustained independent study of Bt cotton on a season-long basis for three years in 87 villages of the major cotton

growing districts of AP - Warangal, Nalgonda, Adilabad and Kurnool - and found against Bt cotton on all counts. Some of the main findings of this report are:

- a. Bollgard failed miserably for small farmers in terms of yields; non-Bt cotton surpassed Bt in yield by nearly 30% with 10% less expense
- b. Bollgard did not significantly reduce pesticide use; over the three years, Bt farmers spent Rs. 2571 on pesticides on average, while the non-Bt farmers spent Rs.2766
- c. Bollgard did not bring profit to farmers; over the three years, the non-Bt farmers earned on average 60% more than Bt farmers
- d. Bollgard did not reduce the cost of cultivation; on an average, the Bt farmers had incurred 12% more costs than non-Bt farmers
- e. Bollgard did not result in a healthier environment; researchers found a special kind of root rot spread by Bollgard cotton, infecting the soil so that other crops would not grow.

A copy of the said report titled, 'Bt Cotton in AP: A 3-year assessment' by Abdul Qayum and Kiran Sakkari is annexed hereto as **Annexure S15**.

36. In spite of Monsanto's ban in Andhra Pradesh, their faulty cotton was allowed in Madhya Pradesh. According to a November 14, 2005 article in NewKerala.com, it has been a disaster there too. Rampant wilting in 200,000 acres caused an estimated \$87.5 million USD in damages. The article also described a health report that showed "Bt cotton was causing severe to moderate allergy to people coming in contact with it." On November 10, 2005, *The Hindu* reported that "Up to 75 per cent of the Bt cotton seeds" planted in parts of Tamil Nadu "failed to germinate this season," and on November 27 they said that India's central government "conceded the failure of Bt cotton in Andhra Pradesh and Rajasthan."

37. That Petitioner No.1 met with representatives of farmer groups in Barwani and Dhar in MP. Their report on the 'Impact of Bt Cotton on Farmers' Health, Oct-Dec 2005' is annexed hereto as **Annexure S16** to this Rejoinder Affidavit. It would be relevant to mention here that 23 labourers and farmers from 5 villages who complained of allergies were interviewed. Substantial detail is recorded of mild to severe allergies, skin, eye and respiratory, and definitely linked to Bt cotton as a direct result of Bt cotton picking. In the 2004 season too, there were reports of a number of buffalo deaths (milch) and allergies to farmers/labourers. A copy of the news item titled 'Bt cotton causing allergic reactions in MP: cattle dead' is annexed hereto as **Annexure S17**. When the Indian experience mirrors similar allergies to a Bt crop reported from elsewhere like the Phillipines, and cows dying in Germany, then the government must be doubly alerted that something is seriously wrong. By doing less than nothing, they have sent out a crystal clear signal of their support of the biotech industry no matter what the cost.

38. That Petitioner No.1 also spoke at length to Kishore Tiwari, Farmer Groups representative and activist in the Yeotmal area of the Vidharbha region in Maharashtra, which has seen some of the worst cases of farmer suicides in the Country. The agony is unspeakable. He says, biotech is making hay: up to 6 varieties of illegal Chinese Bt cottonseeds have been booked for the next season. The glib rider on orders booked is, "pending approval". The State Government's Department. of Agriculture has made the quite ineffectual remark that Bt. Cotton is not suited to the region! This inane remark is the sum total of their involvement and is an insult to farmers who have been desperate enough to commit suicide. The suicide rate over the last 4months is 3 farmer/day. This brings the total count in Vidharba to over 400 of which 300 suicides are directly linked to Bt cotton, farmers who opted for Bt cotton but which ultimately failed. A copy of the report titled,

‘Vidharba Farmers victims of Government Policy and Monsanto’s False Promises’ by Kishore Tiwari is annexed hereto as **Annexure S 18**.

