THE SUPREME COURT OF INDIA
I.A. No._____ OF 2006
IN

WRIT PETITION (CIVIL) No. 260/2005

IN THE MATTER OF:-

Aruna Rodrigues & Ors. …Petitioners

Versus

Union of India & Ors. …Respondents

APPLICATION FOR URGENT INTERIM ORDERS ON BEHALF OF PETITIONERS

To,
The Honourable Chief Justice
And His Companion Judges of
The Supreme Court Of India: -

MOST RESPECTFULLY SHEWETH:-

1. That the above mentioned Writ Petition was 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 each GMO is sought to be approved and released into the environment. Since the 4 months of the filing of the Rejoinder Affidavit, matters have escalated to such an extent that India is faced in the present, with an unprecedented, full scale onslaught of GE crops thrust on our nation by a deeply errant, irresponsible Regulator. The plan to allow large-scale field trials of Bt brinjal by the biotech company Mahyco (Indian collaborative and partner company of Monsanto), preparatory to its commercialisation is a major crises facing India of untold magnitude, as will be apparent from the evidence in this Application. Mahyco has also been bold enough to file for a patent, on this important vegetable, a major presence on every table in the country, most so the poor, urban and rural. This clearly demonstrates an unwavering eye for commercial advantage. It is also clear that the concerns with Genetic Engineering and its handling in India have reached such a crisis that it can no longer be entrusted to a Regulator that is betraying the national trust. These facts are being brought in evidence and are the reason for this Application for

Urgent Interim Orders. However, beyond presenting the evidence, the more critical issue before this Hon'ble Court in terms of an applied timeframe, is the fact that while it deliberates on the PIL before it, if the GEAC is allowed to continue in its current course of an implacable determination to approve GM crops no matter the consequences, without a proper assessment of the unique hazards that the GE process presents, India's food chain and the environment will be irreversibly contaminated and in perpetuity, within months, (this process starting as early as August 2006), and subsequently, by a whole range of GM foods (as opposed to animal feed like Bt cotton), which are planned and are in the 'pipeline', a situation not faced by any other country. A lack of action at this time as required will render this writ petition infructuous. It is therefore necessary for the Petitioners to provide this Hon'ble Court with practical and sane resolutions to the problem, which can be fairly judged. The debate is not arcane and is of concern quite simply to everyone that eats to live and live healthily. It is relevant to bring to the notice of this Hon'ble Court, that genetic engineering is not synonymous with 'biotechnology'; the latter encompassing a much wider definition and science. However GE has grabbed such a disproportionate share of the headlines because of its hazards and claims that it has eclipsed developments in biotechnology that hold genuine benefit for our world. It is also relevant, to now, first present an historical recap of how the Regulator 'advanced' with Bt Cotton. Encouraged by its power and ability to disregard all dissent based on farmer-feedback on the failure of Bt cotton and the increasing incidence of health hazards, it is now emboldened to pursue a major phase 2 thrust into Bt Foods, as opposed to animal feed, in support of the biotech agenda and the 'American Indo-US Agricultural Initiative' already placed in evidence before this Hon'ble Court in the Rejoinder Affidavit. For example, the USAID-backed initiative, Agricultural Biotechnology Support Project-II (ABSP-II), is based and directed from Cornell. ABSP partners have included Asgrow, Monsanto, and Pioneer Hi-Bred. Promoting GM is, of course, an official part of USAID's remit - one of its roles being to "integrate GM into local food systems." The copy of the profile of the USAID and copy of the newspaper

articles showing involvement of USAID in the development of GM crops and Bt brinjal in India titled 'Global consortium vouches for Bt Brinjal' by Ashok B Sharma of the Financial Express is annexed hereto as **Annexure A1 (Colly)**. Furthermore, in the process, the GEAC is also demonstrating a presumptuous disregard of the spirit of the order of May 1, 2006, by this Hon'ble Court.

RECAP OF 6 YEARS OF BT COTTON TRIALS AND COMMERCIALISATION

2. As early as 1999, the Research Foundation for Science, Technology and Ecology (RFSTE) challenged the permission given by the Government to M/s Maharashtra Hybrid Seeds Company Limited in the Supreme Court, vide their Writ Petition No. 71 of 1999 for carrying out multi-centric trials (these are limited field trials) at 15 locations in 7 states without framing proper guidelines, rules and systems for evaluating the bio-safety and ecological and environmental impacts of genetically modified organisms used in crops. Thus, it is on record that right from the first early MLTs (multi-location trials/ limited field trials/multi-centric trials) for Bt cotton, "*improper and illegal procedures"* were followed by the GEAC/DBT and that contamination from these limited field trials (MLTs), were a major source of concern. These early observations by RFSTE (which are part of the record of the Rejoinder Affidavit), was a portent of things to come and the experience with Bt cotton in India in the six years to date, has led to a major crisis; a crises that has escalated on multiple fronts, of health hazards, as well as farmer losses and the ensuing suicides due to its non-performance and its proven adverse farming economics. The Indian taxpayer is now paying Monsanto's debt. It therefore follows that the entire Government machinery of Maharashtra geared itself to eliminate the link between farmer suicides and Bt cotton during the Prime Minister's visit to Vidharbha at the end of June 2006. In fact, currently, Bt cotton farmers account for 70% of the suicides among cotton farmers. Despite the politically well-orchestrated attempt during the visit of the Prime Minister to Vidharbha, to excise all mention of the immediate reason for cotton farmer suicides, i.e. that they are due to the failure Bt cotton and its

economics, he has nevertheless been astute enough to realise the truth. The Prime Minister's Panel has recommended that suitable seeds, which are appropriately priced, should be made available to stop farmers from falling in the Bt cotton trap and has asked the Centre to send "*advisories against Bt cotton"* in un-irrigated areas. The copy of the newspaper article titled 'Vidarbha Farmers' Suicides, Bt cotton linked: Experts': published in Business Standard on 8th July, 2006 along with the copy of the article titled 'Prime Ministers Panel Warns against Bt cotton Trap' downloaded from GM Watch.org is annexed hereto as **Annexure A2 (Colly)**.

3. The Writ Petition and Rejoinder Affidavit have extensively documented Bt Cotton's biosafety hazards. In India, these include buffalo deaths in MP and serious allergenicity reports from different States in India where Bt cotton is grown, with extensive documentation again from Madhya Pradesh. Serious health hazards continue to escalate. During the latter part of April, the Centre for Sustainable Agriculture (CSA) uncovered deadly toxic reaction in sheep and goats in Warangal in AP from grazing in Bt cotton fields in Feb/March, post the last cotton harvest of 2005-2006. Local shepherds estimate the total mortality for the area to be around 10,000 dead sheep and goats. The link to Bt cotton grazing is established since there were no problems in near-by fields of Non-Bt cotton where the animals also grazed. It is by now not exactly surprising that these facts were uncovered by civil society (the CSA) and no real timely action has been forthcoming from the GEAC. Last year too, there were similar incidents and no response. A fact-finding team was constituted to ascertain the facts. The team consisted of five members: two from Anthra, an NGO working on livestock issues, a veterinary scientist, Dr. Ramesh, a field researcher, Mr. Apparao, along with Mr. Jamalaiah, Secretary, Andhra Pradesh Shepherds Union and two scientists from Centre for Sustainable Agriculture working on Bt cotton issues, Mr. S. Ramprasad, and Mr. G. Rajashekar. The team covered three mandals in Warangal district, taking in 4 villages on 22 April, 2006 and met several shepherds and farmers. The animals fell sick as a result of eating leaves in the

harvested Bt cotton fields with a mortality rate in these villages of 25%. The shepherds said that the Assistant Director, Animal Health Centre, Warangal, told them that these deaths appeared to be due to grazing in Bt-cotton fields, as she had seen such cases before this. The report of the fact-finding team constituted by the AP Shepherds Union (Andhra Pradesh Gorrelu Mekhala Pempakam Darula Sangham), titled Mortality in Sheep Flocks after grazing on Bt Cotton Fields – Warangal District, Andhra Pradesh dated 29/04/2006 is annexed hereto as **Annexure A3.**

4. All this must point to the simple truth that something is seriously amiss; and especially since the Indian experience has been accurately heralded by similar reports from other parts of the world as recorded in the submissions to this Hon'ble Court. Yet, a seriously errant GEAC has consistently ignored every submission from civil society and farmer representatives reporting these very serious problems. Instead, this year The GEAC has perversely authorised further approvals including stacked Bt genes encoding for two Cry Proteins. This is a tacit acknowledgement of growing resistance to the Cry1Ac toxin, clearly predicted as an agronomic response and now scientifically proven. The Rejoinder Affidavit filed in April of this year provides the detailed evidence. Yet Bt cotton was supposedly approved by the GEAC on the basis of extensive biosafety testing by the crop developer, on the basis of which the Regulator determined that neither Bt proteins nor Bt cotton are toxic to animals or humans or have negative environmental impacts. The Respondents in their submission to this Hon'ble Court have stated that they have *"acted with due care for the benefit of society".* It is abundantly clear from the above brief recapitulation of the history of the experience with Bt cotton that the GEAC has indeed acted with *due care,* however to protect and promote the commercial interests of the biotech industry instead. It is also clear that the intention is to repeat the process through new GM products and approvals and in so doing, ignore all health and environmental safety concerns reliably documented by independent scientists of world renown.

This will cause the extensive and irreversible transgenic contamination of our country.

5. On the 1st May 2006, the Supreme Court (SC) through its Order, acknowledged the serious consequences of the absence of compliance with biosafety norms that have become the hallmark of the 'Regulators' and the consequent impacts of contamination during limited field trials or MLTs: The Order states:

"*Till further orders, field trials of genetically modified organisms (GMOs) shall be conducted only with the approval of the Genetic Engineering Approval Committee (GEAC)".*

The implicit direction of the Order to the GEAC is to carry out its mandate under the Environment Protection Act (EPA) of the Ministry of Environment and Forests (MoEF) and institute rigorous and stringent biosafety protocols with due regard for the processes in safety testing procedures, which are required to be executed with honest purpose and integrity. However, in the '67th Meeting of the Genetic Engineering Approval Committee' held on 22.05.2006, the GEAC brushed aside all such concerns. In defiance of the spirit of the Order it has acted to rubberstamp the RCGM request for:

(a) an astonishing 91 GM products for MLTs;

(b) addressing the request to approve large-scale field trials for Bt Brinjal this Kharif as a prelude to its commercialisation, as well as; (c) Bt potato and rape later this year.

A copy of the minutes of the 67th meeting of GEAC is annexed hereto as **Annexure A4**.

6. The GEAC then embarked on a farcical attempt to involve civil society in a critique of its biosafety tests on Bt brinjal. Initially it provided a mere 15 days to civil society to reply to such a serious issue as an appraisal of the biosafety data concerning Bt Brinjal, conducted yet again by the crop developer, in this case Mahyco, to promote the company's transgenic seed and crop. Later, as a result of vociferous protests by civil society including Petitioner No 1, a one month

extension to July 15, 2006 was given with a grudging hand-out of more data on the Ministry website. Now, however, it will further allow examination of some more data, but only under supervision of Ministry officials in their office, to protect Mahyco CBI (confidential business information)! This is the continuing charade on this critical issue. The outcry from Indian citizenry has been swift, denouncing and voluble. It includes millions of farmers represented by the Bharatiya Kisan Union (BKU) and the All India Kisan Sabha (AIKS). Yudhvir Singh, President, Delhi state, BKU, (which represents millions of farmers in a coalition comprising Bharatiya Kissan Union in North India, Shetkari Sanghatan, Maharashtra, Karnataka Rajya Raitha Samithi (KRRS) in Karnataka and the Tamil Nadu Farmers Association), as well as K. Varadharajan, General Secretary of the AIKS have written forcefully to the Prime Minister, providing the solid reasoning that must prevail against the GEAC's plans for the country. *Green Peace India and Civil Society, through a sign-on letter of 250 signatures, comprising the 'Coalition for a GM-Free India', have also written, protesting the GEAC plans.* The copy of the press release of the BKU titled 'Genetically Modified (GM) Technology is No Solution to Agriculture Crises', the copy of the AIKS's appeal to the Prime Minister titled 'Stop GM Brinjal Trial' and the copy of the cover story done by the Frontline titled 'Seeds and protests' by Venkitesh Ramakrishnan is annexed hereto as **Annexure A5 (Colly).** The copy of the submissions made by the Green Peace to the GEAC on the approval for open-air field trial of Bt Brinjal, the copy of the letter written to GEAC by the Coalition for GM free India and the copy of the letter written by Petitioner No.1 to GEAC regarding the approval given by them for Bt Brinjal trials is annexed hereto as **Annexure 6 (Colly)**.

THE BIOSAFETY DATA BY MAHYCO ON BT BRINJAL

7. It is completely unacceptable that public policy with regard to the unique risks of genetic engineering is based on the crop developer's studies and assurance, termed by the Regulators as biosafety studies. As a matter of principle, which must be upheld for rigorous, independent and honest science, such a bias is indefensible and invalidates the test protocol, which must now be held to be void.