- 39.** That on 4th March 2005, GEAC held its 52nd meeting where it was agreed that until an alternate mechanism for monitoring large-scale trials is established; these Bt trials could be monitored by the MEC (The Monitoring and Evaluation Committee [MEC] across the country. The MEC was set up by Adivasi Ekta Sangathan, AKRSP, CEAD, Centre for Sustainable Agriculture, Grameen Vikas Trust, Greenpeace India, Jan Saahas, Kheti Virasat Mission, Krishnadevaraya Rythu Sankshema Sangam, Krushi, MARI, Navajyothi, Pasumai Tayagam, Prasun, Rashtriya Satyagrah Dal, Sampark, Sarvodaya Youth Organisation, SECURE, VASPS and YUVA). The MEC reports gross irregularities in field trials across India. They constitute major biosafety violations involving ‘refuges’ to limit transgenic contamination, monitoring, non compliance with regulations and serious safety issues with regard to produce being sold in the open market, and lack of unscientific guidelines in conducting these trials. A copy of the The MEC Report titled, ‘Field Trials of GM Crops In India: Illegal and Unscientific’ is annexed hereto as **Annexure S19 (Colly)**.
- 40.** The latest findings by the MEC show that in the Kharif season of 2005, cumulative losses by AP farmers is around Rs 400 crores. The cost of cultivation per acre of Bt Cotton was around 67% higher than NPM/Organic Cotton, while net incomes were lower in Bt Cotton by at least 37% compared to NPM (non-pesticidal management)/Organic Cotton. The study also found that the pest incidence in Bt Cotton was higher than in NPM/Organic Cotton and that the pesticide cost on Bt Cotton was 378% more than on NPM/Organic Cotton. The government’s own assessment is in agreement with these finding with regard to pest incidence. Data collected by the CSA from the agricultural department also substantiates the findings of lower yields of Bt cotton of 406 quintals per

acre, far below the promised yields for Bt cotton. Stress intolerance and high susceptibility to sucking pests was also acknowledged. Furthermore, a question mark has been raised over the viability/validity of hybrid varieties of Bt with the acknowledgement by the government that it is suitable under specific conditions only; fertile soils with good INM (Integrated Nutrient Management) and assured irrigation. The experience of India is not unique. Non-performance of GM cotton in other locations around the world is reported. The petitioners draw attention to the evidence cited of 90 Texan farmers who are suing Monsanto for non-performance of its GM cotton because it has failed to give promised yields under drought and heat conditions. The evidence concerning the above is also appended as **Annexure S20 (Colly): 'No respite for Bt cotton farmers in AP'**

41. The above evidence clearly demonstrates deliberate apathy, amounting to virtual tyranny of our farming community, non-compliance and clear violations of the law and procedures on genetic engineering. Since this is the repeated evidence with regard to the approvals and release of Bt cotton, there is by now abundant proof of an official regulator turned approver of GM technology in India. The following reports provide even more damning evidence.

Bt OKRA, RICE AND BRINJALS

42. That the Petitioners, for the sake of brevity, are not repeating the facts regarding the open field trials of Bt Okra, Rice and Brinjals as they have already been comprehensively covered in their 'Application for Urgent Interim Orders' filed on 23.03.2006 with relevant Annexure Nos. P3 & P4. Major violations were accidentally found by the CSA. They cover fraud, extremely serious biosafety lapses and major issues of ethics. A recent CNN IBN news item dated 27th March 2006 reports that 40 food crops

including maize and mustard are also under trial awaiting government approval before they can be commercially grown. *“For starters, the Genetic Engineering Approval Committee, or the GEAC, the final authority on regulating GM cropping in India, has no idea where the field trials are taking place. In fact, private companies like Monsanto and Mahyco actually keep the field trials secret”*. Co Chairman of the GEAC DD Verma says:

“We don't know the exact fields where they are taking place. But we do know how many and in which districts”.

The trials are taking place across India. In Warangal, for instance, CNN-IBN found a field trial plot where the farmer *“has just finished harvesting the crop. But strangely, most of the trial guidelines have been violated and it's not just a one-off case”*. A copy of the report made by CNN IBN and reported by GM Watch titled, 'Transgenic Threat to Indian Crops' is annexed hereto as **Annexure S21**.

43. That therefore, such sovereign issues as India's farming policy and farmer economics, food safety, food security, health safety and the larger huge issue of biosafety are astonishingly in the hands of the likes of Monsanto and other multinational biotech corporations, put there by the official regulator, the GEAC. The implications are dire for India. There isn't even a token attempt by the GEAC to scrutinise the decision to conduct the trials in the first place, (some of which have not been conducted elsewhere, like okra), leave alone to conduct them extremely carefully and safely. Centre stage focus must be given to the fact that internationally, India is recognised to contain some of the few remaining ecological 'hotspots' that exist worldwide. India is also the treasure trove of the largest depository of rice genes in the world. These field trials are very dangerous. The Petitioners stress that transgenic contamination is irreversible.