The crop developer cannot be expected to prove that his own crop is allergenic and unsafe. Since the Regulator has shown such a lack of concern for the affairs of biotech, at the expense of the public interest, it may be concluded that it is neither naivety nor gullibility that is the basis of its acceptance of such obvious bias. Following on from the demonstrated fiasco of Bt cotton, these attempts now, to promote Bt brinjal without proper testing and the best-regarded international peer review procedures, are completely unwarranted and unscientific. They also conclusively discredit the GEAC. Furthermore, significant examples have been provided by the Petitioners in the WP, of the history of fraud and cover-up of such industry-sourced and sponsored studies. This includes the situation in India with regard to Bt cotton. In the US, the FDA assumes that gene altered foods are safe, based solely on *scant information* that biotechnology companies submit in consultations with the FDA. It is clear from the history of the last 4 years with GM in India, including the MLTs with Bt cotton, vegetables and rice, as well as the current Bt brinjal study, that the Regulators have adopted a similar, thoroughly lax, gravely irresponsible and unsafe regulation with regard to safety concerns with GM crops. It is of relevance to mention here that on the 9th June 2006, a lawsuit was filed against the US government, (FDA) which aims to establish strict safety laws for all genetically engineered foods, and require these to be labelled once they are approved. These aims are precisely the same as the PIL. It reinforces and upholds the credibility of the evidence presented by the Petitioners to this Hon'ble Court. The Centre of Food Safety (CFS) now calls for rigorous testing of genetically engineered (GE) foods before they are marketed, in order to ensure that these do not carry certain risks as a result of their different breeding techniques. These risks include triggering unexpected food allergies, creating toxins in food, or hastening the spread of antibiotic-resistant disease. The copy of the news report dated 06.09.2006, titled 'FDA sued for lax regulation of GM foods' is annexed hereto as **Annexure A7**.

8. The recently signed Indo-US Agricultural Initiative and evidence of the involvement of USAID in the research and development of Bt brinjal in India

reinforces the official GM link between the two countries and gives credence to the belief that the approaches to safety issues are similar, and essentially absent. The response time of a quite riduculous15 days furthermore, underlines the regulators' continued contempt for democratic procedure in spirit and in letter, as typified by the lack of open public domain consultation and within a generous time-frame, on GM safety to establish the truth; indeed it well underscores a departmental vacuum in a deeply errant Regulator, with regard to GM safety concerns across the board. Notwithstanding the flawed rationale of relying on the biotech industry as the prime source for safety studies on GM crops, in this case a dire biosafety hazard like Bt brinjal, if the initial data given by Regulator on its website is the full extent of the biosafety test data, then it means that incredibly, the GEAC is taking a decision on the biosafety of Bt brinjal on virtually no data. There is an outcry by leading international scientists, (many of whom have provided affidavits for the PIL, in evidence of the hazards of GE), who are aghast at the new depths being plumbed and allowed by the Indian Regulator, of abysmal standards in so-called biosafety studies, not yet observed elsewhere. The repercussions of the Regulator's releases of GM foods in India will be global. Dr. Arpad Pusztai, the world renowned toxicologist and leading expert in protein lectins in a telephone conversation with Petitioner No 1 said *that in all these years of scrutinising industry studies, (and most of these have passed through his hands), he has never seen anything quite like this.* According to David Schubert, the safety testing data on the Ministry (GEAC) website is "*very poorly done and in the absence of REAL DATA it is impossible to make any assessment of the validity of their claims".* Dr. Doug Gurian Sherman, Senior Scientist at the Centre For Food Safety concurs. Dr. Robert Mann formerly senior lecturer in biochemistry at the University of Auckland and Advisor to successive Ministry's of Health in NZ, says, "*I regard the 'Bt'-brinjal field-trial proposal as one of the most ill-conceived I have encountered in my three decades of critical appraisal of GM. The risks and hazards, while not exactly known or indeed precisely foreseeable, appear to be so grave that the proposed field-trials should be enjoined pending a thorough assessment such as has yet to be performed."*

Dr. Mae Wan Ho (of the Independent Science Panel) and Prof. Joe Cummins, Prof. Emeritus of Genetics, University of Western Ontario, Canada, say: "*In India, brinjal would be comparable to potato or tomato in the American diet. GM Egg Plant Contains Bt Toxin Linked to Hundreds of Allergy Cases and Thousands of Sheep Deaths. It would be unthinkable and irresponsible to approve the genetically modified eggplant. Dr. Mae-Wan Ho and Prof. Joe Cummins find neither published studies nor experimental details on safety tests in the application for field releases of the Bt brinjal and raise serious questions. Instead of approving more GM crops, regulatory authorities in India should start a comprehensive enquiry into the health impacts of Bt cotton and impose a ban on further releases of all GM crops".*

Thus, this biosafety study is nothing more than an ill-conceived PR Exercise by Mahyco, masquerading as a scientific document, with little supporting data to verify the claims. Petitioner No 1 in her response to the GEAC, (reference is made to Annexure A6 colly) regarding the quality of data in the Mahyco study, brought the following to the notice of the Regulator:

" If you have more data, not making it available to civil society and scientists (across national borders) to study & assess, again demonstrates both your committed mind-set in support of the industry and complete abrogation of your duty to the national cause. This then is the sum total of the explanation for your puzzling reliance on the crop developer for safety studies and data and the direction that GE is being given in India".

The copy of the Press Release dated 13.07.2006 on the statement made by Dr. Mae Wan Ho and Prof Joe Cummins, the copy of the statement by Prof David Schubert, the copy of statement Doug Gurian-Sherman, the copy of the article titled 'Transgene Products and Bt Toxins' by Pusztai and the copy of the 'Statement for the Supreme Court of India on the WP of Aruna Rodrigues' by Dr Robert Mann is annexed hereto as **Annexure A 8 (Colly).**

.

THE GRAVE HAZARDS OF BT BRINJAL BEING INTRODUCED IN INDIA: A CENTRE OF ORIGIN AND DOMESTICATION OF BRINJAL

9. While various Bt toxins have been incorporated into GE corn and cotton for animal feed, it has never before been expressed in a vegetable crop for commercial production anywhere. There is a big difference between GE corn and cotton which are primarily grown for animal feed and only small amounts are eaten by humans in the from of corn chips etc and refined cottonseed oil, which are highly processed and contains little or no cry toxins. Bt brinjal on the other hand would be the *FIRST internationally, widely grown vegetable/food product with a Bt toxin***.** It is a major source of calories in India, because of its fat content, it is widespread, is part of the diet of most Indians, is eaten in significant quantities and while cooked, there is less processing. In Ayurvedha preparations, it is eaten raw, mainly root and stem and purity is a basic premise, which by definition must exclude any transgenic brinjal or contamination. Many varieties are used including wild species and it is also part of folklore. These facts are appended in **Annexure A 8.1** 'Use of Brinjal in Ayurvedha and Other Traditional Systems of Medicines'. Broadly, there are at least 5 major concerns about the safety of Bt Brinjal and why it would be a grave mistake to introduce Bt brinjal in India:

i. Its hazardous potential for effecting human health

ii. Potential environmental harm from the Bt Cry1Ac gene

iii. It will certainly contaminate the many varieties of brinjal currently grown in India as well as its wild relatives. Because India is a centre of origin and biodiversity of brinjal, where cultivated forms originated, there is special concern and responsibility to consider environmental impacts on wild organisms and brinjal biodiversity.