SOY PRODUCT IMPORTS FROM THE US AND PARTICULAR HAZARDS CONNECTED WITH SOY

44. The most common allergen in soy is called trypsin inhibitor. GM soy contains significantly more of this compared with natural soy. The British Medical Association had warned that GM foods might lead to the emergence of new allergies. A finding in March 1999 is telling. Researchers at the UK's York Laboratory tested 4,500 people for allergic reactions and sensitivities to a wide range of foods. Soy had previously affected 10% of consumers. In 1999, however, that jumped to 15%. Soy entered the list of top ten allergens for the first time in the seventeen years of testing. Reactions included irritable bowel syndrome, digestion problems, skin complaints, chronic fatigue, headaches and lethargy. Blood tests confirmed an antibody reaction to soy. *GM soy had recently entered the UK and the soy used in the study was largely GM.* John Graham, spokesman for the York laboratory, said, "We believe this raises serious new questions about the safety of GM foods."

- There are no formal guidelines in place to test a new food's potential to cause an allergy. It is left to the industry to decide this. According to the FDA's own scientist, who had written years earlier, "*Are we asking the crop developer to prove that food from his crop is non-allergenic? This seems like an impossible task.*" According to the US EPA Scientific Advisory Panel, "*Only surveillance and clinical assessment of exposed individuals will confirm the allergenicity.*" Unfortunately, no such surveillance exists. The Codex is also clear on this: "*At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein*". In the absence of labelling, epidemiological studies are impossible. Yet, this very lack, with reference to the general population in the US and Canada, who have been exposed to ten years of GM crops, is twisted around by the Respondents as evidence of their safety! The Regulator therefore is

seen yet again, to tout the industry line of spin and deceit and thoroughly erroneous science.

- The FAO/WHO does suggest criteria that minimize the likelihood that allergenic GM crops would get approved. *The GM soy already on the market, however, fails those criteria*—sections of its GM protein are identical to known allergens; also maize and papaya. The EU imports GM soy for use in animal feed. Many European food producers however are committed to switch to non-GM sources. This is why the demand for Indian soy is rising. Reference to this is made in **Annexure S22**: 'Indian Soymeal exporters eye big sale; Reuters Report 26-9-2005. It is to be noted that Soy oil imported by India from the US and Argentina is GM
 - Since the inserted gene transfers to gut bacteria, even if you stop eating GM soy for the rest of your life, you still might have this foreign protein being created inside your intestines.
 - The promoter, which is inserted into soy to activate the foreign gene, also transfers to gut bacteria, and may switch on one of the bacterium's genes at random, creating problems.
- 45.** That what follows is also part of the evidence in the 'Application for Urgent Interim Orders', dated 23.03.2006 along with its relevant Annexure P5. A précis is therefore provided here. The American Soybean Association (ASA) is a body of US farmers engaged in lobbying for overseas markets. It claims to be 'a non-profit, farmer-controlled organization but it enjoys a remarkably close relationship with Monsanto and other biotech corporations. In fiscal year 2000 it is known to have received \$2.1 million of its \$26.7 million budget from Monsanto, Pioneer Hi-Bred International, BASF, Stein Seed Co. and others. Current levels of imports of \$10 million worth of American soy products are targeted (by this body), to rise to \$30 million. Furthermore, there is conclusive proof that soy imports including oil from Argentina and the US are GM and that in the absence of labeling requirements in these countries, that this fact is being knowingly used as a backdoor entry for GM imports into India.

- 46.** That the Petitioners have provided extensive evidence in their WP of the pervasiveness of transgenic contamination and that at 0.1% it has been proven that there can be no co-existence between GM and Non-GM agriculture. In America, and Canada the system is contaminated. 75% of foods and processed foods and feeds with ingredients based on soy, corn or rape have GM content and even organic certified foods sourced from the US and exported, have been found to be contaminated.
- 47.** That furthermore, wild rape or Charlock in the UK being contaminated by GM rape reinforces beyond doubt the seriousness of the issue of contamination. Thus secret open field trials of rape and other foods in undisclosed and un-known-to-the-GEAC locations, emphasise the extreme urgency for remedial action if the food chain is to be protected from GM contamination and potential biosafety hazards. That in view of these facts, the Petitioners are constrained to state that the GEAC and DBT actions reflect a serious dysfunction in the democratic process and are manifestly unfit to declare GE policy for India. That given the crisis situation regarding transgenic contamination, most urgent legal action is required to redeem the situation once and for all thorough a moratorium pending the stringent, transparent and open-to-the-public biosafety testing protocols as prayed for in the WP; that a concurrent ban is also necessary as submitted in the application for an ex-parte injunction dated 13.05.2005, on 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. This safeguards a situation where an irresponsible Government Agency has the terrible power to commit India on a path, which has irreversible consequences for its people and the bio-safety of the Country. The further evidence that follows reinforces the grounds for this plea.