iv. It will evoke dissemination of mutant insects resistant to *Bacillus thuringiensi*s. The natural bacterium *B. t.* is very important in advanced organic agriculture, so insects resistant to this pesticide would be a

serious threat to many types of agriculture on which a country such as India inevitably & rightly relies.

v. It will eliminate a current and potential export market once it is known that it is a GM product that is being sold. In the US, farmers rejected GM (HT (herbicide tolerant)) wheat for this reason and it is not grown in that country. Within India, non-GM farms including organic farms will be contaminated. This will be largely surreptitious and therefore unknown, will not be labelled and will therefore affect both farmers' rights and consumers and their food and health choices.

10. HEALTH HAZARDS: GM foods have not been safety tested anywhere, least of all Bt food crops and vegetables. Bt crops are toxic. No toxicology testing has ever been done. The WP provides irrefutable evidence of the toxicity of Bt proteins repeatedly. In brief and to recap:

i. It has been established that the toxin Cry1Ac is a potent antigen in mice, following gastric administration. The Cry 1Ac protein can also be taken up from the intestinal mucosal to be processed in peripheral lymphoid organs and several human cell cultures (including liver cells) demonstrate a number of cytotoxic reactions when exposed to Bt toxins. The well-documented examples of allergenicity among farm workers in the US and the Philippines has been cited in the WP and RA and the mounting evidence in India of toxic reactions, including thousands of dead sheep and goats must act to reinforce the evidence of the toxicity of Bt crops and therefore invite the most cautious response from a responsible Regulator.

ii. It is emphasised that Bt toxins expressed in transgenic plants have never been systematically tested in mammalian or other vertebrate organisms, neither have the effects of the integration of cry genes in vertebrate cells/organisms been studied. *Furthermore, serious limitations of current allergy-testing procedures for GMO proteins, is widely recognised.* For example, the recent case in Australia, fully documented in the Rejoinder Affidavit filed in April 2006, revealed that a

protein previously consumed safely in beans had become immunogenic (allergic reaction), when engineered into GMO peas. In other words when the transgenic DNA from a GM plant/food is taken up, integrated and expressed in vertebrate organisms, like the alpha-amylase inhibitor gene from beans, when expressed in peas they exhibited altered functions and allergenic properties. Other forms of unintended effects are possible which would confer unanticipated activities to cry genes. It took 10 years to discover the 'bean altered effect in peas' and the tests were abandoned. The immunogenicity of the GMO peas would not have been detected by currently used tests -the tests that revealed the problem, are not currently part of required protocols for any regulatory agency. This means that new allergy tests and careful long-term tests are needed to assure the safety of all Bt crops and particularly food crops like Bt brinjal. It also demonstrates unequivocally, the problems that emerge with the process of genetic engineering, that they are intrinsic to the technology. "*It is routinely assumed that the effects of genes inserted by radically unnatural methods are predictable, when in fact they are known to be extremely variable (frequently lethal). It is pretended that a cell surviving such genes-insertion processes, and then selected on just one property, (resistance to an antibiotic), and then grown into a whole organism, e.g. an eggplant (brinjal), will have all properties at least as good as those of a normal organism. On the contrary, insertional mutation damaging the target genome in unpredictable ways, compounded by somaclonal variation, (*plants grown from single cells, are known to exhibit much more variability than plants grown from normal seed) *in the GM-progeny, make their properties unforeseeable":* Robert Mann in his affidavit to this Hon'ble Court in Annexure A8 Colly above.

iii. **SAFETY TESTING**: At the very minimum, the testing methods outlined by Dr. Pusztai must be first conducted to demonstrate that the crop presents no unacceptable health risk. These include long term, Multigenerational Animal Feeding studies. Animal testing is but a first step. If the animals do

not suffer any adverse health effects, then and only then, the results must be validated with human volunteers in clinical double blind, placebo-controlled drug-type tests. "*For these reasons and those that follow and because GE crops present unique and irreversible risks, no new GM crops should be allowed to be cultivated, commercially traded or incorporated into human food or animal feeds without the minimum required testing methods referred to."* These facts are further reinforced through fresh evidence by Dr. Pusztai and already appended along with this application as Annexure 8, titled 'Transgene Products and Bt Toxins'.

iv. Notwithstanding the necessity for the correct testing protocols, these are of little account without the uttermost commitment and integrity to the processes that make up the protocol. "*In over 40 years of experience in animal experimentation, the methods of GM risk assessment by animal feeding tests as carried out by the GM biotechnology companies to support their request for growing and using GM crops in food, are wrong in principle and flawed in execution".* Arpad Pusztai goes on to describe how tests need to be performed and the critical requirement for an 'animal house'. *"To be able to carry out such animal risk assessment tests, a top-class animal house is absolutely essential. To set one up is obviously very expensive business probably somewhere around £3-4 million. The animal house must be purpose-built, consisting of two separate buildings and run by separate dedicated personnel, the buildings only connected, one-way, through a hatch that the small newly weaned animals (rats, mice) from the breeding colony could be delivered to the experimental house. The breeding colony is essential for the delivery on time and in sufficient numbers of young animals closely matched in weight. This cannot be achieved or can only be done with great difficulty by buying-in animals from commercial breeders. --- The animal house personnel are well- trained and licensed animal technicians capable of helping the scientists to carry out the experiments. It is expensive but without such a facility no really proper and scientifically valid animal experiments can be done. ---"-I have seen most of the GM biotechnology companies'*

submissions to the EU and national regulators and I can testify that none of the animal testing done and described in these documents would be acceptable for publication in high-class international nutritional journals because they fall far short of the requirements as outlined above". Hopefully, this will provide guidance for you, the Court and other involved parties and to allow you to evaluate and assess any documentation provided by the GM biotechnology companies". The above evidence of Dr Pusztai tilled, 'Animal House' is annexed hereto as **Annexure A 9.**

11. It is abundantly clear that the GEAC is quite lacking in commitment to the methods involved in the serious business of test protocols, in their design, their processes, execution and independence, or the critical need for "sc*eptical analyses of GM proposals to assess their hazards".* All of these are conspicuous by their absence in the Bt brinjal study. Instead, the Regulator is resorting to tweaking the Mahyco study here and there, as if it can be strained of weaknesses. "*In the case of GM-brinjal, the evidence summarised by the 'experts'* on behalf of the GM PIL, *is, in my opinion, overwhelming"*, (Dr. Robert Mann, in Annexure 8 Colly. referred to above). The Bt brinjal biosafety tests stand completely discredited.