C. MONSANTO CORN 863: A HEALTH SAFETY HAZARD

- 48.** Evidence surrounding MON 863, dealing with a part of the history of cover up, manipulation and secrecy under a false claim of CBI (confidential business information) by Monsanto was presented in the WP paragraph 41. The following information has been made public subsequent to the Petitioners WP and underscores and augments the need for urgent action by this Hon'ble Court to enforce the 'Prayers' requested in the Writ Petition.
- 49.** MON 863 is a Bt corn variety engineered to attack corn 'rootworm', a pest. Monsanto's assessment of their own study into the effects of feeding rats Mon 863 for 90 days was completed in September 2003. This was required to obtain EU approval for Mon 863 for animal feed. The 1139 page study found 'statistically significant' differences to kidney weights and certain blood parameters in the rats fed on the GM maize as compared with the control groups. A number of scientists across Europe who saw the study (and heavily-censored summaries of it) expressed concerns about the health and safety implications if MON863 should ever enter the food chain. There was particular concern in France, where Prof Gilles-Eric Seralini, a molecular endocrinologist at the University of Caen, agrees that the results indicate a toxic reaction. He is a member of two French government commissions that evaluate GM food, one of which originally rejected a request for approval of Mon 863 in October 2003 due to the adverse findings contained in Monsanto's own study. Seralini won a French lawsuit allowing him to express his concerns in public. He also tried for 18 months without success, to obtain full disclosure of all documents relating to the MON863 study. The French authorities tried to cover-up the scientific debate. Monsanto denies there is a health safety hazard and explains away statistically significant effects.
- 50.** In the autumn of 2004, concerns were expressed about the study findings by a number of other national regulatory bodies including Belgium and

Germany. Germany commissioned Dr. Arpad Pusztai, the world-renowned research biologist, toxicology expert and specialist in plant genetics and animal feeding studies, to evaluate Monsanto's 90-day rat feeding study. He had to sign a "declaration of confidentiality" on grounds of CBI (confidential business information), before Monsanto would allow him access to the research dossier, which the German government acceded to. (This is the same Dr. Pusztai whose work seven years ago, in the only systematic feeding trials ever carried out with a GM food, found stomach lesions in young rats fed GM potatoes. He was discredited by British government ministers and forced into retirement by the public-funded Rowett Institute. Dr. Pusztai has also given evidence to this hon'able court, which includes a protocol for bio-safety testing which is recorded in Annexure P6 of the Writ Petition). His review of the 1139 page report in three parts is appended to this Rejoinder Affidavit as **Annexure S23: 'Mon 863 feeding study in 3 parts by AP'**. In brief, rats fed Mon 863 developed several reactions, including those typically found with allergies (increased basophils), in response to infections, toxins and various diseases including cancer (increased lymphocytes and white blood cells), and in the presence of anaemia (decreased reticulocyte count) and blood pressure problems (decreased kidney weights). There were also increased blood sugar levels, kidney inflammation, liver and kidney lesions, and other changes. His evaluation was also highly critical of the methodology of the study, which was confusing, flawed, even rigged to avoid feeding problems and full of omissions. These concerns were similar to those of Prof Seralini and scientists in Germany and elsewhere. According to Arpad Pusztai, based on the evidence no one can say that Mon 863 will cause cancer or allergies or anything specific. The results are preliminary and must be followed-up to rule these out. He warns, however:

"It is almost impossible to imagine that major lesions in important organs. . . . or changes in blood parameters. . . . that occurred in GM maize-fed rats, is incidental and due to simple biological variability."

- 51.** On 20th June 2005, in response to a Greenpeace petition, a German court ordered Monsanto to make public their 1139 page dossier on MON 863. The data upheld the claims of prominent scientists including Prof. Seralini and Dr. Pusztai. It also revealed that European regulators accepted the company's assurances that their corn is safe in spite of the unscientific and contradictory rationale that was used to dismiss significant problems. Both Pusztai and Seralini are uniquely qualified to evaluate the study. Seralini studies endocrine disruptors and the impact of pesticides on health. He was one of four experts appointed to respond to the WTO challenge filed by the US against the European Union's policy on GM food and crops. He has read all of the industry's GM-food submissions to Europe as well as all the commentaries on the submissions. Pusztai is the leading authority in his field of protein science (lectins) and had been commissioned by the UK government in the 1990s to develop the ideal testing protocol for all GM foods. Although his protocol (now part of the Writ Petition, Annexure P17) was supposed to be adopted by the UK government and eventually in Europe, Pusztai's controversial finding that GM potatoes damaged the health of rats ultimately stopped the work. Pusztai has also been commissioned to evaluate all published studies on GM foods, and has analysed most of the confidential submissions made by industry.
- 52.** Both scientists have expressed alarm about the unsupported arguments that Monsanto and some European regulators use to force product approvals. Mon 863 is not the first GM food in Europe to have shown significant health effects in rats. According to Seralini, an oilseed rape GT 73, roundup Ready corn (NK 603) and two Bt corn varieties (Bt 11 and

Mon 810) all showed statistically significant problems that regulators did not pursue with follow-up research. Speaking on the need for more studies, rigorous tests on MON 863 that can stand scientific scrutiny, Seralini says:

“Other experiments with rats during one and two years, and also with two other species of mammals should be conducted in order to study potential adverse effects of the genetic modification, to know if these are linked to the Cry3Bb1 toxin or not, like it is regularly performed for other pesticides. GMOs should not be exempted from pesticide evaluation if they contain pesticides or specific pesticide metabolites. In the absence of such results, the agreement for maize release into the environment, for food, feed or cultures, may present a serious risk for human and animal health and the release should be forbidden”.

53. He says that the effects of GM crops were similar to that of pesticides. *“I believe it is not an isolated case and that the pesticides contained within GMOs have the same kind of side effects as chemical pesticides”.* The expert view of Seralini, a scientist who specialises on health effects of pesticides is particularly critical for India and the faulty approvals by the GEAC for Bt. Cotton for which no toxicology tests have been conducted anywhere in the world. The above evidence along with the flawed and faulty comparisons in Monsanto’s animal feeding studies are appended as **Annexure S 24 (Colly)**; also **Annexure S25 (Colly)**: ‘Report for India’ by Prof Gilles Seralini and ‘GM Corn Study Reveals Health Damage and Cover Up’, by Jeremy Smith
54. According to Pusztai, the quality of Monsanto’s study was well below that normally required for peer review publication. He says, *“it is odd, therefore that it remains the central document considered by government regulatory authorities upon which to make a decision to protect the health*

of European citizens-- Nutritional scientists and leading journals would not accept these blatant inadequacies and misinterpretations”.

CONTAMINATION OF WILD CHARLOCK (UK RAPE), BY GM RAPE

55. The study, ‘The Potential For Dispersal of Herbicide Tolerance Genes From Genetically-Modified, Herbicide-Tolerant Oilseed Rape Crops To Wild Relatives’ annexed hereto as **Annexure S26**, was conducted for DEFRA (Department for Environment Food and Rural Affairs), as a follow-up of the British government’s 3year Farm Scale Evaluations (FSE) which were completed two years ago. The dangers of hybridisation or horizontal gene transfer where it does happen are well documented. GM corn brought into Mexico from the US has contaminated Mexican landraces and its wild progenitor, Teosinte, via pollen and in Canada and Argentina, GM rape volunteers or super weeds resistant to herbicides are a plague for farmers. To stop their farm crops being overwhelmed with superweeds, farmers have had to resort to using older, much stronger varieties of "dirty" herbicide long since outlawed as seriously harmful to health and damaging to biodiversity. Farming is becoming increasingly noxious. In both the US and Canada, the whole system is contaminated. Yet, in the UK, in spite of the evidence to the contrary, government scientists had thought that GM oilseed rape and charlock were too distantly related for transgenic contamination to occur, something “virtually impossible”. Now, British agricultural scientists have found that a genetically modified (GM) variant of rapeseed has cross-fertilized with local wild charlock plants, creating a herbicide-resistant “superweed” in the process. The resulting charlock plants, which showed no ill effects after treatment with a normally lethal herbicide, were discovered among many other unaffected plants in a field that had been used to grow GM rapeseed as part of the British government’s three-year FSE of GM crops. Ecological geneticist Brian Johnson, who is head of the biotechnology advisory unit and head of the

land management technologies group at 'English Nature', the government nature advisers, said: *"Unlike the researchers I am not surprised by this. If you apply herbicide to plants, which is lethal, eventually a resistant survivor will turn up. You only need one event in several million. As soon as it has taken place the new plant has a huge selective advantage. That plant will multiply rapidly."* Scientists also collected seeds from other weeds in the oilseed rape field and grew them in the laboratory. They found that two - both wild turnips - were herbicide resistant.