12. It has also become clear that civil society cannot reign in a Regulator that is malfunctioning with intent and deliberation. We just do not have the resources, the expertise and experience to do so. It would therefore be extremely unwise for these reasons to risk the nation's biosafety and sovereign interests. Furthermore, the GEAC has no credibility left in the eyes of civil society. Thus, it has become both necessary and urgent to institute the office of an Ombudsman, autonomous, independent, free of government interference, or the presence of bureaucrats in its management: with the specific mandate to protect India's biosafety, starting as a first order of priority with assessing the unique risks posed by GE and its impacts. A panel of independent scientists of eminence from India and abroad, need to be deployed to work out sound processes for safety testing protocols,

who have the *experience to fill the current gaps in safety testing procedures and assessment*.

13. **ECOLOGICAL & AGRICULTURAL IMPACTS OF BT BRINJAL**: The Implications of the introduction of Bt Brinjal in India are extremely serious as India is a centre of origin and domestication of brinjal. Because Brinjal originated in India, there are many varieties of both wild, such as *Solanum Incanum,* and cultivated plants. Therefore it is likely that the Bt gene will be transferred from the crop to those wild relatives. If the gene confers an advantage to the wild plants, it will spread in those plants and cause possible harm. "*This is a very different risk than for the crop itself, since most crops, unlike their wild relatives, cannot survive without cultivation" (Doug GS)*. The U.S. National Academy of Sciences, in a report in 2004, said that genes that control pests, like Bt genes, have a good chance of giving wild plants an advantage and thereby spreading in the environment. Several published experiments with Bt in rapeseed and sunflower have provided preliminary data that Bt genes can indeed give some wild plants a competitive advantage.

    i. 4 countries grow most of the GM crops planted worldwide –The US, Canada, Argentina and China. Of this the US and Argentina account for 90%. In the US, the major GM crops are HT (herbicide tolerant) soybean and Bt cotton and maize. In Argentina, it is HT soybean and in China Bt cotton. *All of these are animal feed crops and importantly, the shared characteristic is that none of these countries (growing these transgenic varieties of maize, cotton and soybean), is a centre of origin or domestication of these crops.* Domestication, the process by which farmers over long periods of time select wild plants for adaptation to cultivated conditions according their usefulness to consumers, has actually taken place mainly in areas of megadiversity and India is one of 17 worldwide. India is both the centre of origin and domestication for brinjal, rice, among other crops: India is a treasure trove for rice varieties as recorded in the WP. The foremost environmental issue is the presence of sexually cross-compatible relatives, both domesticated (landraces) or wild.

These fulfil important roles as production capital of farmers, repositories of genetic diversity for plant breeders and farmers alike and socio-cultural identities. An important feature is that they cross readily with introduced cultivars. This feature is the reason for potentially extensive gene flow in centres of domestication between GM plants and their relatives. There are two potential consequences of transgenic contamination of native plants: (a) the risk of accumulation of different transgenes in native materials (stacking), which may then serve as relays for unwanted introduction of transgenes to other plant material destined for food or organic production. The problem is exacerbated in areas of domestic production and India's traditionally small farm-size because physical isolation becomes more difficult. Stacking may also lead to untested combinations of these genes in the same plant; (b) the impact of gene flow on the genetic diversity of 'landraces' (locally adapted and distributed domesticated plants maintained by farmers).

ii. Environments in centres of domestication are quite different from those where GE crops are grown. Both pests and non-target organisms are different. If the gene spreads in wild relatives of brinjal, *its escape into the environment will likely be permanent*. The toxin produced by the gene may then kill insects that feed on the wild plants. These insects, in turn provide food for other organisms such as birds and mammals, which may then suffer harm. *For these reasons, it is important to determine the possible harmful effects of the Cry1Ac gene in sexually compatible wild relatives.*

iii. Bt crops are not sufficiently selective and specific for pests and by inflicting damage to beneficial insects they destroy the natural balance between pests and useful organisms.

iv. Farmers in traditional agriculture as in India play a markedly different role from farmers in industrial agriculture whose role is limited to the production of crops. In traditional agriculture, farmers play a role in conservation, development of new cultivars, actively maintaining crop landraces. Since transgenic crops have the potential to reduce genetic diversity, Bt brinjal

varieties could displace local brinjal landraces that hold genetic diversity important to local farmers and the world, as sources of important traits. Farmers may desire “improved” Bt brinjal varieties for their ability to control certain insects, but may loose other properties that are not as obviously or immediately important. Loss of genetic diversity would mean that important new traits, not currently recognized, such as for disease control or drought tolerance, could be lost forever.

v. Once GM brinjal is cultivated on a large scale these tremendously important sources of genetic diversity will be lost forever due to transgenic contamination. The genetic diversity is important because some of the strains will be naturally resistant to lethal pathogens, which would be fatal to crops in the future. Once lost, this lack of diversity can lead to the complete loss of the crop. *The most recent example is the demise of the banana due to the loss of fungus resistant wild relatives*. It is to be expected that like any new technology, (microwaves, mobiles for example) farmers will experiment with GE crops, especially in India, where the government, sarkari, endorsement through ‘approval’ carries great weight that the transgenic seed is indeed better than their own, though the reality is that they are not as good as the seeds that they have developed over the centuries. In fact, this is exactly what the Regulator is saying by completely discounting the evidence of reduced yields and increased pesticide use! They are also ‘told’ that it is better with all the ‘hype and hula’ of the biotech companies’ propaganda and their deep pockets. GM has become the ‘magic bean’ phenomenon to be tried out by unsuspecting farmers and needs to be countered by a concerned and responsible Regulator, which India does not have. This is also a significant contributing factor for the loss of diversity.

vi. When risk assessments were done in the US and EU for these crops, no evaluations of possible impacts on ‘centres of origin’ were even conducted. These questions were never ever considered.

The above evidence is based on the statements of Doug Gurian-Sherman and Prof Schubert, referred to above in Annexure 8 Colly and the further evidence appended in **Annexure 10 (Colly)**: the work of Doug Gurian-Sherman, 'Contaminating the Wild' and Prof. Paul Gepts 'Introduction of Transgene Crops in Centres of Origin and Domestication'. It is relevant to mention that Prof. Gepts of the Department of Agronomy and Range Science, University of California at Davis, is a recognised authority on gene flow from crops, crop evolution and issues related to genetics.