56. What especially worries environmentalists is that because millions of charlock seeds can remain in the soil for 20-30 years before germination, it would be nearly impossible to remove any of the genetically modified strains. Potential problems such as these are what led many other European Union representatives, especially the French and Greek delegations, to seek an outright ban on GM rapeseed. The copies of the news reports and article published in Guardian and This Week titled, 'GM crops Created Superweeds say Scientists' and 'GM Crops Lead to Herbicide-Resistant "Superweed" dated 25th July 2005 and August 2, 2005 are annexed hereto as **Annexure S27 (Colly)**.

RUSSIAN RAT STUDY: 55.6% MORTALITY WHEN MOTHER RATS ATE GM SOY

57. This peer-reviewed study by Dr. Irina Ermakova, a biologist at the Institute of Higher Nervous Activity and Neurophysiology of the Russian Academy of Sciences (RAS) was presented by Jeffrey Smith to the American Academy of Environmental Medicine. The study, which was originally presented on October 10, 2005 to the symposium on genetic modification, organized by the National Association for Genetic Security (NAGS), showed that when female rats were fed Roundup Ready genetically engineered soy flour before and during pregnancy, and during lactation an astounding 55.6% of the offspring died within three weeks, compared to

only 9% from the group whose mothers consumed non-genetically engineered soy flour. Furthermore, those in the Roundup Ready group also exhibited significant reduction in weight compared to the controls.

“Given the magnitude of the findings and the implications for human health, we urge the National Institutes of Health to immediately replicate the research”.

A copy of the abovementioned study titled, ‘Russian Rat Study’ is annexed hereto as **Annexure S28 (Colly)**.

58. There have been other important studies involving Glyphosate-resistant RoundupReady (RR) GM, which have raised serious concern because of the expanding areas worldwide under cultivation of RR. Further findings have confirmed and extended previous results on the damaging effects of glyphosate, the main ingredient of RR formulations: it delayed the hatching of sea urchin embryos, (herbicide sprays have 25 times the concentration of the active ingredient than is used in transcription inhibition studies); in another study, French researchers showed that RR formulations were toxic to human placental JEG3 cells at concentrations lower than that used in agriculture. There have been pregnancy problems reported in agricultural workers using RR formulations. All this demonstrates the urgency for systematic and direct studies, independent of the biotech industry. Reference to these facts, are documented in the Pusztai document appended as Annexure S9.

GM PEA STUDY ABANDONED AFTER 10 YEARS:

59. A project to develop genetically modified peas with built-in pest-resistance has been abandoned after 10 years, when tests showed they caused allergic lung damage in mice. It was determined that the results were too

dangerous to continue with the project. The researchers - at Australia's National Research Organisation, CSIRO - took the gene from a protein capable of killing pea weevil pests from the common bean and transferred it into the pea. When extracted from the bean, this protein does not cause an allergic reaction in mice or people. But the team found that when the protein is expressed in the pea, its structure is subtly different to the original in the bean. They think this structural change could be to blame for the unexpected immune effects seen in mice.

60. According to New Scientist, Paul Foster of the Australian National University in Canberra, who led the immunological work on the GM pea is *"calling for improvements in screening requirements for genetically engineered plants, to ensure comprehensive tests are carried out."* 'Unintended' effects make it essential that "each new GM food (is) very carefully evaluated for potential health effects. Jeremy Tager, Greenpeace Australia's campaigner on genetic engineering, agrees. *"These results indicate the potential for unpredicted and unintended changes in the structure of transferred proteins. And I'm not aware of any country that requires feeding studies as part of its approval process. It is rare for an investigation of the potential health effects of a GM product to be published in a peer-reviewed journal"; he adds: "If it had been a private company doing this, it might never have seen the light of day". Reference is made to these facts in **Annexure S29: Gm Pea study.***

**BT RESISTANCE SCIENTIFICALLY PROVEN FOR THE FIRST TIME:
AUSTRALIA & HUNGARY**

61. Farmers have been right and were there FIRST. They have long reported resistance to pests from Bt crops. This is true of India as well and is no doubt the reason why we are now faced with the prospect of Bollgard II, which encodes for two Bt Cry proteins. The GEAC was warned of this.

The visible proof of resistance through super pests and super weeds has been demonstrated again and again in the US, Canada, Argentina, Australia and is part of the WP. Now, farmers have been proved right by formal science in the matter of Bt crops. There are two separate scientific papers proving resistance:

- i. **In Australia:** The May 2005 issue of the journal Applied and Environmental Microbiology, 'New Resistance Mechanism in Helicoverpa armigera Threatens Transgenic Crops Expressing Bacillus thuringiensis Cry1Ac Toxin' provides *"unequivocal evidence"* that, in Australia, a strain of cotton bollworm (Helicoverpa armigera) has developed resistance to the *Cry1Ac toxin* in "Ingard" Bt cotton. The research concluded that the cotton bollworm silver strain, bred from field survivors of Cry1Ac resistance monitoring, was clearly resistant to Cry1Ac toxin. Resistance was associated with *"elevated levels of esterase enzymes, which bind to and detoxify Cry1Ac."* ---Of further concern is the *semi-dominant status of the resistance mechanism, which would make it more difficult to manage bollworm resistance with 'Bollgard II' cotton* (which encodes for both Cry1Ac and Cry2Ab toxins, and is increasingly planted). *Cry1Ac resistance places additional selection pressure on the Cry2Ab toxin component of 'Bollgard II' cotton"*. The scientists conclude that given that H. armigera is a global pest of cotton and other crops, the existence of an *"esterase-mediated resistance mechanism may pose a considerable threat to the future efficacy of Bt crops worldwide"*. Survival on transgenic cotton further emphasizes the field significance of resistance to Cry1Ac.

It may be noted that Bt cotton in India is encoded for the Cry 1Ac toxin and large-scale field trials are currently on for Bollgard II. A copy of the abovementioned study titled, 'Insect Resistance To Bt Crops' is annexed hereto as **Annexure S 30**.

ii. **In Hungary:** 3 abstracts by Bela Davars and his scientist colleagues from the Hungarian Academy of Science show, both damage to critical butterfly species as well as resistance to the Bt toxin. A summary of the findings with regard to Bt resistance is as follows:

- The several-year monitoring study measured the quantity of Cry1Ab toxins in DK-440 BTY corn (MON 810). Although Cry toxins are used in various biopesticides, in Bt crops toxin release is related to the extent and duration of exposure. Unlike biopesticides, the Bt protein in Bt crops is *“produced on a continuous basis during the entire vegetation cycle, as long as the gene section(s) added artificially to the plant and responsible for encoding the protein, is active”*.
- Measurements have confirmed that the Cry toxin is produced in the plant during the whole period of growth, and is present to the greatest extent in the leaves. In a dry plant, under moderate temperature, the toxin remains biologically active for several years. Following the harvest of the maize, the stubble contains a significant quantity of Cry toxin. Cry toxin, over-wintering in the stubble, can still be detected in plant residues after a period of one year. (The buffalo deaths in MP were attributed to the animals eating Bt cotton stalks, as reported by farmer representatives to Petitioner No. 1).
- A significant part of the remaining quantity in the stubble enters the soil, where it may affect soil life (animals and micro-organisms). Therefore, there is sufficient ground for a detailed investigation in this field.

(It may be recalled that in AP farmers have reported a kind of soil rot as a result of Bt cotton with soil conditions being unsuited to growing any other crops).
- MON 810 Bt-corn produces 1500-3000 times more Cry1Ab toxin than a single-dose application of the biopesticide ‘Dipel’, that was selected for comparative study.

- Investigations to reveal the development of insect resistance of the Indian Meal Moth (IMM) to Cry-toxin, were conducted with dry and ground Bt-corn leaves of MON 810 (a Bt maize variety). 4th generation stock of the IMM showed tolerance to the equivalent of toxin produced by the corn stem. The 30th generation of the IMM population resistant to Cry1Ab toxin, showed *cross-resistance* to the biopesticide Dipel, which contains several types of Cry1 and Cry2 toxins. The growth of tolerance was almost four-fold.
- When the selection pressure was abandoned during 10 generations, the acquired resistance persisted, which shows that the change is inheritable. *"Our investigations show that Bt-corn varieties could have a relatively short time of expiration. This will generate the problem that there will be a growth in the number of insect populations on which Bacillus thuringiensis products – used almost exclusively in organic farming" – will not be effective.*

These facts are appended in **Annexure S31**: 'Hungarian abstracts on Bt resistance'

- 62.** Insect/pest resistance to Bt crops and weed resistance to HT (herbicide resistance) GM crops, destroys the foundational basis for the introduction of GM, whose platform is based on wooing farmers' with the irresistible claim that GM crops are the answer to all the pest and weed problems on the farm. Scientists, based on the empirical proof of DDT, always knew the bogus quality of these claims. The proof now, is both ample and definitive with the added anxiety of entirely eroding long-applied solutions of 'integrated pest management'. It also exposes the sheer pervasiveness of the untruth of the Counter Affidavit of the Union of India.