14. FIELD TRIALS, MLTS (MULTI-LOCATION TRIALS): The preceding analyses have very important implications and conclusions for the manner in which field trials are entertained by the Regulator and approved. The Mahyco study admits that the Bt brinjal MLTs started as early as 2004. Field trials for testing pollen flow were conducted even earlier. Limited field trials or MLTs as they are termed by the Regulator are approved as the norm, before comprehensive biosafety testing demonstrates their safety or otherwise. On the basis of the evidence provided, MLTs are therefore a major cause of transgenic contamination and the recognition of this by this hon'ble court led to its 1st May 2006 Order. Given that it is now proven that even rudimentary safeguards are lacking, the likelihood of transfer of transgenes to wild relatives must be accepted. This is a major source of concern because they contain experimental genes, which have undergone no risk assessment.

15. The GEAC's stated position on GM crops is based on the invalidated claim of 'substantial equivalence' and therefore the supposition that contamination is of no real consequence even should it occur. This is the conclusion that must be drawn from the way field trials are conceived and planned and the complete lack of safeguards flouting laid-down biosafety norms. In 2005 there were in excess of 50 field trials for brinjal, cabbage, cauliflower, corn, groundnut, mustard, okra, pigeon pea, rice and tomato collectively. This evidence is appended as **Annexure 11**: 'Letter from the DBT' to Petitioner No 1 providing data under the

Right to Information Act, dated 7th June 2006. Furthermore, the 67th GEAC minutes (Annexure A4) records the approval of 91 MLTs by the GEAC on the recommendation of the RCGM. These approvals were given *subsequent* to the hon'ble Court's Order of May1, 2006, which recognised the appalling lack of even routine safety measures with regard to field trials, which are covered extensively in the RA. In the UK the transgenic contamination by GM rape during field tests, of wild charlock (also documented in the Rejoinder A) was considered *virtually impossible because they were too distantly related*, but British agricultural scientists *discovered* that a genetically modified (GM) variant of rapeseed has cross-fertilized with local wild charlock plants, creating a herbicide-resistant "superweed" in the process. 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*. GM corn brought into Mexico from the US has contaminated Mexican landraces and its wild progenitor, Teosinte, via pollen, (recorded in the WP and RA).

16. The confinement requirements for field trials cannot ensure that gene flow cannot occur. Doug Gurian-Sherman in his report 'Contaminating the Wild' on contamination in the US from field trials, provides evidence of contamination even with 'isolation distance' according to US procedures, which are therefore inadequate. Permanent escape of largely untested experimental genes is virtually inevitable even with stringent precautions and because the research on them is incomplete, their risks are largely unknown. In the US, the FDA recently adopted guidelines that recommend that preliminary tests should be carried out for human safety *before* there is a chance that contamination including from field trials, can occur. "*Those guidelines are voluntary (like the rest of FDA's risk assessment) and way too weak (only some minimal allergy testing, etc. of the GE protein), but show that even in the US, there is growing concern about*

contamination from field trials. In India, where farmers routinely save seed, contamination could have an even greater cost and possible harm".

17. In India, given the complete disregard for even routine precautions by the Regulators, there is undoubtedly contamination waiting to be 'discovered'. 'Contaminating the Wild', appended above as Annexure A 10 Colly. and whose author is Doug Gurian Sherman of the Centre for Food Safety (CFS) provides evidence that the process called "*gene flow*," occurs when:

> "*pollen from experimental crops fertilise wild species related to such crops: examples are wheat, grapes or carrots (*and in the Indian examples, rice and brinjal among others). *Experimental genes that make their way into crop wild relatives may become a permanent part of the landscape because, unlike most crops, these wild plant species can grow without cultivation by farmers.* Once a gene is widely distributed in a wild relative, evidence and experience from Canada/US and elsewhere confirm that it is very difficult if not impossible to eradicate weedy species. Their presence would not be known without genetic testing and until it is widely dispersed, *"with likely permanent escape of experimental transgenes with unknown consequences, into the environment".*

18. Thus field trials must be part of an '*end process*' of biosafety testing (rather than the unscientific current procedure described above), and should therefore follow on from first, other comprehensive and rigorous biosafety testing protocols and processes as provided in the Writ Petition. "*It is crucially important that a clearly defined agency conduct scrutiny of GMOs before they are allowed into field trials. And that agency must, to be scientifically reliable, take due account of evidence against a proposed field-trial*" (Robert Mann). Given the serious crises India faces because of a reckless Regulator, it has therefore become necessary, in order to avoid the extensive and irreversible contamination of India, to apply a freeze on all field trials starting immediately. There is no other effective alternative. This forms part of the 'Prayers' to this Hon'ble Court.

THE SCIENTIFIC UNTRUTH OF THE EVENT-BASED SYSTEM OF APPROVING GE CROPS

19. The GEAC has decided to follow the "event-based approval system" for approving GM crops, instead of the present system of a case-by-case approach. This change in the policy has come after the CD Mayee Panel report suggested such a change. The Mayee Panel deliberating on biosafety issues of Bt cotton said: "*Extensive biosafety and agronomic testing are not necessary for the approved event. Once an event has been tested for its biosafety and approved for environmental releases, it should be treated at par with the non-Bt hybrids."* The GEAC, accepting the report, has said switching over to event-based system for approval will reduce unnecessary delays. A copy of the article titled GEAC Shifts to Event-based approval for GM Crops' by Ashok B Sharma of the Financial Express 5 July 2006 is annexed hereto as **Annexure A12.**

20. There is no scientific evidence published or otherwise to show that event-based regulation is scientific and therefore acceptable. Quite the contrary, evidence shows that *splicing the same transgene into different crops can lead to different unforeseen and unpredictable consequences known as 'unintended effects', an accepted euphemism for scientific ignorance.* Dave Schubert in his peer-reviewed document 'Safety Testing and Regulation of Genetically Engineered Foods' documented in both the WP and RA, makes the science quite clear. He says that totally "*un-predicable changes unrelated to the nature of the transgene can occur, because of the complexity of interactions between genes, as well as the more obvious problems of gene disruption by insertion of the transgene itself".*

21. This is why the stance of the US FDA and the GEAC on 'substantial equivalence' is so thoroughly discredited. There can be no 'equivalence' with its conventional counterpart with the GE process. In view of the critical importance of this question to the regulatory process and the grave risks employed in applying erroneous science, the Petitioners request the indulgence of this Hon'ble Court to

clarify the issues conclusively. In so doing, the Petitioners rely on the evidence of Prof David Schubert, a world renowned molecular biologist of the prestigious Salk Institute, both in published reviews and already referenced in the WP and RA and now, on further evidence prepared specifically for this Hon'ble Court, to help the process of elucidation and clarity.