THE 35S CaMV PLANT VIRUS PROMOTER IS ACTIVE IN HUMAN ENTEROCYTE-LIKE CELLS

- 63.** The 35S cauliflower mosaic virus (CaMV) promoter is commonly used to drive transgene expression in genetically engineered (GE) crops. Whether, and how far, the 35S promoter might be active in mammalian cells has been scientifically unsettled and controversial. Terje Traavik, scientific director of the University of Tromsø's Institute of Genetic Ecology, has just published a study in 'European Food Research and Technology'. *"The initial exposure of a human organism to DNA from GE food takes place in the gastrointestinal tract (GIT). Hence, we have now investigated the promoter capacity of 35S in human enterocyte-like cells"*. He demonstrates that an element of the genetic structures used to modify a plant, the catalyst 35S CaMV, can provoke gene expression in cultured human cells. Now, according to GMO promoters, (and echoed by the Union of India in their Counter Affidavit), *"that catalyst normally only operates that way in plants"* (and therefore does not carry human health risks when used in GM crops to drive gene expression). *"----- Some of the identified motifs indicate that transcriptional activation by the 35S CaMV promoter may be stronger in other human and animal cell types than in those investigated so far"*. Prof Traavik's study is appended as **Annexure S32: The 35S CaMV plant virus promoter is active in human enterocyte-like cells'**
- 64.** The draft rules for the labelling of GM foods imported and locally produced, to amend the Prevention of Food Adulteration Rules, 1955, presuppose in essence, that GM crops are a foregone conclusion. The Petitioners submit that the enactment is part of the stealth and cover-up behind the plans for a full-scale release of GM crops and foods on to the Indian market. This will lead to the predicted fait accompli of contamination that is the objective of a regulatory body, which is manifestly in a conspiracy of collusion and UNTRUTH with the biotech industry. The draft rules are appended as **Annexure S33: 'Draft Rules for Labelling GM Products'**

65. It is a truism that the goal of health safety-assessment is that a *“food should not cause harm when prepared, used or eaten according to its intended use”* (Codex Alimentarius guideline 2003). Or, to expand the logic, if a product causes cancer in animals, it should not be put in food. This is in fact the ‘Delaney Amendment’ in the US, which is being used in the case against Monsanto’s Aspartame, which has been proven to cause cancer amongst other serious hazards as outlined in the Writ Petition. If GMOs cause cancer in rats, as has been demonstrated along with other significant health risks, then, eminent world scientists are absolutely right to call for stringent, independent and peer-reviewed long-term animal feeding studies to determine the health safety of GM crops. Until then they have called for a global moratorium. This is also the impeccable logic of the Petitioners prayer in the WP. The Petitioners submit that the ‘Precautionary Principle’ is the superior scientific principle and path that must be followed most urgently for GM crops because the spread of GMOs will alter the molecular structure of the world’s food supply in PERPETUITY. Even if, eventually, for the sake of argument, the evidence against GM were to be proved wrong on all dimensions of biosafety, it would still prove to be ‘right action’ based on prudence, for India to apply the precautionary principle in the SHORT TERM in order to be reasonably sure of the biosafety of GM crops. The short term is a mere blip on the horizon of perpetuity and worth every nano-bit of trouble to avoid a disaster of unimaginable and many magnitudes, should even a small part of the evidence be proved right.

In the light of the substantial evidence provided in the WP of the serious hazards of GM crops on multiple dimensions of biosafety, and underscored and clarified through the additional evidence of this Rejoinder, it is therefore, most respectfully prayed that the prayer made by the Petitioner in the Writ Petition be granted; that this Hon’ble Court may please: (i) Direct the Respondents not to allow any biological organism, food or animal feed until they are certified and labelled to be GM free by

the exporting country; (ii) Order, ex-parte, a moratorium on the release of any GMO into the environment till such time as a Protocol in consonance with prayer A(a) and prayer A (b), i.e. that each GMO to be released into the environment is subjected to all the required bio-safety tests, prepared according to the safety protocol guidelines provided in the Writ Petition and in this Rejoinder Affidavit, of the Writ petition is put in place, , by agencies of independent expert bodies, and the results of which have been made public.

DEPONENT

VERIFICATION :

I, the deponent above named do hereby verify that the contents of the above affidavit are true and correct to the best of my knowledge and belief, nothing material has been concealed there from.

Verified at MHOW on this 11th day of April 2006

DEPONENT