I. The major problem with the making of a GE plant is not always the specific gene that is inserted, *but the results of the GE process itself*. The procedures used to make the GE plant create large numbers of mutations completely independently of the GE gene; and the insertion sites of the GE gene into the DNA are random and unique to each event, causing more mutations. *"---therefore, no two GE plants are the same, and indeed each 'event' is unique, creating different mutations, each with the potential to create a harmful product".*

ii. When the identical GE gene is put into different plants, (as in the case of Mahyco's Bt brinjal which has the same construct as Cry1Ac Bt cotton), the plants each modify the protein in different ways, resulting in slightly different proteins. "*The most common form of this type of modification is the addition of sugars to the protein, which each plant, and in fact each part of the plant, does differently. The potential for serious harm or even death from this type of 'event' was clearly and unambiguously demonstrated in a published manuscript that showed that a GE protein made by one plant does not cause an immunological reaction, while the identical GE gene expressed in another plant causes a severe immune reaction, and even worse, causes an allergic response to other plant proteins".* Prof Schubert is referring to the pea study in Australia titled, 'Amylase in Pea From Bean' provided in evidence in the Rejoinder Affidavit and also annexed here for ready reference as **Annexure A 13**. The pea immunology text is very important because it "*formally proves that the assumptions underlying the 'event based' approval process are fundamentally wrong*".

iii. *"Enzymatic pathways introduced to synthesize small molecules, such as vitamins, could interact with endogenous pathways to produce novel*

molecules. The potential consequence of all of these perturbations could be the biosynthesis of molecules that are toxic, allergenic, or carcinogenic; and there is no a priori way of predicting the outcome". In the 1980s, hundreds of people were effected and hundreds died in the US because genetic manipulation carried out to increase the yield of tryptophan (an essential amino acid for use as a nutritional supplement), resulted in a product that caused a novel illness never before seen by doctors in the frequency reported, and was discovered for this reason and correlated with the aberrant appearance of specific trace contaminants. Showa Denko has paid around US$ 2,000,000,000 to avoid damages trials. Reference to the tryptophan incident is given in **Annexure A14:** 'The Thalidomide of Genetic Engineering' by Robert Mann, D Straton and W E Crist.

22. Prompt toxicity of a GM product might be rapidly detected once the product entered the marketplace if it caused a unique disease, and if the food were labelled for traceability, as were the GM batches of tryptophan. However, cancer or other common diseases with delayed onset would take decades to detect, and might never be traced to their cause. Conversely, plant flavonoids and related molecules have great health benefits, and there is evidence that these can be depleted in GM crops.

23. Extensive testing procedures are required to ensure the safety of GM foods as outlined in the WP. For example, *"secondary modifications could be assayed by monitoring of the introduced gene product by mass spectroscopy; changes in gene expression could be assayed by DNA chips; and metabolically active molecules could be measured biochemically*". The problem says Schubert is, of course,

"that, unless we know exactly what to look for, we are likely to miss the relevant changes. To me, the only reasonable solution is to require that all GM plant products destined for human consumption be tested for long-term toxicity and

carcinogenicity before being brought to market. These safety criteria must be met for many chemicals and all drugs, and the magnitude of harm caused by a widely consumed toxic food could well be much greater than that from any single drug. However, even extensive animal testing might not detect the consequences of deficiencies in beneficial plant products. GM food is not a safe option, given our current lack of understanding of the consequences of recombinant technology". The above facts are provided in **Annexure A 15 (Colly)**: Prof. Schubert's statement for this submission and 'A Different Perspective on GM Foods' published in Nature Biotechnology, 2002.

24. The GEAC's regulatory performance is a sad commentary on Indian regulation. The attempt to pass off the Mahyco-sponsored Bt brinjal testing as legitimate biosafety tests is a new low in Indian standards, and integrity. Furthermore, the insidious move to event-based regulation is unparalleled anywhere. At best, the Regulator may be accused of ignorance in which case it stands disqualified to carry out its mandate under the EPA. It is of profound concern that a regulator and a department of government can abuse its powers by subverting democratic processes to such an degree, that it is able to subject India to the incalculable consequences of its hubris and extreme folly for evermore, in perpetuity, impacting the many dimensions of the problem in India, and globally, presented by the unique risks of genetic engineering and GM crops.

A RECAP OF ALL THREE SUBMISSIONS MADE TO THIS HON'ABLE COURT

25. Well aware of the dismay of your Lordships at the voluminous tomes placed in evidence in this Hon'ble Court, and the difficulty of the subject, the Petitioners therefore feel it would be useful to provide the briefest recap on the facts regarding the genetic modification of crops and the dangers they represent, gleaned from the evidence of all three submissions, including this Application:

- The unique risks of genetic engineering are inherent in the technology because the techniques that are used to move the trans-gene into the crop are no more precise than a shotgun. It is established that unpredictable and

unforeseen changes can occur as a result of the GE process, and these are called ‘unintended effects’. Current safety assessment is inadequate to catch most of the harmful effects even in the long term, as scientists do not know what to look for. The ‘bean pea ’ study in Australia was called off after 10 years. The techniques used to determine the change and allergenicity effects that occurred in the pea, though absent in the bean, which was perfectly safe, are not part of any safety protocol of any regulator.

- When a foreign gene is artificially inserted into a living organism such as a GM crop, the pre-existing natural gene of the organism can unintentionally be deleted, switched off, permanently switched on, mutated or fragmented. Hundreds of natural genes may change the way they generate their proteins (basic molecules that form living cells), and even the newly introduced protein may differ from what was intended. This is why the Indian Regulator’s attempt to alter the science to an ‘Event’ basis is so shockingly bad and reveals the ‘agenda’ without an iota of doubt.
- The current technology was rushed to market long before the science was worked out. Its introduction was accompanied with rigged research, bribes, gagged scientists, cover-ups and regulatory agencies stacked with industry representatives. A significant and routine ruse is 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. This is manifestly true in India and has never been so apparent as now.
- The study of Bt corn Mon863 was based on a 90-day trial conducted by Monsanto. Monsanto’s assessment of their *own study* into the effects of feeding rats 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 endrocrinologist at the University of Caen, agrees that the results indicate a toxic reaction.

- There is mounting international evidence of serious health and environment problems and the GEAC is embarking on a dangerous charade and abuse of the public trust.
- The introduction of Bt brinjal will be a universal first; Bt corn and cotton essentially for animal feed and HT ((herbicide tolerant) animal feed crops like soy) are the only crops grown worldwide and none of these are grown in a centre of origin or domestication because of serious health and environmental concerns with Bt including the certainty of transgenic contamination of wild relatives. Questions relating to the safety of such crops have never even been considered in the US or EU. , Bt foods are untested and no toxicology tests have ever been conducted.
- Key assumptions used as the basis for safety claims have been overturned and several adverse findings suggest that GM foods are unsafe. GM-fed animals had problems with their growth, organ development and immune responsiveness, blood and liver cell formation, as well as damaged organs (bleeding stomachs, excessive cell growth, inflammation in lung tissue), sterility problems and increased death rates, including among the offspring.
- HGT (horizontal gene transfer) is an established fact. Therefore, risks are increased by the fact that the genes inserted into GM food not only survive digestion, but transfer into body organs and circulation. Transgenes or their fragments have been found in the blood, liver, spleen and kidneys. DNA can even travel via the placenta into the unborn. The only human clinical trial showed that transgenes from soy transfer into intestinal bacteria.
- Claims that no one has become ill from GM foods are misleading, since no one monitors human health impacts. However, one study found that soy allergies skyrocketed by 50 percent after GM soybeans were imported to the UK, and the deadly epidemic in the 1980s, that killed about 100 Americans and

caused 5,000-10,000 to fall sick, was traced to a brand of a food supplement (L-tryptophan) that was genetically engineered.

- The effects of GM crops are similar to that of pesticides and ought to undergo the same rigorous long term testing. Bt engineered crops create their own Bt pesticide in the entire plant. Their approval relies on the assumption that *Bt*-toxin is not bioactive in mammals. But Bt-protoxins and -toxins caused powerful immune responses and abnormal and excessive cell growth in the small intestine of mice. According to medical and eyewitness reports, Filipinos living next to *Bt* cornfields developed symptoms during pollination and blood tests also showed an immune response to *Bt*. Indian workers handling *Bt* cotton developed allergic responses. There have been buffalo deaths and this year 10,000 dead sheep and goats. HT soy genes transfer to gut bacteria. If Bt also transfers in the same way then it could turn our internal flora into living pesticide factories.
- Despite the Public Relation spin, (and the 'hula' around farmers is very loud in India), GM crops *increase* the use of herbicides, *do not increase* the average yield, and *endanger* food security. They are detrimental to sustainable and organic farming, and trap farmers in a cycle of indebtedness and dependence. Of the 450 cotton-farmer suicides in Vidharbha, 314 or a hefty 70% opted for Bt cotton. They endanger biodiversity, harm beneficial insects, damage soil bacteria.
- Transgenic contamination is undisputed, a biological certainty. Thus, eventually the contamination of non-GM varieties including organic farming is inevitable.
- The gravest threat is to irreversible global ecological damage.

26. There are two major and far reaching crises facing mankind. The first is undoubtedly 'climate change'. The second is the profound truth that the unique risks of GE and GM crops have potential impacts of many magnitudes that are still not understood and would affect our world in ways unimaginable. Arguably, it stands with climate change as two of the most serious crises to be challenged

and overcome; However, its threats (GE) are not perceived or recognised by peoples, because it is still a new technology and is being subjected to the same spin and swift boating as ‘climate change’ was for years and indeed still is, with the support of the White House. We are only now waking up to the realisation of the fallout of this immense folly. The interventions required globally for reductions in CO2 emissions to be effected by national governments are both complex and structural. On the other hand, with GM crops, the intervention necessary is still remarkably simple, within the powers of National Governments, given the political will, honesty to recognise the risks and ability to withstand US pressure. Not all African Nations are capitulating to this inordinate pressure. Furthermore, the scope for correction and redemption that lies within the powers of the Indian justice system makes the possibility of such an intervention, timely, effective and full of hope. It is the Petitioners’ case that this Writ Petition cannot be allowed to fall by the way side because of the utter irresponsibility and recklessness of a Regulator-turned-approver of GM. Approvals have already been given for an astonishing array of 91 field trials. This is of the greatest concern. The timescale during which the Regulator plans approvals for large-scale field trials of Bt brinjal is in August 2006 with further plans for other crops later in the year. Therefore, time is of the essence for remedial action. Based on the evidence in this Application and this is the reason for filing it, we are at a crossroads *now*. In the time that it takes for this Hon’ble Court to be seized of the debate and evidence before it, India will be irreversibly contaminated and this WP will become infructuous. Genetic engineering if allowed to proceed unchecked will change the molecular structure of the world’s food. In India, if the GEAC’s reckless rush into GM foods is not checked, this process will be the fastest and riskiest experiment anywhere, with irreversible impacts on our farmers, their crop choices, our food and health, our wild places and our countryside. Truly we need sense and it would appear, an uncommon sense: sound science must prevail in the debate over GE to ensure the safety of consumers and the environment. It truly presents the gravest global threat alongside ‘climate change’.

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

PRAYER

(i) Direct the Respondents to stop *all* field trials, for all GM products anywhere and everywhere in the country with immediate effect;

(ii) Direct Respondents to institute a autonomous panel of Independent scientific and credible experts mandated to protect public health and the environment, as an ombudsman, to oversee GM biosafety and GM policy;

(iii) Direct the Respondents that environmental releases of GMOs will not be permitted till each GMO to be released is cleared by such a panel as above, of independent scientific and credible experts, having first been subjected to a comprehensive, rigorous biosafety test protocol in the public domain as prayed for in the WP

Petitioners/Applicants

Through Mr. Prashant Bhushan

New Delhi: (Counsel for the Applicants)

INDEX

AYURVEDHA AND OTHER TRADITIONAL SYSTEMS OF MEDICINES' BY DR. P.K.V. ANAND

11. **ANNEXURE A-9** – COPY OF E-MAIL BY DR. PUSZTAL TITLED 'ANIMAL HOUSE'

12. **ANNEXURE A-10 (COLLY)**
    - COPY OF STUDY TITLED 'CONTAMINATING THE WILD' BY DOUG GURIAN-SHERMAN
    - COPY OF STUDY TITLED 'INTRODUCTION OF TRANSGENE CROPS IN CENTRES OF ORIGIN AND DOMESTICATION' BY PROF. PAUL GEPTS

13. **ANNEXURE A-11** – LETTER FROM DBT DATED 7.6.2006 TO THE PETITIONER NO.1

14. **ANNEXURE A-12** – COPY OF ARTICLE TITLED 'GEAC SHIFTS TO EVENT-BASED APPROVAL FOR GM CROPS' BY ASHOK B. SHARMA OF THE FINANCIAL EXPRESS DATED 5TH JULY 2006

15. **ANNEXURE A-13** – COPY OF STUDY TITLED 'AMYLASE IN PEA FROM BEAN' BY VANESSA E. PRESCOTT AND OTHERS

16. **ANNEXURE A-14** – COPY OF ARTICLE TITLED 'THALIDOMIDE OF GENETIC ENGINEERING' BY ROBERT MANN, D. STRATON AND WE CRIST

17. **ANNEXURE A-15 (COLLY)**
    - PROF. SCHUBERT'S STATEMENT
    - COPY OF ARTICLE TITLED 'DIFFERENT PERCEPTIVE ON GM FOOD' PUBLISHED IN NATURE BIOTECHNOLOGY 2002 BY PROF. DAVID SCHUBERT